

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C.R. Bard, Inc.,
Petitioner,

v.

Medline Industries, LP,
Patent Owner.

Case IPR2025-00400

U.S. Patent No. 11,684,347

**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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1001	U.S. Patent No. 11,684,347	'347 patent
1002	Declaration of Karl Leinsing	Leinsing Decl.
1003	Declaration of Dr. Edward Yun	Yun Decl.
1004	Prosecution History of 11,684,347	'347 Prosecution History
1005	U.S. Patent No. 7,278,987 to Solazzo	Solazzo
1006	Japanese Patent Application Publication No. 2006-131284 to Numata et al	Numata-JP
1007	Certified English Translation of Japanese Patent Application Publication No. 2006-131284 to Numata et al	Numata
1008	U.S. Patent No. 3,166,189 to Disston	Disston
1009	U.S. Patent No. 3,329,261 to Serany, Jr. et al.	Serany
1010	U.S. Patent No. 4,226,328 to Beddow	Beddow
1011	Japanese Patent No. 2007-229520 to Imai et al.	Imai- JP
1012	Certified English Translation of Japanese Patent No. 2007-229520 to Imai et al.	Imai
1013	U.S. Patent No. 5,931,303 to Salvadori	Salvadori
1014	Final Written Decision on Remand (Paper 102), IPR2019-00035 (November 23, 2022)	IPR2019-00035 Remand Decision
1015	Final Written Decision on Remand (Paper 102), IPR2019-00036 (November 23, 2022)	IPR2019-00036 Remand Decision
1016	Final Written Decision on Remand	IPR2019-00223

Ex.	Description	Document Name
	(Paper 87), IPR2019-00223 (November 23, 2022)	Remand Decision
1017	Inter Partes Review Certificate for '088 Patent	'088 IPR Certificate
1018	Inter Partes Review Certificate for '596 Patent	'596 IPR Certificate
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1021	U.S. Patent No. 4,160,505 to Rauschenberger	Rauschenberger
1022	Institution Decision (Paper 9), IPR2015-00513 (July 15, 2015)	IPR2015-00513 Institution Decision
1023	Final Written Decision (Paper 57) IPR2019-00208 (June 3, 2020)	IPR2019-00208 Decision
1024	Medline Urologicals Better By Design Brochure (2008)	Medline Brochure
1025	Norman, Donald A., The Design of Everyday Things, 2002 ed. (Excerpt)	Design of Everyday Things
1026	Initial Final Written Decision (Paper 73) (IPR2019-00035)	Initial FWD (IPR2019-00035)
1027	Guide to the Elimination of Catheter-Associated Urinary Tract Infections (CAUTIs): Developing and Applying Facility-Based Prevention Interventions in Acute and Long-Term Care Settings, Association for Professionals in Infection	CAUTI Guide

Ex.	Description	Document Name
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1029	U.S. Patent No. 7,967,137 to Fulbrook	Fulbrook

I. INTRODUCTION

Petitioner C.R. Bard, Inc. respectfully requests *Inter Partes* Review of U.S. Patent No. 11,684,347 (“the ’347 patent”), assigned to Medline Industries, LP, and cancellation of claims 1-8, 10-11, 13-20 (“Challenged Claims”). Those claims are unpatentable as obvious in view of the prior art references described below.

As explained by the Leinsing and Yun Declarations,¹ the ’347 patent is directed to well-known and trivial features of urinary catheter trays. Indeed, the Board has previously found claims having materially identical limitations unpatentable over the same prior presented in Grounds 1-3. With respect to the few limitations not previously found unpatentable, Petitioner relies upon the Numata reference (EX1007), which was not considered during prosecution or by the Board in the related IPRs.

II. MANDATORY NOTICES PURSUANT TO 37 C.F.R. § 42.8(a)(1)

A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

The real parties-in-interest for Petitioner are C.R. Bard, Inc. and its corporate parent, Becton, Dickinson and Company.

¹ Mr. Leinsing is an expert in medical devices and the packaging of medical devices. Dr. Yun, a urologist, is an expert in urinary catheterization and irrigation procedures, and provides opinions regarding the clinical aspects of the claimed invention.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

The following judicial or administrative matters may affect or be affected by a decision in this proceeding: *Medline Industries, LP v C.R. Bard, Inc.*, 1:23-cv-05827-JPB (N.D. Ga.) (“District Court litigation”). In that action, Patent Owner has asserted the ’347 patent. Patent Owner also asserts U.S. Patent Nos. 11,661,219 (“the ’219 patent”), and 11,661,220 (“the ’220 patent”). The ’347 patent claims priority to common priority applications as the ’219 and ’220 patents and has a specification with overlapping disclosures as the ’219 and ’220 patent.

Petitioner concurrently is filing a petition challenging the asserted claims of the ’219 patent, and ’220 patent and thus lists: Petitions for *Inter Partes* Review of U.S. Patent Nos. 11,661,219, and 11,661,220, (Petitions filed contemporaneously).

C. Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3)-(4))

Petitioner hereby identifies its lead and backup counsel as follows:

Lead Counsel	Back-Up Counsel
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Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney has been filed herewith.

D. Service Information (37 C.F.R. § 42.8(b)(4))

Please send all correspondence to the lead and backup counsel at the addresses shown above. Petitioner consents to service by e-mail at the following address: Medline-Bard-QE@quinnemanuel.com.

E. Payment of Fees (37 C.F.R. §§ 42.103 and 42.15(a))

The requisite filing fee of \$41,500 (request fee of \$19,000, post-institution fee of \$22,500) for a Petition for *Inter Partes* Review is submitted herewith. Claims 1-8, 10-11, 13-20 of the '347 patent are being reviewed as part of this Petition. If any additional fees are due during this proceeding, the Office is authorized to charge such fees to Deposit Account No. 505708. Any overpayment or refund of fees may also be deposited in this Deposit Account.

III. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a); 37 C.F.R. §§ 42.101(a)-(c))

Petitioner certifies that the '347 patent is available for IPR and that Petitioner is not barred or estopped from requesting this review. Patent Owner filed its lawsuit on December 18, 2023, and on January 10, 2024, Petitioners accepted and acknowledged service of the summons and complaint in the District Court litigation on Petitioner effective January 5, 2024, which is not more than one year from the filing of this Petition. *See e.g., Brinkmann Corp. v. A&J Mfg., LLC*, IPR2015-00056, Paper No. 10, 6-7 (P.T.A.B. March 23, 2015).

IV. IDENTIFICATION OF CHALLENGE AND RELIEF REQUESTED

A. Identification of Challenge (37 C.F.R. § 42.104(b))

Petitioner requests IPR of claims 1-8, 10-11, 13-20 of the '347 patent and that the PTAB cancel those claims as unpatentable.

B. Grounds of Challenge (37 C.F.R. § 42.204(b)(2))

Petitioner respectfully requests that the Board grant institution of IPR based on the following grounds:

Ground	35 U.S.C. § ²	Claim	Prior Art References
1	103(a)	1, 2, 5, 7, 8, 14, 17	Solazzo, Serany, Disston, Imai
2	103(a)	6, 10, 11, 13, 15, 16, 18, 19	Solazzo, Serany, Disston, Imai, Salvadori
3	103(a)	1, 2, 5, 7, 8	Numata, Serany, Disston
4	103(a)	3, 4	Numata, Serany, Disston, Beddow
5	103(a)	6, 10, 11, 13	Numata, Serany, Disston, Salvadori
6	103(a)	14	Numata, Serany, Disston, Imai
7	103(a)	15, 16	Numata, Serany, Disston, Imai, Salvadori
8	103(a)	17, 18, 19, 20	Numata, Serany, Disston, Imai, Salvadori, Beddow

V. THE '347 PATENT

A. Overview

The '347 patent is directed to “a storage container” for “a catheter, and related medical devices.” (EX1001.1:41-45; EX1002.¶¶31-34.) Tray 100 is shown in Figure 7 (annotated and colorized):

² The pre-AIA versions of Sections 102 and 103 apply here.

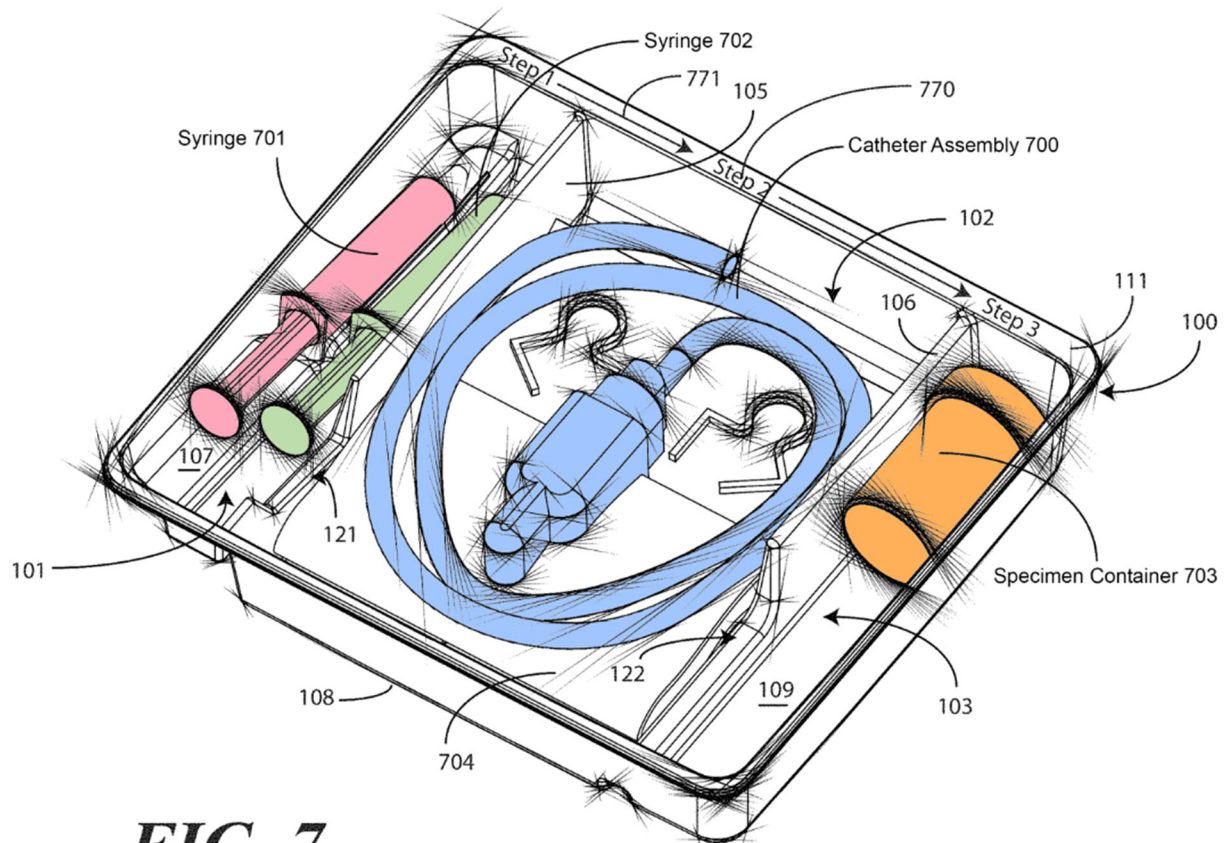


FIG. 7

(EX1001.Fig.7.) Tray 100 is double-wrapped to ensure that components in the tray remain sterile with tray 100 being wrapped in CSR wrap 1000 and then outer sterile wrap 1002. (EX1001.11:8-11,17:8-12,Fig.10.) Tray 100 includes three compartments 101, 102, 103 to receive various items used in a catheterization procedure. (EX1001.4:59-61.) First compartment 101 accommodates syringes 701, 702 (red, green) containing sterile water or lubricants. (EX1001.8:62-64,9:16.) Second compartment 102 accommodates catheter assembly 700 (blue). (EX1001.8:64-66,9:67.) Third compartment 103 accommodates specimen container 703 (orange) for capturing samples taken from the patient via catheter 700.

(EX1001.8:66-9:1.) Additional objects can be included with the tray, including swab sticks, a securement device, and so forth. (EX1001.5:25-30.)

The '347 patent claims priority to several provisional and non-provisional applications, the earliest of which was filed on June 3, 2009. Without conceding the propriety of any of these priority claims, Petitioner adopts the June 3, 2009 date for purposes of this petition.

B. The Challenged Claims

Among the Challenged Claims, claims 1, 14, and 17 are independent. For ease of reference, Petitioner has labeled the limitations of these claims as follows:

Claim 1	
1.p	A medical procedure kit, comprising:
1.a	a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly;
1.b	a first syringe and a second syringe disposed within the first compartment; and
1.c	the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter;
1.d	wherein one of the first syringe or the second syringe contains lubricating jelly and another of the first syringe or the second syringe contains water; and
1.e	wherein the first compartment and the second compartment are adjacent and separated by a barrier.

Claim 14	
14.p	A medical procedure kit, comprising:
14.a	a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly;
14.b	a first syringe and a second syringe disposed within the first compartment; and
14.c	the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter;
14.d	wherein: one of the first syringe or the second syringe contains lubricating jelly and another of the first syringe or the second syringe contains water;
14.e	the first compartment and the second compartment are adjacent and separated by a barrier;
14.f	the first syringe and the second syringe are ordered within the single layer tray in accordance with their use during a catheterization procedure; and
14.g	the first compartment supports the first syringe and the second syringe at different heights.
Claim 17	
17.p	A medical procedure kit, comprising:
17.a	a surface defining a single layer tray having a first compartment, adjacent to and separated by a barrier from, a second compartment configured for receiving a Foley catheter, a coiled tubing, and a fluid drain bag;
17.b	a first syringe and a second syringe disposed within the first compartment, the first syringe containing lubricating jelly and the second syringe containing water, wherein the first syringe and the second syringe are arranged at different heights within the first

	compartment in accordance with their use during a Foley catheterization procedure; and
17.c	the Foley catheter, the coiled tubing, and the fluid drain bag situated in the second compartment with the coiled tubing positioned between the Foley catheter and the fluid drain bag.

C. Prior Proceedings on Related Patents

In IPR2019-00035, IPR2019-00036, and IPR2019-00223 (collectively “Prior IPRs”), the Board invalidated the majority of the challenged claims in two related patents, U.S. Patent Nos. 9,745,088 (“’088 patent”) and 9,808,596 (“’596 patent”) based on the same prior art presented in Grounds 1 and 2. (EXS1014-16; EX1002.¶¶36-70.)³ Indeed, there are no material differences between claims 1-2 and 5-11, and 13-19 of the ’347 patent and claims found invalid by the Board.

In the Prior IPRs, the Board issued FWDs finding that all of the claims were not unpatentable. Bard appealed and the Federal Circuit vacated the Board’s FWDs. *C.R. Bard v. Medline Indus. Inc.*, 2021 WL 3574043 (Fed. Cir. 2021). The Federal Circuit found, *inter alia*, that it would have been obvious to place two syringes in one compartment and to arrange them at different heights based on their order of use. *Id.* at *5-*7. The Federal Circuit remanded and instructed the Board to consider the remaining claim limitations and secondary considerations.

³ The Remand Decisions issued on October 8, 2022. Bard cites here the public versions of these Decisions that issued on November 23, 2022.

On remand, the Board found the vast majority of the challenged claims obvious. In doing so, the Board found, *inter alia*, that Solazzo discloses or renders obvious “a surface defining a single layer tray,” water and lubricant syringes, swabsticks, a catheter securement device, and underbuttocks and fenestrated drapes. (EX1015.0015-40.) And it rejected nearly all of Medline’s evidence on secondary considerations—finding only that copying and industry praise weigh “slightly” in favor of a finding of nonobviousness. (EX1015.0050,0044-57.) In sum, the Board found: “Patent Owner’s objective evidence of nonobviousness does not weigh significantly against a conclusion of obviousness for any claim at issue on remand.” (EX1015.0057.) Medline initially appealed the remand FWDs, but then voluntarily dismissed its appeal, thereby allowing the remand FWDs to become final. On August 19, 2024 and October 4, 2024, cancellation certificates for 70 claims of the ’088 patent and 5 claims of the ’596 patent were issued respectively. (EXS1017-18.)

D. Prosecution History

The ’347 patent issued from the ’718 application, which was filed on December 19, 2019. (EX1002.¶¶71-79.) On July 14, 2020, Medline submitted an IDS that included the Board’s *initial* Final Written Decisions (“Initial FWDs”) in the Prior IPRs. (EX1004.0190-91.) On July 17, 2022, the examiner issued an office action, rejecting nearly all pending claims under nonstatutory double patenting in

view of the '088 and '596 patents, (EX1004.0214-35.), and Medline filed a terminal disclaimer in response. (EX1004.0334-35.) On October 26, 2022, the Examiner issued a Notice of Allowance that did not discuss Solazzo. (EX1004.0783-91.) The Examiner found that the closest prior art (U.S. Patent No. 4,811,847 to Reif) “lack[ed] a second syringe, and does not arrange the syringe and catheter in separate compartments.”⁴ (EX1004.0789.) Medline then filed five additional IDSs with the last coming on April 6, 2023, but did not include the Remand FWDs that issued on October 8, 2022, leading to a final Notice of Allowance on April 11, 2023. (EX1004.0850-51,0864-66,0872-74,0903-05,0916-18,0021-23.)

VI. MEDLINE IS COLLATERALLY ESTOPPED

As noted above, the Prior IPRs involved related patents, including many claim limitations that are materially identical, most of the same prior art, including Solazzo, Serany, Disston, Imai, Salvadori and Beddow, and the same or similar arguments regarding secondary considerations. In finding many claims of the '088 and '596 patents unpatentable, the Board made numerous factual and legal determinations against Medline. Thereafter, Medline initially appealed to the Federal Circuit, but later dropped its appeal, thereby allowing the Remand FWDs to

⁴ These are claim elements that had been found obvious in view of Solazzo in the Remand FWDs.

become final. Accordingly, Medline is collaterally estopped from challenging the Board’s findings in the Remand FWDs. *Papst Licensing GMBH & Co. KG v. Samsung Elecs. Am., Inc.*, 924 F.3d 1243, 1250-53 (Fed. Cir. 2019) (applying collateral estoppel after appeal of earlier-filed IPR was dismissed).

VII. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSA”) as of the earliest possible priority date of the patent (June 3, 2009) would have a bachelor’s degree in mechanical engineering or equivalent technical degree and at least two years of experience in the medical device packaging field. (EX1002.¶¶13-18.) A POSA would not need to be a practitioner, but would have learned about urinary catheterization procedures from those skilled in such procedures (e.g., a nurse or urologist). (EX1002.¶¶13-18.)

VIII. CONSTRUCTION OF THE CHALLENGED CLAIMS⁵

Rules 42.104(b)(3) and (4) require a petition to identify, for each challenged claim, “[h]ow the challenged claim is to be construed” and “[h]ow the construed claim is unpatentable” under that construction. 37 C.F.R. §§ 42.104(b)(3), (4).

⁵ Petitioner reserves the right to pursue different claim constructions in related proceedings and in any district court litigation.

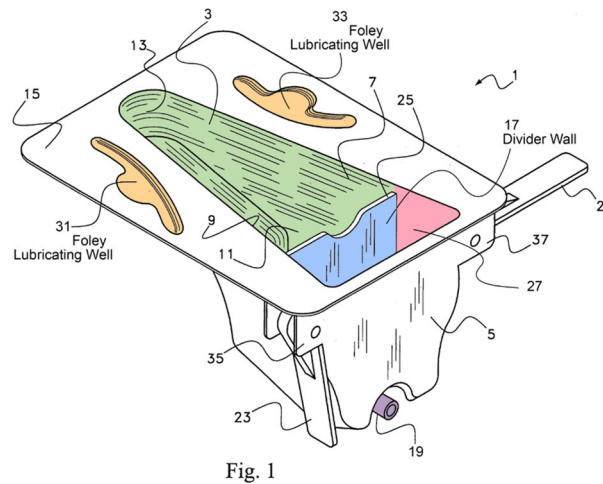
The Board construed “a surface defining a single layer tray having a first compartment separated by a barrier from a second compartment” as “requiring that the first and second compartments and the barrier separating them be part of the same surface.” (EX1015.0033.) Bard proposes that the remainder of the claim terms in the ’347 patent are given their plain and ordinary meaning.

IX. THE PRIOR ART

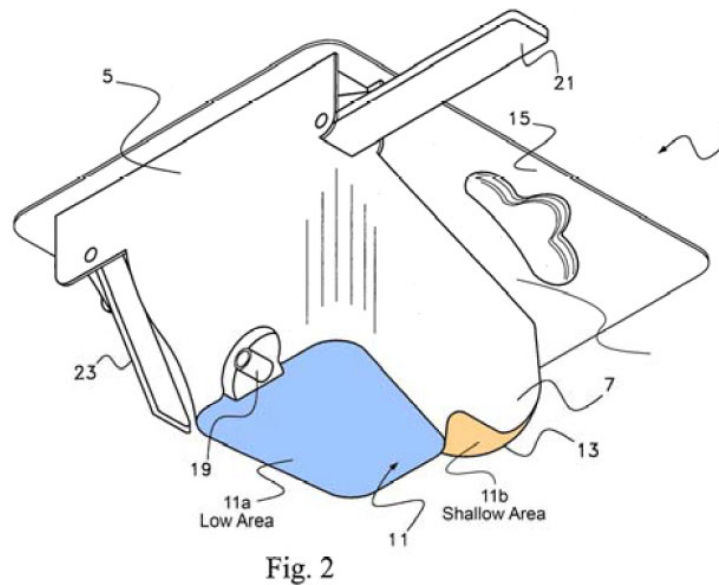
The packaging of medical assemblies, including Foley catheters, was extremely well-developed by 2009. (EX1002.¶¶82-150.) The prior art taught the recited tray structure of the ’347 patent (a single layer tray formed from a single contoured surface with multiple compartments), the equipment stored within the tray (a closed-system Foley catheter, water and lubricant syringes, a catheter securement device, and swabsticks), and the functional elements of the tray (a compartment to lubricate the catheter and equipment arranged in their order of use). (EX1003.¶¶27-60.)

A. Solazzo

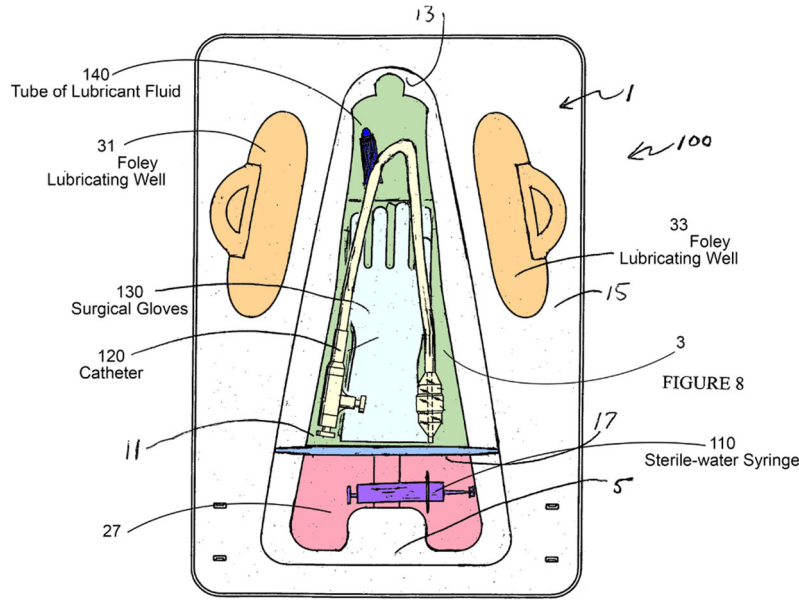
Solazzo is a U.S. patent issued on October 9, 2007, making it prior art under 35 U.S.C. § 102(b). Solazzo is directed to an ergonomic, single layer catheterization/irrigation tray having multiple compartments, including compartment 3 (“recessed area 3”), compartment 27, and lubrication wells 31, 33. (EX1005.4:15-25, Fig. 1; EX1002.¶¶85-90; EX1003.¶¶61-94.)



The tray has a terraced bottom 11 having low area 11A and shallow area 11B as shown in annotated Figure 2 below. (EX1005.3:61-66.Fig.5.)



Inflation syringe 110 is stored at low area 11A, while lubricant fluid 140 is stored at shallow area 11B. (EX1005.4:41-45.Fig.8.)



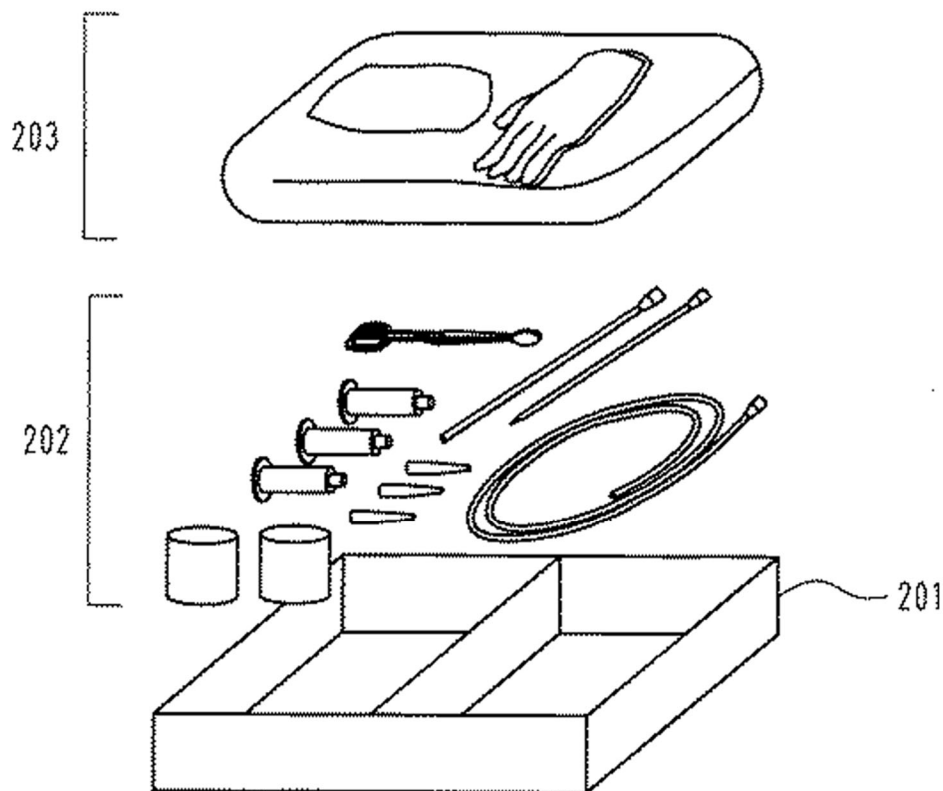
In use, recessed area 3 and compartment 27 fit between the legs of “[a] patient requiring a urological procedure.” (EX1005.1:8-12,3:66-4:10,4:26,4:32-33,Fig.1.)

B. Numata

Numata is a Japanese patent application that was published on September 13, 2007, making it prior art under 35 U.S.C. § 102(b). (EXS1006,1007.) Numata is directed to a package body for storing medical instruments, such as catheters, that allows the removal of instruments from the package while maintaining an aseptic state. (EX1007.Abstract,¶¶0019,31; EX1002.¶¶91-100; EX1003.¶¶95-126.) Numata discloses that “the instruments to be used for a catheter procedure are packaged together in a **single tray**” in order “to reduce the effort of purchasing and arrangement and prevent usage errors and preparation errors.” (EX1007.¶¶0005 (emphasis added).)

The single layer tray of Numata that stores catheterization equipment is shown in Figure 4 below:

(FIG. 4)



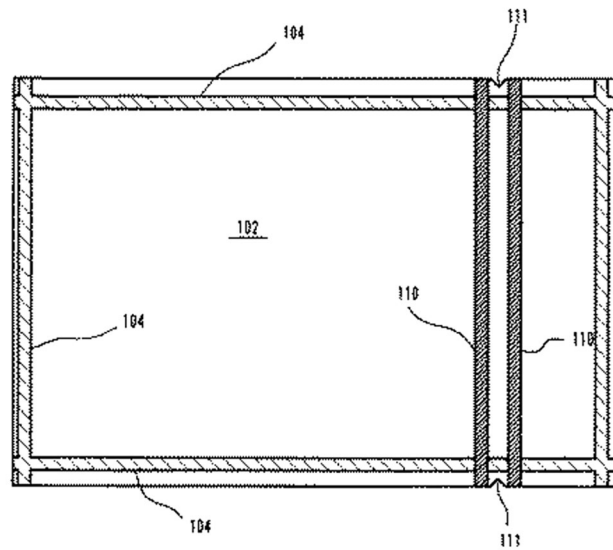
(EX1007.Fig.4.)

Figure 4 above shows a multi-compartmented “tray 201” that stores “medical instruments 202 such as catheters, syringes, injection needles, forceps and degreasing cotton.” (EX1007.¶0031.) Items 203, which are placed above the medical instruments, include “gloves,” “a drape,” etc. (EX1007.¶0031.)

Numata's packaging solution allows for the removal of sterile medical instruments from inside a packaging bag "without directly touching the instruments with one's hands." (EX1007.¶0004.) Numata notes that "physicians who have undergone thorough disinfection for direct contact with a patient ... are not allowed to touch the outside of the packaging" because it "may be microbially contaminated." (EX1007.¶0004.) Thus, the removal of sterile instruments from a medical kit was traditionally performed instead by persons who have *not* undergone a "thorough disinfection." Because such persons cannot directly touch the sterile instruments, it was necessary to remove them from the package "using tools such as forceps," which is cumbersome. (EX1007.¶0004.)

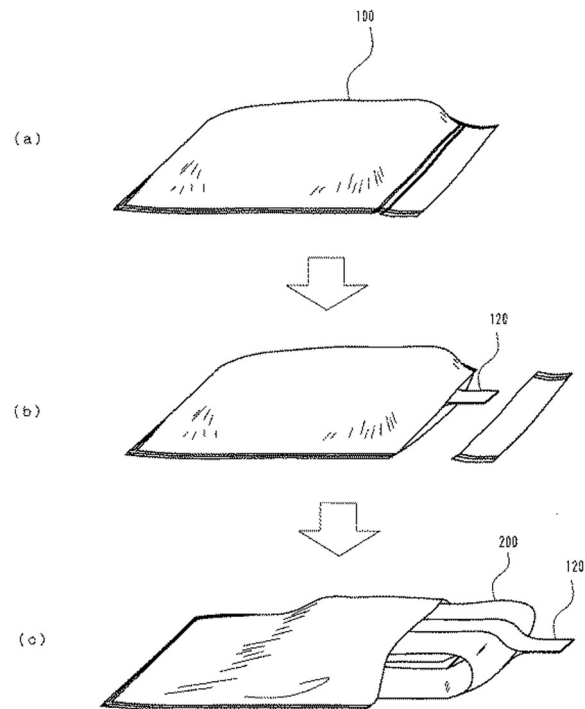
To solve this problem, Numata allows for the removal of the medical instruments from the packaging bag without touching them. (EX1007.¶0009.) As shown in Figure 1, Numata discloses a packaging bag with a notch 111 and a tape [110] forming a cut line along the notch." (EX1007.¶0020.)

(FIG. 1)



“Cutting off the end of the medical product storage pack 100 from the notch 111” exposes “the end of band 120” as shown in Figure 7(b). (EX1007.¶0036, Fig. 7.) The medical product 200 can then be removed from the packaging bag by “pulling the band 120”:

(FIG. 7)



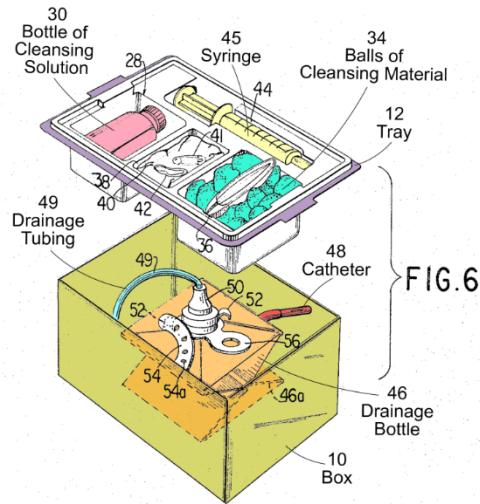
(EX1007.¶0036, Fig. 7.) This allows for the removal of medical product 200 without the need to “directly touch[] the medical product 200 with one’s hands.”

(EX1007.¶0036.)

C. Serany

Serany is a U.S. patent issued on July 4, 1967, making it prior art under 35 U.S.C. § 102(b).

Serany discloses a Foley catheter kit as shown in Figure 6 below (annotated with color and description):



(EX1009.Fig.6; EX1002.¶¶101-107; EX1003.¶35.) The kit includes a closed-system Foley catheter with the “catheter and drainage tube preconnected to [a collapsible drainage] bottle” disposed within. (EX1009.4:36-40.) As shown in Figure 6 above, “[t]he catheter 48 and drainage tubing 49 connecting it to the bottle 46 are coiled in the box about the bottle.” (EX1009.3:32-34.) The collapsible drainage “bottle 46 is made of flexible plastic material having fold lines 46a ... so that it may be folded flat for storage ... and expanded into cube form when in use.”

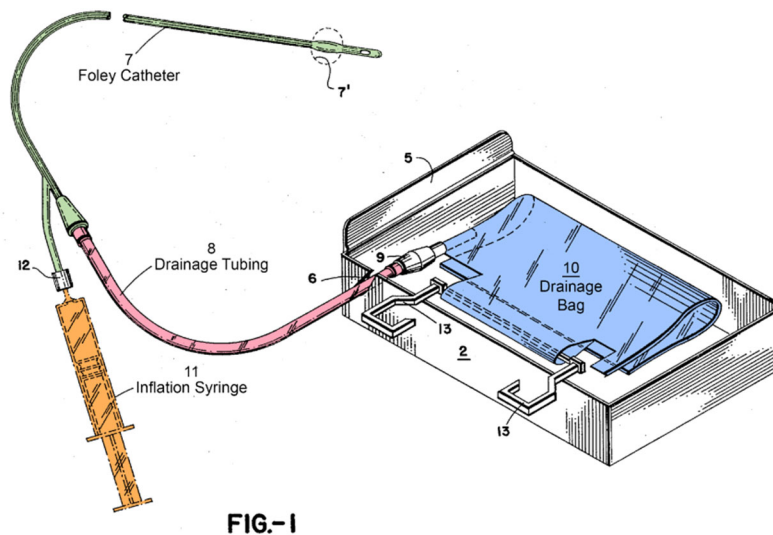
Serany includes an inflation syringe 45 and lubricating jelly 40 and states that “[e]verything is available in the proper order of use” and that the “sterile components” of the kit are “packaged in their order of use.” (EX1009.1:23-30,3:1-7, Fig.6.) Serany further states that the kit “provides the convenience of having *all the components* arranged in a logical *step-by-step order* to facilitate the nurse’s or physician’s task.” (EX1009.1:31-35 (emphasis added).)

D. Disston

Disston is a U.S. patent issued on January 19, 1965, making it prior art under 35 U.S.C. § 102(b).

Disston “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.” (EX1008.1:59-67,2:60-63,Figs.2-3; EX1002.¶¶108-112; EX1003.¶35.) The single tray 2 contains catheterization devices “arranged in such order and position as to be most conveniently available when the container is opened.” (EX1008.2:15-23.)

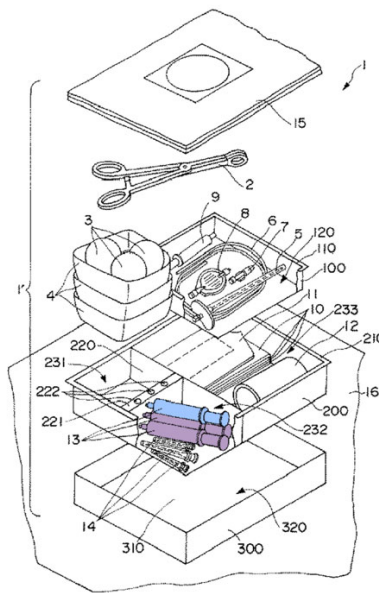
The closed-system Foley catheter of Disston is shown below:



E. Imai

Imai is a Japanese patent application that was published on September 13, 2007, making it prior art under 35 U.S.C. § 102(b).

Imai teaches that “[t]he purpose of the present invention is to provide a package which organizes treatment tools with high usability.” (EX1012.¶0004; EX1002.¶¶113-18.) As shown in annotated Figure 1, Imai teaches an epidural catheter kit with multiple syringes 13 where the syringes are stacked together in the same compartment. (EX1012.¶0014, Fig. 1.)



F. Salvadori

Salvadori is a U.S. patent issued on August 3, 1999, making it prior art under 35 U.S.C. § 102(b).

Salvadori discloses a urinary catheter kit with components such as swab sticks 60, catheter 62, lubricating gel 64, collection bag 66, and specimen bottle 68 as shown in below:

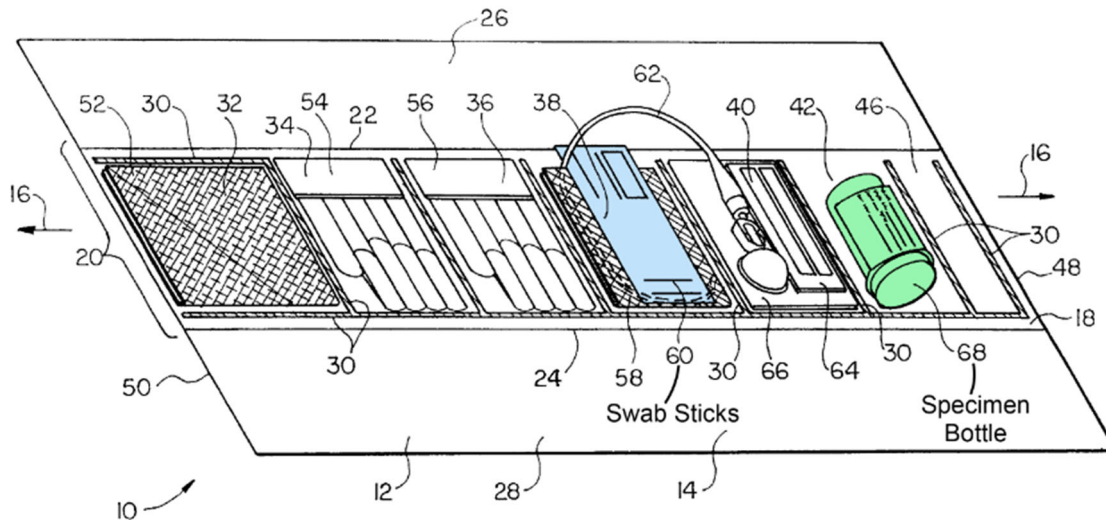


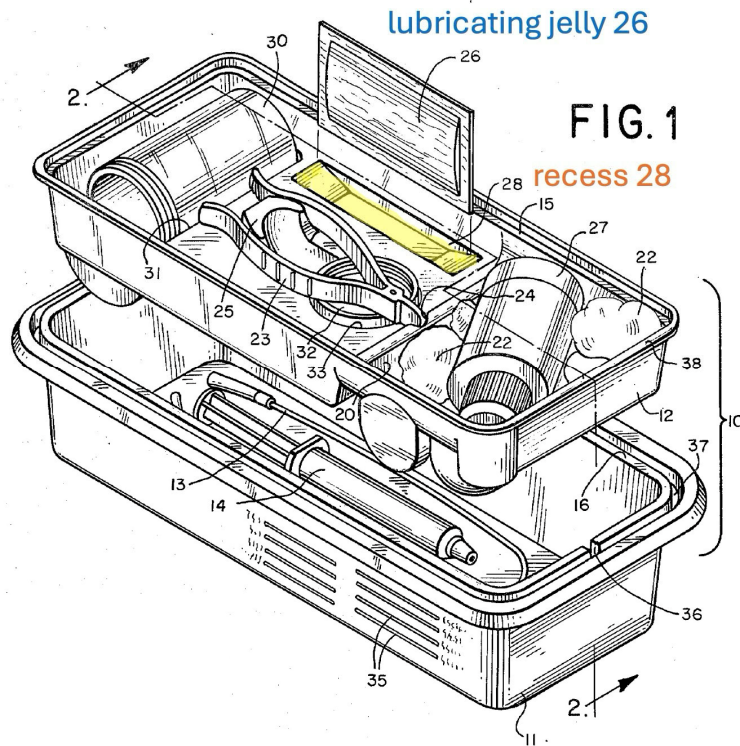
FIG. 1

(EX1013.1:25-31,1:44-49,2:66-3:8,FIG.1.; EX1002.¶¶119-21; EX1003.¶¶144,147-48)

G. Beddow

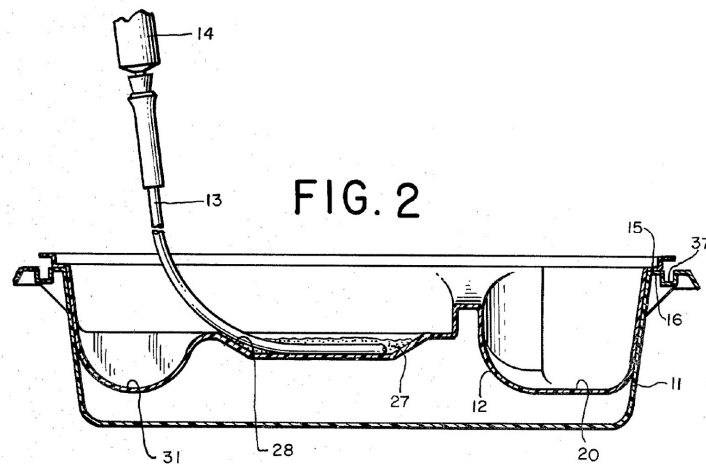
Beddow is a U.S. patent that issued on October 7, 1980, making it prior art under 35 U.S.C. § 102(b).

Beddow discloses a “single-use disposable catheterization package.” (EX1010.Abstract.) As shown in Figure 1 of Beddow, the lubricating jelly is stored in recess 28 (a first compartment of the tray) where the lubricant is also dispensed. (EX1010.3:11-16; EX1002.¶¶122-26; EX1003.¶128)



The catheter is then passed into recess 28 to lubricate the catheter as shown in

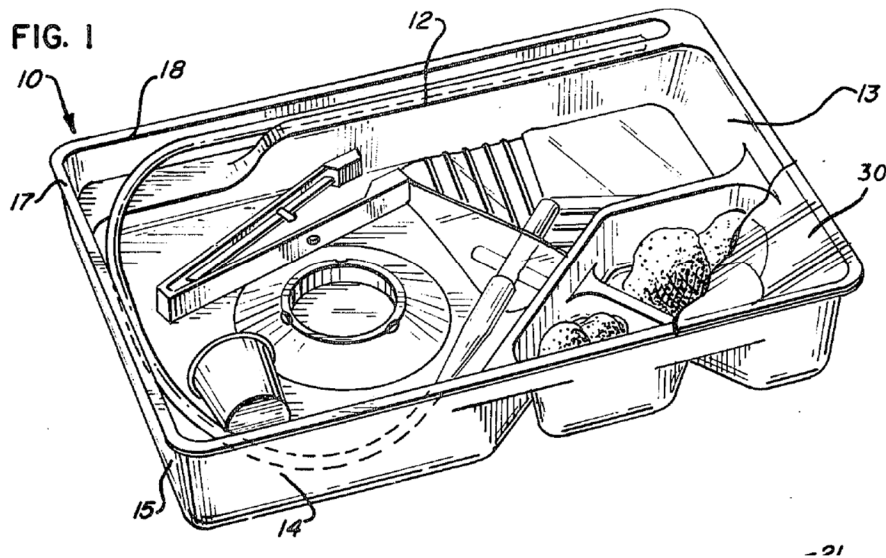
Figure 2:



(EX1010.3:18-22, Fig. 2.)

H. State of the Art

U.S. Patent No. 4,160,505 to Rauschenberger issued on July 10, 1979, making it prior art under 35 U.S.C. § 102(b). Rauschenberger discloses a urethral catheter kit with equipment stored in a multi-compartmented single layer tray that includes a lubrication compartment.



(EX.1021, Fig. 1; EX1002. ¶¶127-32; EX1003. ¶¶39-42, 56-57)

An article in Nursing Standard entitled “Reducing the risks associated with urinary catheters,” was published on March 25, 2009, making it prior art under 35 U.S.C. § 102(a). Nursing Standard describes an “all-in-one Foley tray” and states that closed-system Foley catheters reduce infection rates. (EX.1019.51-55; EX.1002. ¶¶133-38.)

A Nursing Lab: Take Two Male Catheter Insertion video uploaded to YouTube on February 7, 2008 is prior art under 35 U.S.C. § 102(b) (“Catheterization

Video”). It demonstrates the performance of a Foley catheter procedure and shows the compartment where a lubricant syringe had been stored being used to lubricate the catheter. (EX.1020.2:43-2:50; EX.1002.¶¶139-45.)

X. DETAILED EXPLANATION OF GROUNDS FOR INVALIDITY

A. Ground 1: Obviousness Over Solazzo, Serany, Disston, and Imai

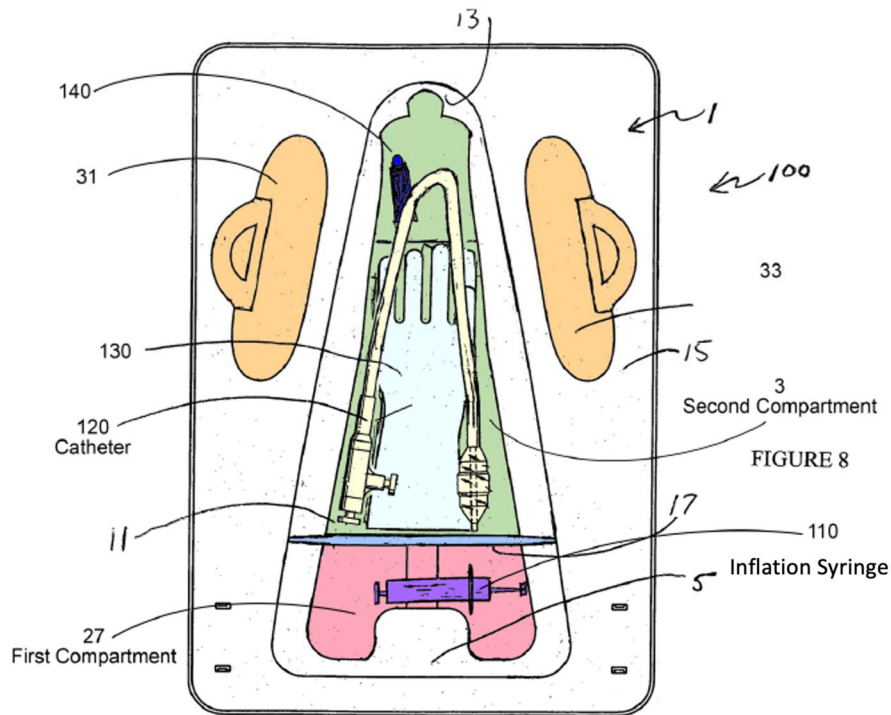
As discussed below, the combination of Solazzo, Serany, Disston and Imai renders claims 1, 2, 5, 7, 8, 14, 17 obvious. (EX1002.¶¶152-260.)

1. Independent Claim 1

(a) Limitations 1[p] and 1[a]

Solazzo discloses “*A medical procedure kit, comprising: a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly.*” (EX1002.¶¶152-61.)

Solazzo discloses a single-layer tray having multiple compartments, including a first compartment 27 for receiving syringes and a second compartment 3 for receiving a medical assembly as shown in annotated Figure 8. (EX1005.2:48-51,3:52-57,Figs.1,8.)



First compartment 27 stores an inflation syringe. It would have been obvious to group multiple syringes in the first compartment, as discussed at 1[b] below.

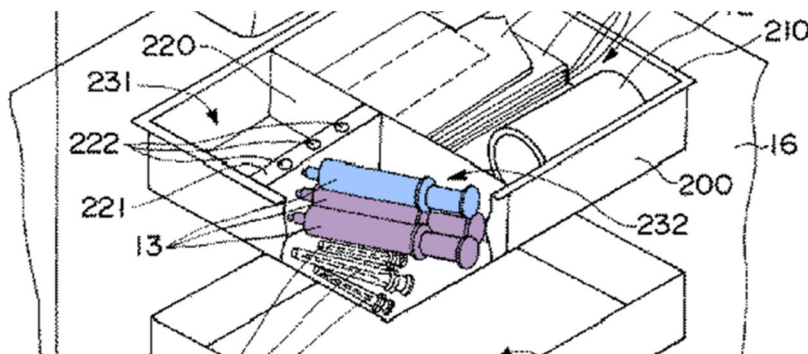
Second compartment 3 stores a medical assembly: Foley catheter 120. Additionally, it would have been obvious to dispose a closed-system Foley catheter (also a medical assembly) in the second compartment of Solazzo in view of Serany/Disston, as discussed at 1[c] below. The PTAB previously found an identical claim limitation obvious in view of the same prior art. (EX1015.0015-17.)

(b) Limitation 1[b]

Solazzo discloses: “a first syringe and a second syringe disposed within the first compartment.” (EX1002.¶¶162-69.)

Solazzo discloses “[t]he kit includes: ... (e.) an inflation syringe ...; (f.) irrigation syringe.” (EX1005.3:15-24.) Compartment 27 of Solazzo holds at least inflation syringe 110. (EX1005.Fig.8.) The location of the “irrigation syringe” within the is not expressly provided. But there are only two locations where it could be held: compartment 3 or compartment 27. It would have been obvious to store the irrigation syringe in compartment 27 because it already holds the inflation syringe. (EX1002.¶163.)

Solazzo also discloses a “tube of lubricant 140.” As explained in limitation 1[d], the tube is replaceable with a syringe. It would have been obvious to store the lubricant syringe in compartment 27 because it already holds the inflation syringe. (EX1002.¶163-64.) It was well-known to group like items in the same compartment of a tray. For example, Serany discloses grouping multiple balls of cleansing material in the same compartment. (EX1009.2:57-61.) Additionally, Imai (EXS1011,1012) discloses grouping syringes in the same compartment of a catheter tray:



Compartment 27 could hold all three syringes (inflation, irrigation, and lubricant) in a stacked configuration. (EX1002.¶¶165-67.) In view of Serany, a POSA would have been motivated to group all three syringes in the first compartment of Solazzo to arrange them in a “logical step-by-step order to facilitate the nurses or physicians task” as taught by Serany.

Finally, it would have been obvious to try grouping the syringes in the same compartment given the finite number of identified, predictable solutions (i.e., storing the syringes in separate compartments or the same compartment) with a reasonable expectation of success. (EX1002.¶168.)

The Federal Circuit and PTAB have previously found an identical claim limitation obvious in view of the prior art presented in this petition. (EX1015.0015-17.); *Bard*, 2021 WL 3574043, at *4.

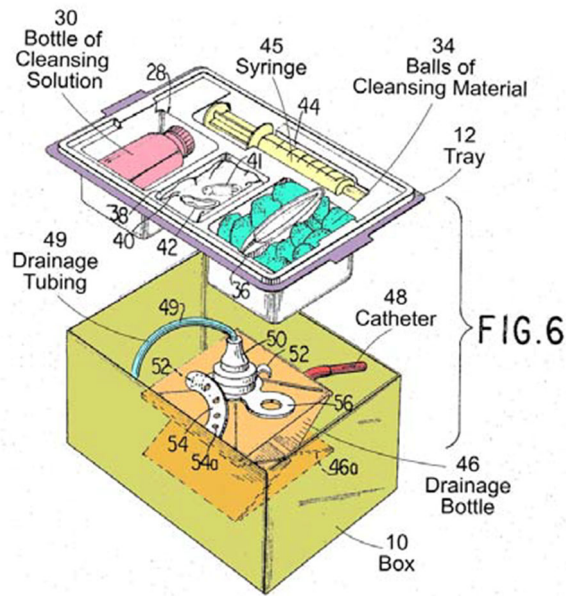
(c) Limitation 1[c]

Solazzo, Serany, and Disston render “*the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter*” obvious. (EX1002.¶¶170-83.)

Solazzo discloses a medical assembly disposed in the second compartment. (EX1005.3:14-24, Fig. 8.) Solazzo notes that a patient may “discharge or be relieved into the tray.” (EX1005.2:42-46.) However, a closed container (e.g., a drainage

bag) is required for a long-term catheterization solution. (EX1003.¶¶65-73; EX1002.¶¶170-74.)

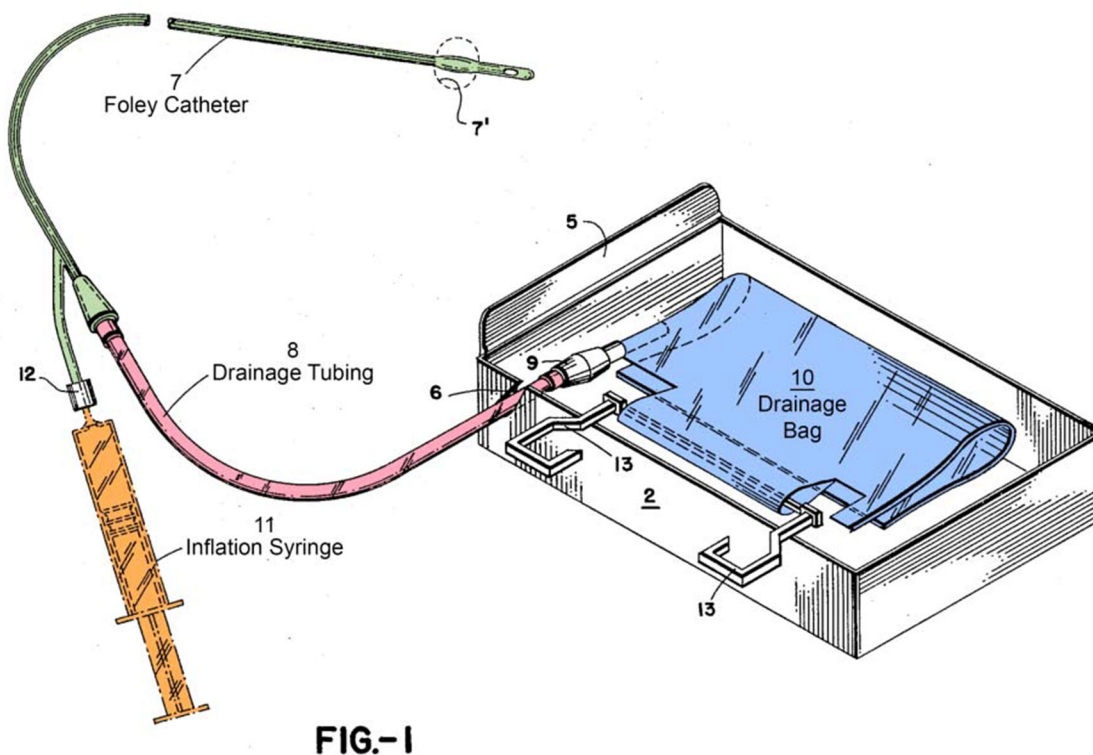
Serany discloses a medical assembly that “comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter.” Specifically, Serany discloses coiled tubing 49 coupled between a Foley catheter 48 and a drainage bottle 46. (EX1009.3:23-36; EX1002.¶¶174-76.)



While Serany refers to catheter as being connected to a “drainage bottle,” it describes the “bottle” as being made out of a “flexible plastic material” that can be collapsed inside the box. (EX1009.3:26-32.) A POSA would understand Serany to therefore also teach a drainage/fluid bag. (EX1002.¶176.)

Disston discloses a “medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter.” Specifically, Disston discloses “a

pre-assembled catheter-tube-bag assembly,” including Foley catheter 7, drainage tube 8, and drainage bag 10. (EX1008.2:15-23, Fig. 1; EX1002.¶177.)



If Medline argues that Serany does not teach a bag, it would have been obvious to substitute the “bottle” of Serany with the “bag” of Disston. (EX1002.¶178.) Doing so would merely involve a simple substitution of one container for another known type of container to produce predictable results.

In view of Serany and Disston, a POSA would have been motivated to include a closed-system Foley catheter (including “a coiled tubing coupled between a fluid

drain bag and a Foley catheter”) in the tray of Solazzo. (EX1002.¶¶179-80; EX1003.¶¶61-92.) First, Serany and Disston teach pre-connected systems that are “ready for use”—eliminating the need to obtain additional components. (EX1003.¶¶80,86.) Second, it was known in the art that closed-system Foley catheters reduce the risk of infection. (EX1002.¶¶181-82; EX1003.¶36; EX1019.51.) Finally, placing the closed-system Foley catheter in Solazzo’s tray does not eliminate the catheterization or irrigation features of the tray. (EX1002.¶182.) Dr. Yun explains that the tray can be best utilized for both purposes when a closed-system Foley catheter is provided in the tray of Solazzo. (EX1003.¶¶61-92.)

The PTAB previously found an identical claim limitation obvious in view of the same prior art. (EX1015.0015-18.)

(d) Limitation 1[d]

Solazzo and Serany render “*wherein one of the first syringe or the second syringe contains lubricating jelly and another of the first syringe or the second syringe contains water*” obvious. (EX1002.¶¶184-88.)

Lubricating Jelly. Solazzo’s kit includes “a tube of lubricant fluid 140” disposed in compartment 3. (EX1005.4:41-46, Fig. 8.) It would have been obvious to provide a lubricant syringe place of the tube. (EX1002.¶185.) Providing lubricant in a syringe as part of a Foley catheter kit was well-known in the art. (EX1002.¶186.)

The Nursing Standard discloses an “all-in-one Foley tray” with a “syringe of urethral lubricant.” (EX1019.52.) A Catheterization Video shows a syringe provided inside a Foley catheter tray that is filled with lubricant. (EX1020; EX1002.¶186.) The substitution of a lubricant syringe for a lubrication tube yielded predictable results. (EX1002.¶187.) A POSA would further have been motivated in view of the teachings of the prior art to switch from a tube of lubricant to a syringe of lubricant because dispensing lubricant of the syringe may require less effort or offer more control than a tube. (EX1002.¶187.)

Water Syringe. Solazzo discloses: “[t]he kit includes: ... (e.) an inflation syringe for inflation of a catheter with fluid.” (EX1005.1:15-21). In the background, Solazzo mentions “a syringe prefilled with bacteriostatic water.” (EX1005.1:38-42.) Thus, a POSA would understand that the “fluid” in the inflation syringe of Solazzo is sterile water. (EX1002.¶188.) Serany also discloses an inflation syringe with “sterile water.” (EX1009.3:50-51.)

The PTAB previously found substantively identical claim limitations obvious in view of the same prior art. (EX1015.0022-23.)

(e) Limitation 1[e]

Solazzo discloses “*the first compartment and the second compartment are adjacent and separated by a barrier.*” Solazzo’s first compartment 27 and second compartment 3 are adjacent and separated by a barrier (divider wall 17):

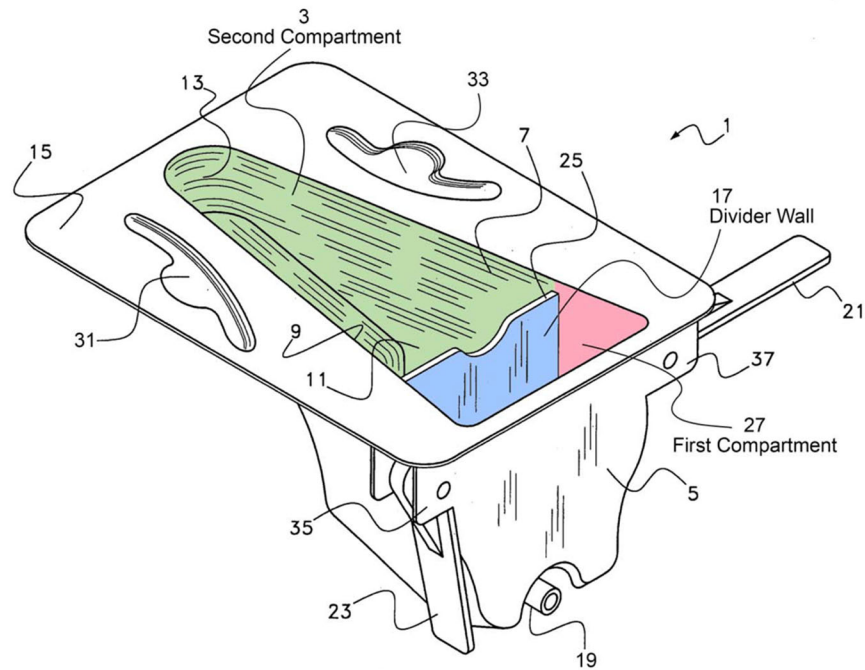


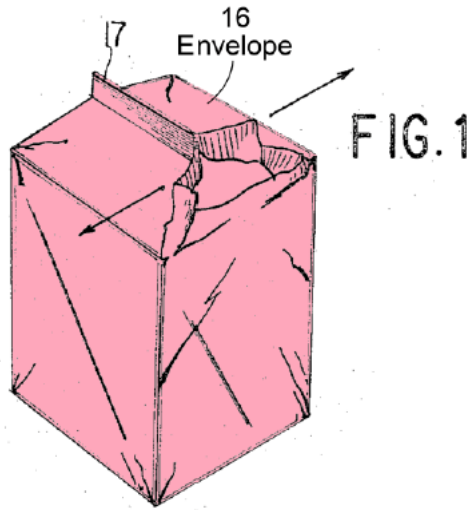
Fig. 1

(EX1005.4:15-16, Fig. 1; EX1002.¶¶189-91.)

2. Claim 2

Solazzo and Serany render “an outer packaging disposed about the single layer tray” obvious. (EX1002.¶¶192-96.)

Serany discloses an outer packaging: a Foley catheter tray “encased within an envelope 16.” (EX1009.1:60-72, Fig. 1.):



It would have been obvious to a POSA to combine the outer packaging taught by Serany with the tray of Solazzo. A POSA would understand that the tray of Solazzo needs to be packaged for shipping to maintain the components within the tray in their respective compartments and to preserve sterility. (EX1002.¶197.) The outer packaging of Serany and the tray of Solazzo are both well-known elements and could be combined with each other with each performing the same function as it does separately. The resulting combination applies a known technique (sealing a tray with an outer packaging) to a known device (a tray for holding a Foley catheter) to yield predictable results (maintaining the sterility of the components of the tray until the package is opened). (EX1002.¶¶198-201.)

The PTAB previously found a substantively identical claim limitation obvious in view of the same prior art. (EX1015.0015-21.)

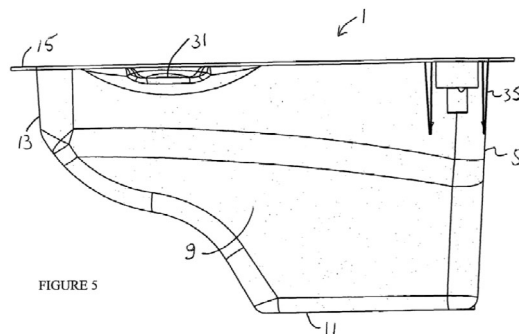
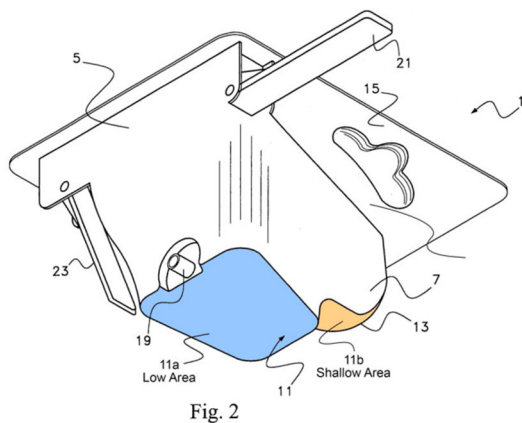
3. Claim 5

For the reasons in 1[d], Solazzo discloses “*wherein the water is sterile.*” (EX1002.¶202.)

4. Claim 7

Solazzo discloses “*wherein the first compartment is bounded by a first base member and the second compartment is bounded by a second base member.*” (EX1002.¶¶203-10.)

Solazzo discloses a tray with a base member—bottom 11 as shown in Figures 2 and 5:



Low area 11A is a first compartment base member and a second compartment base member because it bounds all of first compartment 27 and a portion of second compartment 3. (EX1005.3:63-66,Figs.1,2,8.) This is clear when viewing Figures 1 and 2 together:

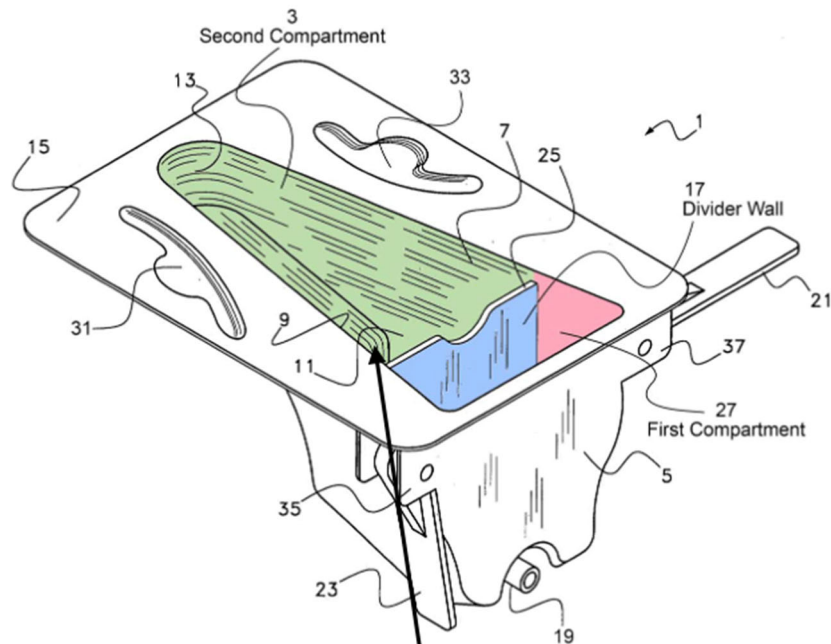


Fig. 1

end of slope

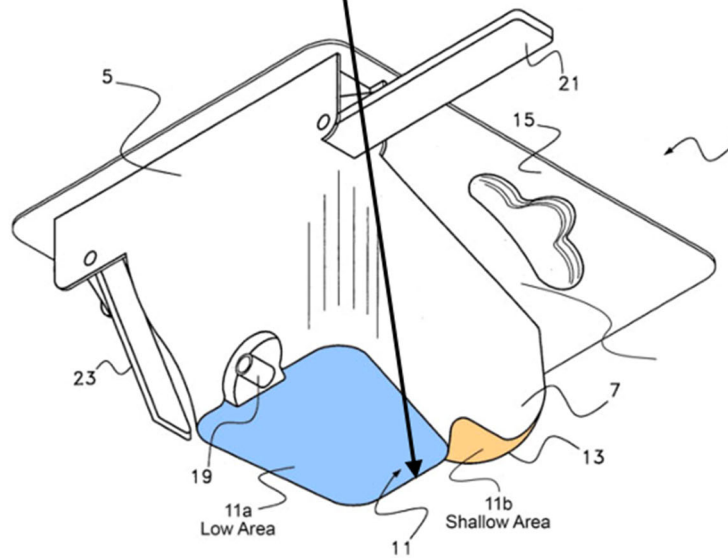


Fig. 2

Shallow area 11b is also a second compartment base member as it bounds the remaining portion of second compartment 3.

5. Claim 8

Solazzo discloses “*wherein a portion of the first base member and another portion of the second base member are substantially coplanar.*” (EX1002.¶¶211-14.)

As discussed at claim 7, the first base member is formed by a portion of low area 11A and the second base member is formed by the remaining portion of 11A and a portion of shallow area 11B. As shown in Figures 2 and 5 below, 11A is substantially coplanar because it lies on the same plane:

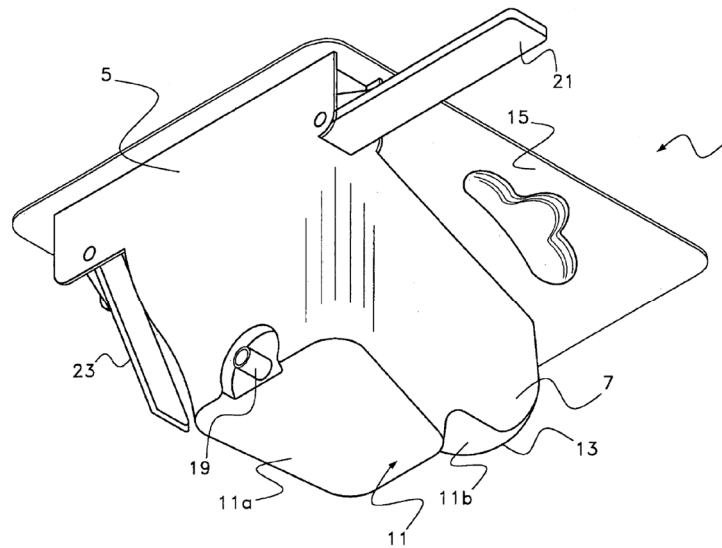
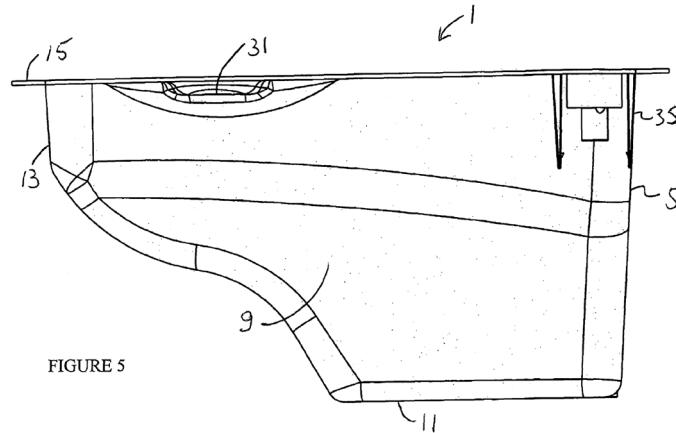


Fig. 2



The Board previously concluded that 11A is not inclined. (EX.1026.23.) Even if low area 11A were inclined (contrary to the Board's previous finding), it would have been obvious to a POSA for low area 11A to be flat to contribute to the stability of the tray. (EX1002.¶¶213-14.)

6. Independent Claim 14

(a) Limitations 14[p] and 14[a]

For the reasons in claim 1[a], Solazzo discloses “*A medical procedure kit, comprising: a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly.*” (EX1002.¶215.)

(b) Limitation 14[b]

For the reasons in claim 1[b], Solazzo, Serany, and Imai render “*a first syringe and a second syringe disposed within the first compartment*” obvious.
(EX1002.¶216.)

(c) Limitation 14[c]

For the reasons in claim 1[c], Solazzo, Serany, and Disston render “*the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter*” obvious. (EX1002.¶217.)

(d) Limitation 14[d]

For the reasons in claim 1[d], Solazzo discloses “*wherein: one of the first syringe or the second syringe contains lubricating jelly and another of the first syringe or the second syringe contains water.*” (EX1002.¶218.)

(e) Limitation 14[e]

For the reasons in claim 1[e], Solazzo discloses “*the first compartment and the second compartment are adjacent and separated by a barrier.*” (EX1002.¶219.)

(f) Limitation 14[f]

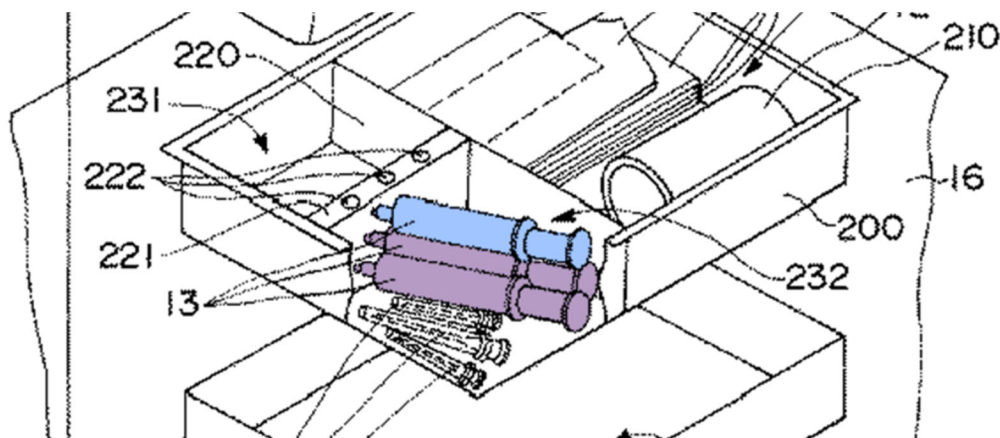
Solazzo, Serany, and Imai render “*the first syringe and the second syringe are ordered within the single layer tray in accordance with their use during a catheterization procedure*” obvious. (EX1002.¶¶220-27; EX1003.¶¶93-94.) First, Solazzo presents the lubricant at a higher height than the inflation syringe because of the “terraced arrangement” of bottom 11. (EX1005.3:63-66, Figs. 2, 8.) This arrangement is consistent with the order of use of these components: “The gloves being worn by the surgeon, the catheter being lubricated, inserted and then inflated with fluid using the syringe.” (EX1005.4:46-48.)

For the reasons in claim 1[b], it would have been obvious to substitute the lubricant tube with a syringe and group both syringes in the first compartment of Solazzo. (EX1002.¶¶222.) A POSA would be motivated to maintain this same arrangement of order of use by height when placing lubricant and inflation syringes in compartment 27.

Second, ordering components within a Foley catheter tray in accordance with their use during a catheterization procedure was well-known in the art and would have motivated a POSA to do so here. (EX1002.¶¶223-26; EX1003.¶¶93-94.) For example, Serany states that “all the components [are] arranged in logical step-by-step order to facilitate the nurses or physicians task.” (EX1009.1:31-35,1:23-25.)

Third, it was well-known in the art of device design (including the design of medical trays) to include affordances to aid a user in performing operations in the correct order. (EX1002.¶¶223-26.)

When placing multiple syringes in compartment 27 in their order of use, the syringes could be stacked on top of each other in compartment 27 in view of Imai:



(EX1012.¶¶0014, Fig. 1.)

A POSA would have been motivated to combine the packaging solution taught by Imai with the tray of Solazzo because it involves applying a known technique (stacking syringes at different heights) to a known device (a Foley catheter tray as shown by Solazzo) to yield predictable results (ordering components in a manner that is convenient for the user and to save space within the tray). Furthermore, it would have been obvious to try stacking the syringe at different heights consistent with their order of use because there were a finite number of identified, predictable solutions (i.e., placing the syringes at the same height or stacking them at different heights) with a reasonable expectation of success (as stacking items within a tray was a well-known solution). (EX1002.¶¶222-27.)

The PTAB previously found a substantively identical claim limitation obvious in view of the same prior art. (EX1014.0035-36.)

(g) Limitation 14[g]

For the reasons in claim 14[f], Solazzo, Serany and Imai render “*the first compartment supports the first syringe and the second syringe at different heights*” obvious. (EX1002.¶¶228-32.)

7. Independent Claim 17

(a) Limitations 17[p] and 17[a]

Claim 17 requires “*A medical procedure kit, comprising: a surface defining a single layer tray having a first compartment adjacent to and separated by a barrier*

from, a second compartment configured for receiving a Foley catheter, a coiled tubing, and a fluid drain bag.”

For the reasons in claim 1[p], Solazzo discloses “*a medical procedure kit.*” For the reasons in claim 1[a] and [e], Solazzo discloses *a single layer tray having a first compartment separated by a barrier from, a second compartment.*” (EX1002.¶¶233-45.)

Solazzo also discloses and/or renders obvious “*a surface defining* a single layer tray” having multiple compartments, including a first compartment 27 adjacent to and separated by a barrier (divider wall 17) from a second compartment 3. (EX1005.2:48-51,3:52-57,4:15-16,Figs.1,8.) A POSA would understand that the tray of Solazzo would have been made using thermoforming or injection molding. (EX1002.¶¶235-37.) Either method allows for the tray, including the divider wall, to be formed a single surface. (EX1002.¶238.) Indeed, the specification of the ’347 patent confirms that either a “thermally formed” or “injection molded” tray is appropriate for forming a “surface defining a single layer tray having a first compartment separated by a barrier from, a second compartment.” (EX1001.4:39-50.)

The Board considered a substantively identical limitation in claim 61 of the ’088 patent and found that Solazzo disclosed it. (EX1015.0030-35.) As the Board found, “Solazzo implies that divider wall 17 is integrally formed with the

adjacent compartments 3 and 27 because divider wall 17 prevents fluid from crossing the wall unless the fluid overflows the top of the wall.” (EX1015.0034 (citing EX1005.4:15–20).)

Even if Solazzo does not disclose an integrally formed barrier (contrary to the Board’s previous finding), it would have been obvious to a POSA to form divider wall 17 integrally with the surface of the single layer tray. (EX1002.¶¶239-245.) It was well-known in the art to form a tray with integrally formed divider walls when using manufacturing techniques such as thermoforming. Manufacturing a tray with thermoforming is cheaper and faster, and allows for stronger trays that are less vulnerable to fractures by utilizing integrally formed divider walls.

(b) Limitation 17[b]

For the reasons in claim 1[b], Solazzo, Serany, and Imai render “*a first syringe and a second syringe disposed within the first compartment*” obvious. (EX1002.¶¶246-47.)

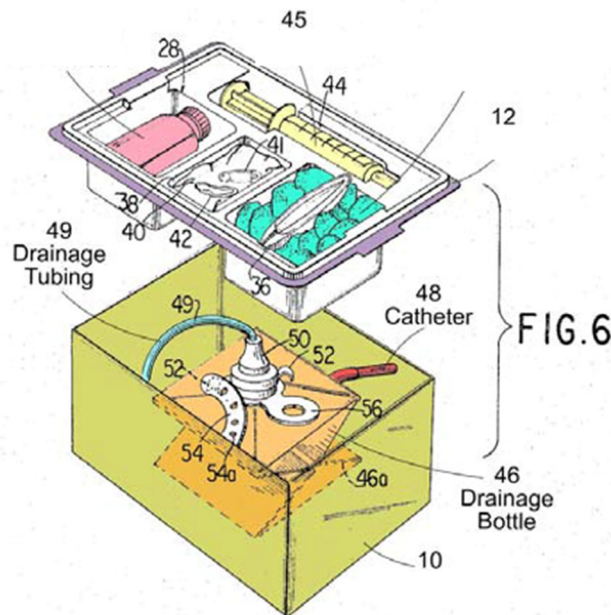
For the reasons in claim 1[d], Solazzo discloses “*the first syringe containing lubricating jelly and the second syringe containing water.*” (EX1002.¶248.)

For the reasons in claim 14[f], Solazzo, Serany, and Imai render “*wherein the first syringe and the second syringe are arranged at different heights within the first compartment in accordance with their use during a Foley catheterization procedure*” obvious. (EX1002.¶249.)

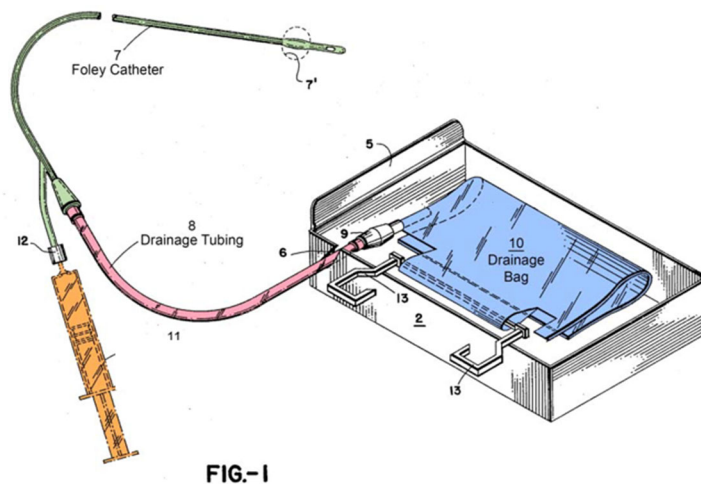
(c) Limitation 17[c]

For the reasons in claim 1[c], Solazzo, Serany, and Disston render “the Foley catheter, the coiled tubing, and the fluid drain bag situated in the second compartment” obvious. (EX1002.¶¶250-60.)

Serany discloses “with the coiled tubing positioned between the Foley catheter and the fluid drain bag.” Specifically, Serany discloses that “drainage tubing 49” “connect[s]” the “catheter 48” to the “bottle 46” as shown in Figure 6. (EX1009.3:32-35.)



Disston also discloses drainage tube 8 positioned between catheter 7 and drainage bag 10 as shown in Figure 1 below:



(EX1008.2:19-23.)

If this claim requires the tubing be positioned in the compartment between the catheter and bag, it would have been obvious to do so because that is the order in which those components are used. (EX1002.¶¶254-60.) This applies a known technique (arranging items in their order of use) to a known device (a catheter kit) to yield predictable results. (EX1002.¶¶256-60.)

B. Ground 2: Obviousness Over Solazzo, Serany, Disston, Imai and Salvadori

As discussed below, the combination of Solazzo, Serany, Disston, Imai, and Salvadori renders claims 6, 10, 11, 13, 15, 16, 18, 19 obvious. (EX1002.¶¶261-310.)

1. Claim 6

Claim 6 requires “a specimen jar disposed within the single layer tray.” Salvadori discloses “a specimen jar,” i.e., “specimen bottle 68.” (EX1009.1:12-16,3:8.)

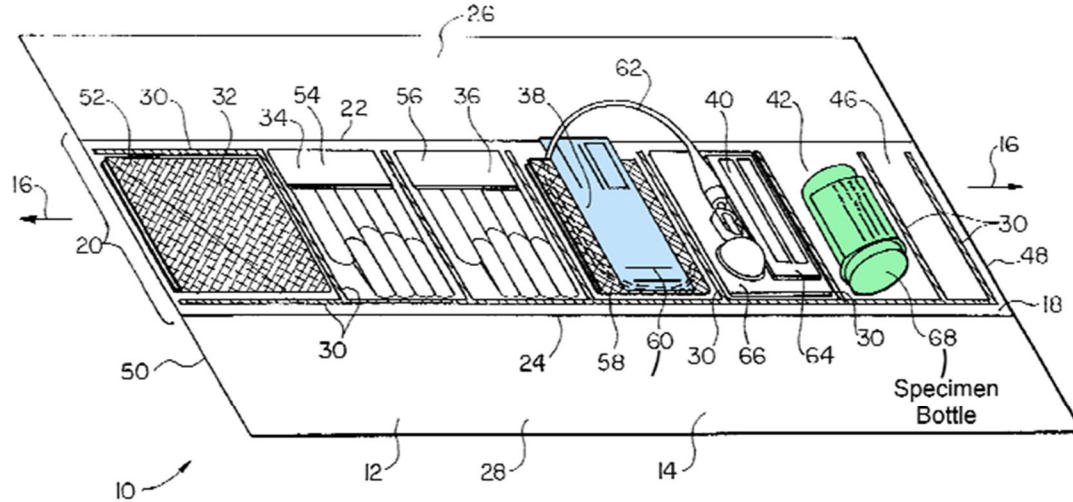


FIG. 1

Specimen jars were common in prior art catheter trays (as in Salvadori and Beddow). (EX1010.1:21-25; EX1013.3:8.) They are used to take a specimen of urine from a patient “if there is a clinical need.” (EX1019.51; EX1002.¶¶261-62.)

In view of Salvadori, a POSA would have been motivated to include a specimen jar in the catheterization kit of Solazzo to allow a practitioner to take a urine sample. (EX1002.¶263.)

This involves the use of a known technique (provision of a specimen jar) to a known device (a Foley catheter kit) to yield predictable results (providing a specimen jar so that the practitioner can take a urine specimen when the patient is catheterized with the Foley catheter disclosed by Solazzo). (EX1002.¶¶264-66.) The

PTAB previously found substantively identical claim limitations obvious in view of the same prior art. (EX1015.0023-24.)

2. Claims 10 and 15

Claims 10 and 15 each recite three identical additional limitations. (EX1002.¶267.)

Outer packaging. For the reasons stated for claim 19, Solazzo and Serany render “*an outer packaging disposed about the single layer tray*” obvious. (EX1002.¶268.)

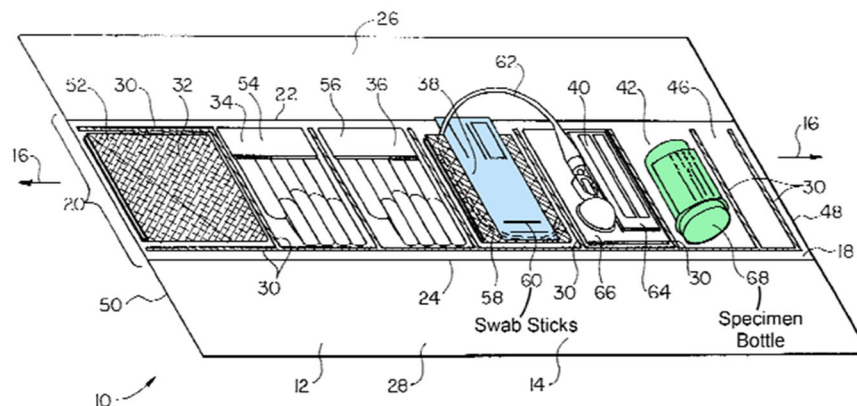
Securement Device. Serany discloses “*a Foley catheter securement device disposed within the single layer tray.*” Specifically, Serany discloses a tray that includes a “safety pin 41” and “rubber band 42” that are used to attach the included drainage tubing to a bed sheet. (EX1009.3:1-5,3:55-58.) The safety pin and rubber band serve as a Foley catheter securement device because the indwelling Foley catheter 48 and drainage tubing 49 are a pre-connected system. (EX1009.3:23-26.) Thus, securing the drainage tubing also secures the attached Foley catheter. (EX1002.¶¶269-73.)

In view of Serany, a POSA would have been motivated to include a Foley catheter securement device in the catheterization kit of Solazzo to allow for the Foley catheter to be properly secured when inserted. Furthermore, the inclusion of a Foley catheter securement device in the catheterization kit of Solazzo involves the use of

a known technique (application of a securement device during a catheterization procedure) to a known device (a Foley catheter kit) to yield predictable results (providing a securement device in the tray so that the practitioner can secure the catheter after it inserted in the patient). (EX1002.¶¶269-73.)

The PTAB previously found substantively identical claim limitations obvious in view of the same prior art. (EX1015.0027-28.)

Swabsticks. Salvadori discloses “one or more swabsticks disposed within the single layer tray.” (EX1002.¶¶274-78; EX1003.¶144.) Specifically, Salvadori teaches a “urethral catheter kit or tray” that includes “swab sticks 60.” (EX1009.1:12-16,3:4.)



Trays with swabs for cleaning a patient were common in the prior art. For example, Serany teaches “balls 34 of cleansing material” that provide the exact same function as swabsticks, i.e., they are used to cleanse the patient prior to insertion of the catheter. (EX1009.2:57-65; EX1002.¶275.) In view of Salvadori, a POSA would

have been motivated to include swabsticks—a common device used with a catheterized patient—in the catheterization kit of Solazzo to allow a practitioner to cleanse the patient’s genitalia prior to insertion of the catheter. (EX1002.¶¶275-78; EX1003.¶¶142-48.)

Furthermore, the inclusion of a swabsticks in the catheterization kit of Solazzo involves the use of a known technique (provision of swab sticks) to a known device (a Foley catheter kit) to yield predictable results (providing swab sticks to allow the practitioner to clean the patient before insertion of the Foley catheter). (EX1002.¶276.)

The PTAB previously found substantively identical claim limitations obvious in view of the same prior art. (EX1015.0026-27.)

3. Claims 11 and 16

Claims 11 and 16 recite identical additional limitations.

Underbuttocks drape. Serany discloses “*an underbuttocks drape disposed within the outer packaging.*” Serany states: “The underpad 20, which may be made of paper with a plastic water-proof coating on one side, is adapted to be placed under the patient. (EX1009.2:21-33.) In view of Serany, a POSA would have been motivated to include a underbuttocks drape—a common device used in a catheterization procedure—in the catheterization kit of Solazzo. (EX1002.¶¶280-83.)

Furthermore, the inclusion of a underbuttocks drape in the catheterization kit of Solazzo involves the use of a known technique (provision of an underbuttocks drape) to a known device (a Foley catheter kit) to yield predictable results (making Solazzo an all-in-one kit). (EX1002.¶¶280-83.)

The PTAB previously found substantively identical claim limitations obvious in view of the same prior art. (EX1015.0027-28.)

Fenestrated drape. Serany discloses a “*fenestrated drape disposed within the outer packaging.*” (EX1002.¶¶284-87.) Serany states: “[a] fenestrated drape 24 folded flat underneath the gloves, is removed, unfolded, and placed in position on the patient.” (EX1009.2:30-33, Fig. 5.)

In view of Serany, a POSA would have been motivated to include a fenestrated drape—a common device used in a catheterization procedure—in the catheterization kit of Solazzo. Serany provides motivation for including a fenestrated drape by noting that it allows for the maintenance of a “sterile field.” This also involves the use of a known technique (provision of a fenestrated drape) to a known device (a Foley catheter kit) to yield predictable results (making Solazzo an all-in-one kit). (EX1002.¶285.)

The PTAB previously found substantively identical claim limitations obvious in view of the same prior art. (EX1015.0027-28.)

4. Claim 13

For the reasons in claim 10, Solazzo and Serany render “*a Foley catheter securement device disposed within the single layer tray*” obvious. (EX1002.¶¶288-93.)

For the reasons in claims 6 and 10, Solazzo and Salvadori render “*one or more swabsticks disposed within the single layer tray*” and “*a specimen jar disposed within the single layer tray*” obvious. (EX1002.¶¶290-91.)

For the reasons in claim 2, Solazzo and Serany render “*an outer packaging disposed about the single layer tray*” obvious. (EX1002.¶292.)

5. Claim 18

For the reasons in claim 10, Solazzo and Salvadori render “*one or more swabsticks disposed within the single layer tray*” obvious. (EX1002.¶¶294-98.)

For the reasons in claim 10, Solazzo and Serany render “*a Foley catheter securement device disposed within the single layer tray*” obvious. (EX1002.¶296.)

For the reasons in claim 6, Solazzo and Salvadori render “*a specimen jar disposed within the single layer tray*” obvious. (EX1002.¶297.)

6. Claim 19

For the reasons in claim 2, Solazzo and Serany render “*an outer packaging*” obvious. Solazzo and Serany also render “*at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material and an outer packaging disposed about the one or more folds of the one or more*

layers of wrap material” obvious. (EX1002.¶¶299-310.) Serany discloses a Foley catheter tray that is “enclosed within a wrap 14.” (EX1009.1:60-63.) Annotated Figure 2 shows the tray enclosed within one or more folds of wrap material 14 in green:

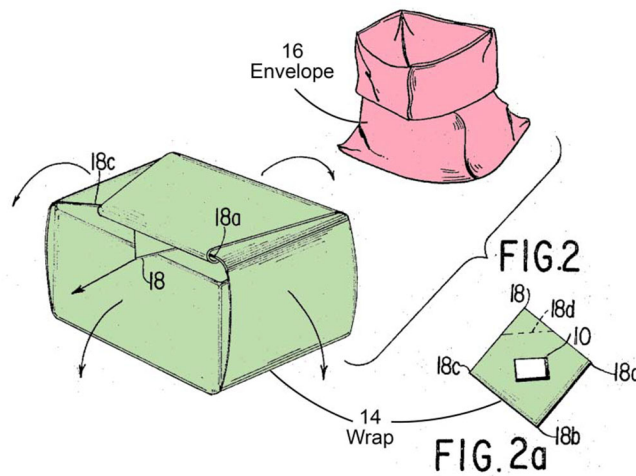
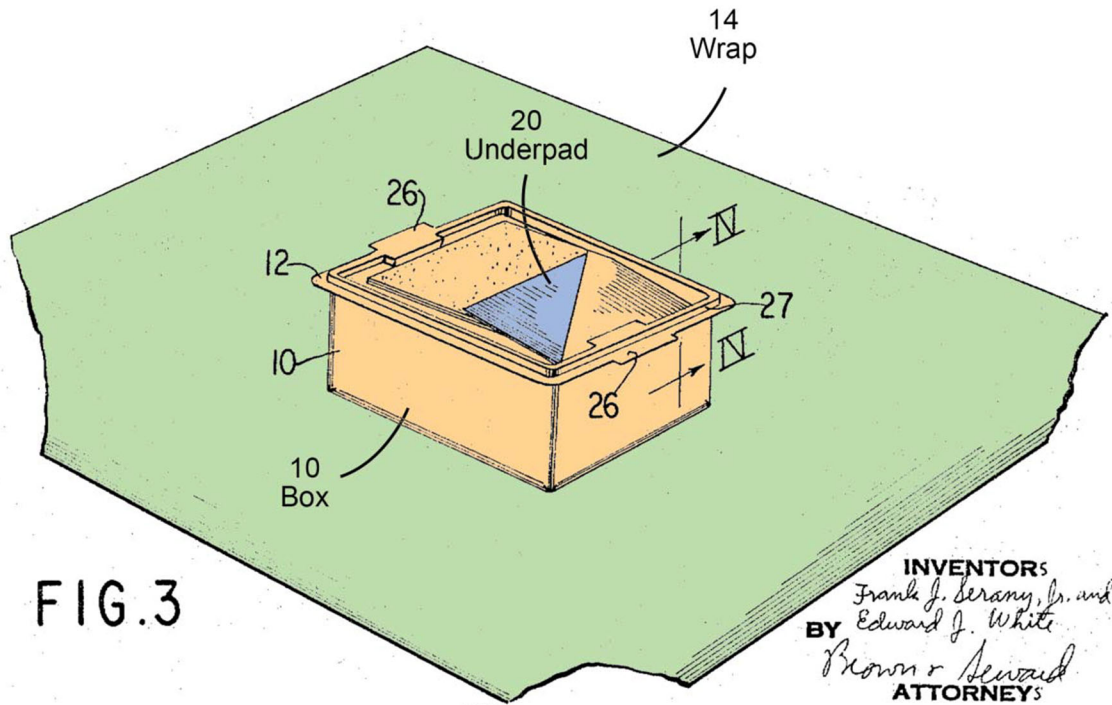


Figure 3 (annotated) shows wrap 14 when unfolded:



The wrap of Serany ensures that “components are maintained sterile until the package is opened.” (EX1009.1:13-16.) Additionally, when wrap 14 is unfolded, a “sterile field may be maintained as the components are removed from the package and used.” (EX1009.1:13-16,2:1-20; EX1002.¶¶301-04.)

A POSA would understand that the tray of Solazzo needs to be packaged for shipping and to preserve the sterility of the components. It would have been obvious to combine the wrap taught by Serany with the catheterization tray of Solazzo. Serany and Solazzo are analogous art because they both disclose trays for holding a Foley catheter and related medical devices. The wrap of Serany and the tray of Solazzo are both well-known elements and could be combined with each other with

each performing the same function as it does separately. The resulting combination would be utterly predictable. (EX1002.¶¶305.)

A POSA would further have been motivated to combine the packaging solution taught by Serany with the tray of Solazzo because it involves applying a known technique (enclosing a tray with a wrap) to a known device (a Foley catheter tray) to yield predictable results (allowing the tray of Solazzo to be shipped with sterile components and allowing for the creation of a sterile field). (EX1002.¶¶306-10.) The PTAB previously found substantively identical claim limitations obvious in view of the same prior art. (EX1015.0015-20.)

C. Ground 3: Obviousness Over Numata, Serany, and Disston

1. Independent Claim 1

As discussed below, the combination of Numata, Serany, and Disston renders claims 1, 2, 5, 7, 8 obvious. (EX1002.¶¶311-60.)

(a) Limitations 1[p] and 1[a]

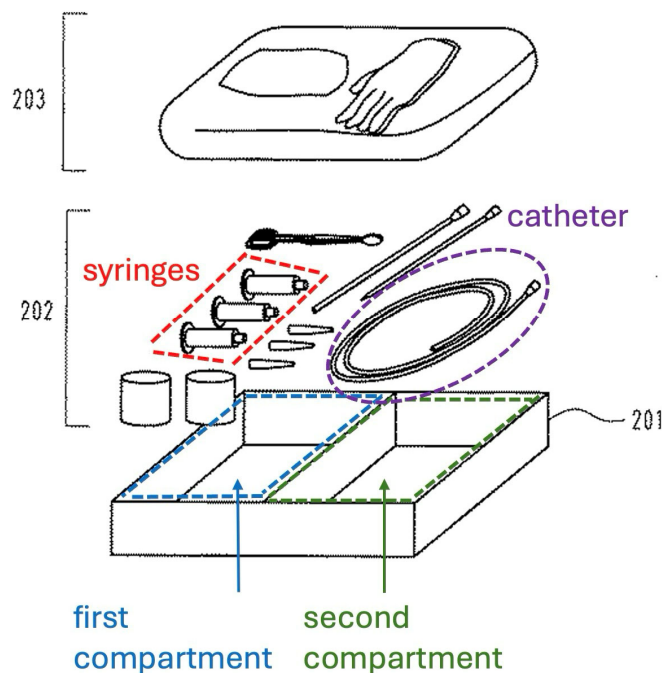
Numata discloses “*A medical procedure kit, comprising: a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly.*” (EX1002.¶¶311-16.)

Numata discloses a medical procedure kit: “a package body for storing medical instruments for use in surgical procedures for diagnosis, treatment, etc., employing disposable medical instruments such as catheters.” (EX1007.¶0001.) The equipment of Numata is stored in a single layer tray: “the instruments to be

used for a catheter procedure are packaged together in a single tray,” which “prevent[s] usage errors and preparation errors.” (EX1007.¶0005, Fig. 4.)

The tray has a first compartment (on the left) for receiving syringes and a second compartment (on the right) for receiving a medical assembly (a coiled catheter) as shown Figure 4 below:

(FIG. 4)



(EX1007.Fig.4.) Figure 4 shows “medical instruments 202 such as **catheters**, **syringes**....” (EX1007.¶¶0031 (emphasis added).)

(b) Limitation 1[b]

Numata discloses: “a first syringe and a second syringe disposed within the first compartment.” (EX1002.¶317.) For the reasons in 1[a], Numata discloses a

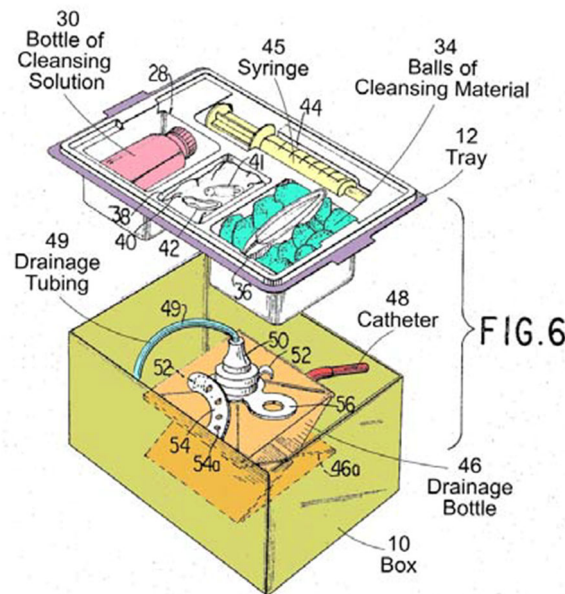
first and a second syringe disposed within the first compartment.
(EX1007.Fig.4,¶0031.)

(c) Limitation 1[c]

For the reasons in 1[a], Numata discloses a medical assembly (a catheter) in a second compartment. (EX1007.Fig.4,¶0031; EX1002.¶¶318-37.) Serany and Disston disclose “*the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter.*” It would have been obvious in view of these references to add Foley catheter equipment, including a closed-system Foley catheter, to the kit of Numata. (EX1002.¶¶319-37; EX1003.¶¶95-126.) And it would have been obvious to place this equipment in the second compartment of Numata, which already houses a catheter. The second compartment of Numata has ample room to house a closed-system Foley catheter, and placing it in the second compartment would separate it from the other equipment stored in the kit (e.g., syringes), thereby protecting it from damage.

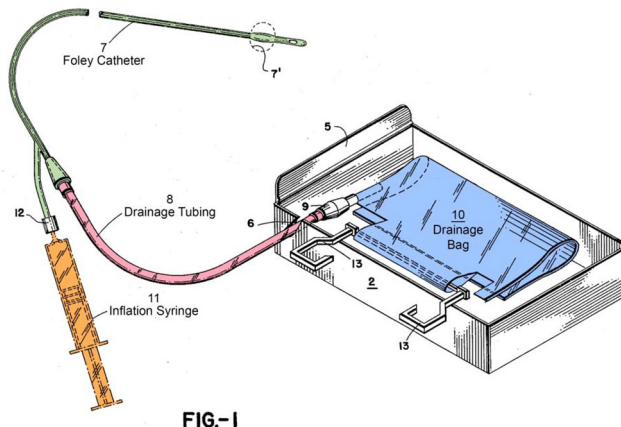
The exemplary embodiment of Numata describes equipment such as “catheters for introduction into blood vessels and their accessories.” (EX1007.¶¶0037.) “However, the invention is also applicable to *any other medical products... which are sold sealed within packaging material in a sterilized state.*” (EX1007.¶¶0037.)

A closed-system Foley catheter is a medical product that is sold sealed within packaging material in a sterilized state. (EX1002.¶321.) Serany discloses a sterilized medical device kit that includes “a collapsible drainage bottle 46 and a Foley catheter 48 (partly shown) connected thereto by the drainage tube 49 and ready for use.” (EX1009.3:23-36; EX1002.¶321.)



Although Serany refers to the catheter as being connected to a “drainage bottle,” it describes the “bottle” as being made out of a “flexible plastic material” that can be collapsed inside the box. (EX1009.3:26-36, Fig. 6.) A POSA would understand Serany to therefore teach a fluid bag because a collapsible drainage receptacle made of a flexible plastic material could also be considered a bag. (EX1002.¶322.) If Medline argues that Serany does not teach a bag, it would have further been obvious to substitute the “bottle” of Serany with a “bag.” Fluid bags

were well-known in the art. For example, Disston teaches a Foley catheter 7 attached to a “drainage bag 10” as shown in annotated Fig. 1 below:



(EX1008.Fig.1,2:19-23.) Doing so would merely involve a simple substitution of one container (a “bottle”) for another known type of container (a “bag”) to produce predictable results. (EX1002.¶322.)

In view of Serany and Disston, it would have been obvious to add a closed-system Foley catheter the tray of Numata. A POSA would have been motivated to do so as set forth below. (EX1002.¶¶323-37.)

First, Numata makes clear that its “invention is also applicable to any other medical products... which are sold sealed within packaging material in a sterilized state.” (EX1007.¶0037.) Numata’s invention therefore applies to Foley catheters, which are sold in a sterilized state. Serany discloses: “The components are maintained sterile until the package is opened....” (EX1009.1:12-16.) This is a

simple substitution of one known element (catheters for introduction into blood vessels) for another (a Foley catheter system) to obtain predictable results (customizing the equipment of Numata to allow the performance of a different medical procedure while utilizing the packaging invention of Numata). (EX1002.¶324.)

Second, while Serany stores its equipment in multiple trays, Numata discloses “the instruments to be used for a catheter procedure are packaged together in a single tray” to “prevent usage errors and preparation errors.” (EX1007.¶0005.) Indeed, these are the same reasons the ’347 patent provided (albeit many years after Numata) for storing its equipment in a single container. (EX1001.7:54-8:2.) Thus, based on the teachings of Numata, a skilled artisan would have been motivated to use the single tray of Numata to accommodate Foley catheter equipment to “prevent usage errors and preparation errors.” (EX1002.¶¶325-26.)

Third, a POSA would have been motivated to add Foley catheter equipment (such as a catheter attached to fluid bag) to the kit of Numata to utilize the packaging invention of Numata. (EX1002.¶327-28.) Numata notes that “disposable medical instruments” are employed “to reduce the risk of nosocomial infections.” (EX1007.¶0002.) Dr. Yun explains that “[a] nosocomial infection is an infection acquired during the process of receiving health care that was not present during the time of admission to a healthcare facility.” (EX1003.¶107.) A catheter associated

urinary tract infection (or “CAUTI”), which most often arises when a Foley catheter is placed in a patient, is the most common form of nosocomial infection in hospitals. (EX1003.¶¶107.) Thus, a POSA seeking a solution to the problem of CAUTI in 2009 would have turned to Numata given its focus on a medical kit “to reduce the risk of nosocomial infections.” Dr. Yun explains that the kit of Numata when provided with Foley catheter equipment would be useful in both surgical and non-surgical settings. (EX1003.¶¶106-126.) Specifically, Numata’s invention would eliminate or reduce the risk of contamination via the outside of the outer packaging. (EX1003.¶¶106-123.) Thus, a POSA would have been further motivated to add Foley catheter equipment to Numata’s single tray to utilize Numata’s packaging solution (i.e., its outer bag, wrap, and band) to perform Foley catheterization procedures to reduce the risk of CAUTI.

Finally, there would be a reasonable expectation of success in combining Numata with the sterile catheter equipment of Serany. (EX1002.¶¶329-32.) Both catheter kits provide (1) sterile equipment within one or more trays; (2) include similar equipment (such as catheters, syringe, forceps, cotton, gloves, and drapes); (3) provide a wrap around the tray[s]; and (4) seal the sterile equipment within an outer bag. (EX1002.¶¶332.) There is also ample space within Numata to accommodate Foley catheter equipment given the dimensions that Numata provides. (EX1002.¶¶333-37; EX1003.¶¶124-26.) And, in any event, it would have been

obvious to modify Numata’s dimensions to conform to the equipment stored within.
(EX1002.¶336.)

(d) Limitation 1[d]

Numata and Serany render “*wherein one of the first syringe or the second syringe contains lubricating jelly and another of the first syringe or the second syringe contains water*” obvious. (EX1002.¶¶338-44.)

As explained in limitation 1[b], Numata discloses a first and second syringe. The contents of Numata’s syringe are not provided, but it would have been obvious to fill Numata’s syringes with sterile water and lubricating jelly when using the kit of Numata for a Foley catheterization procedure for the reasons in limitation 1[c]. This is a simple substitution of one element (syringes) with another (syringes filled with water and lubricating jelly) to yield predictable results.

A POSA would understand that a Foley catheter requires an inflation syringe (filled with sterile water) to inflate the retention balloon of the Foley catheter. (EX1002.¶340.) Serany teaches “a prefilled syringe 45 used to inflate the balloon of the catheter” that is “filled with a fixed amount of sterile water.” (EX1009.3:6-12; *see also* EX1008.Fig.1,2:44-45.)

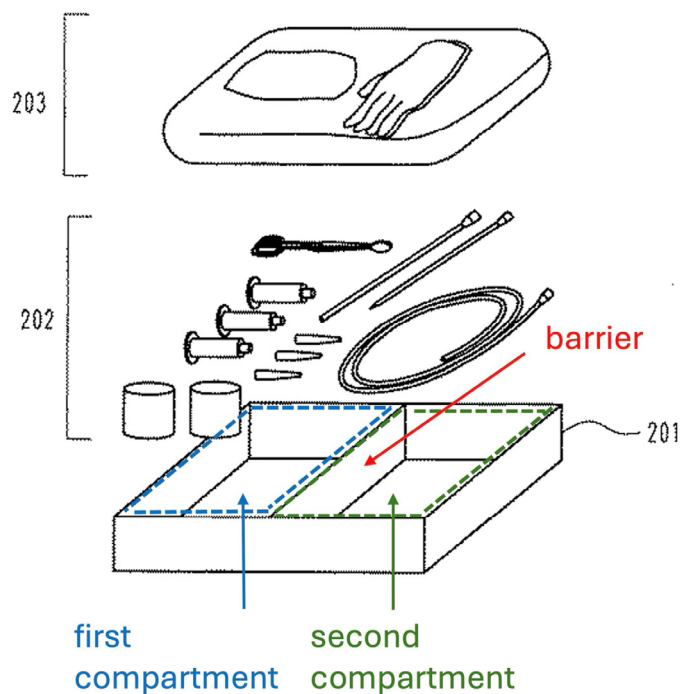
A POSA would understand that a Foley catheter also requires lubricant to lubricate the catheter. (EX1002.¶341.) Serany discloses “lubricating jelly in an individually sealed pouch 40.” (EX1009.3:1-5.) While lubricant can be provided in

a variety of containers, it would have been obvious to provide lubricant in a syringe. (EX1002.¶¶342-44.) Doing so would merely involve a simple substitution of one container (a pouch as taught by Serany) for another known type of container (a syringe as taught by Numata) to produce predictable results. A lubricant syringe also provides more control than a lubricant packet and allows for the injection of lubrication directly into the urethra. (EX1002.¶¶342-44; EX1003.¶49.)

(e) Limitation 1[e]

As shown in annotated Figure 4 below, Numata discloses “*the first compartment and the second compartment are adjacent and separated by a barrier*”:

(FIG. 4)



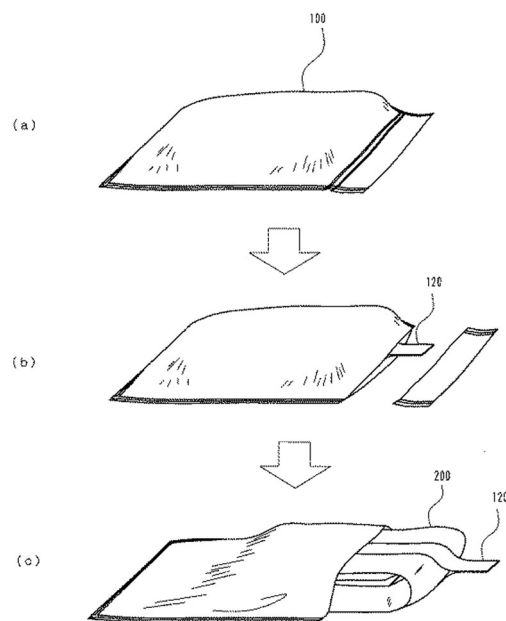
(EX1002.¶¶345-49.)

2. Claim 2

Numata discloses “an outer packaging disposed about the single layer tray.” (EX1002.¶¶350-53.)

Numata discloses a “packaging bag 100 for sealing the medical product 200” as shown in Figure 7. (EX1007.Abstract,¶¶0022-25, Fig.7)

(FIG. 7)



3. Claim 5

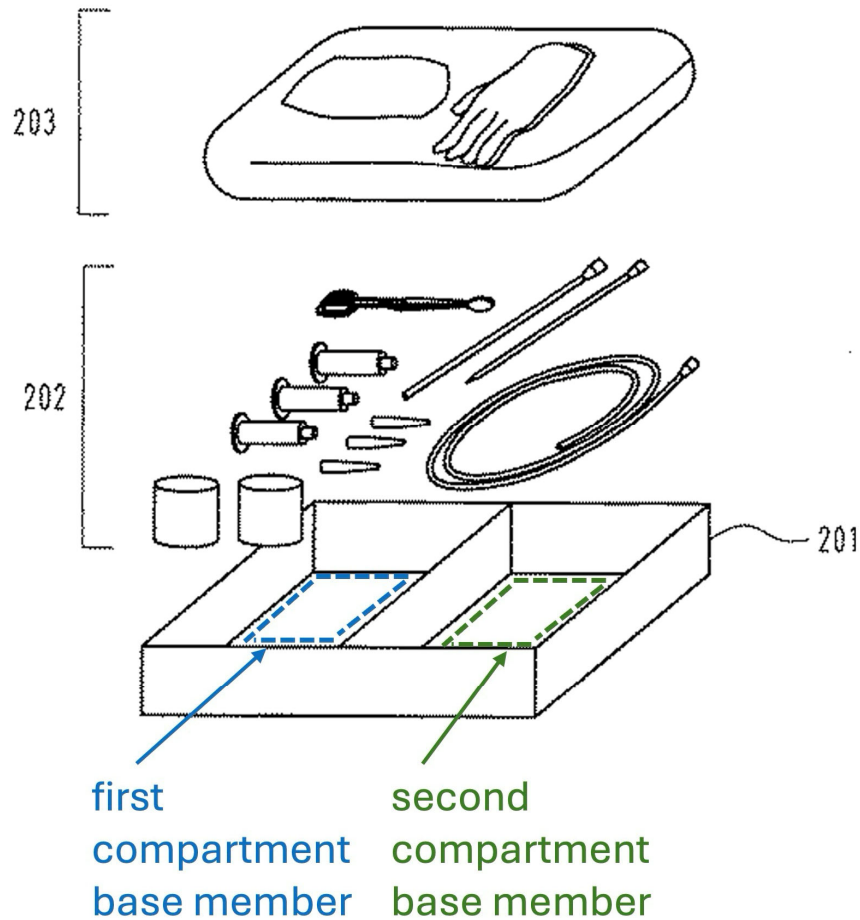
For the reasons in 1[d], Numata and Serany render “*wherein the water is sterile*” obvious. (EX1002.¶354.)

4. Claim 7

Numata discloses “*wherein the first compartment is bounded by a first base member and the second compartment is bounded by a second base member.*” (EX1002.¶¶355-57.)

As shown in annotated Figure 4, Numata discloses this claim:

(FIG. 4)

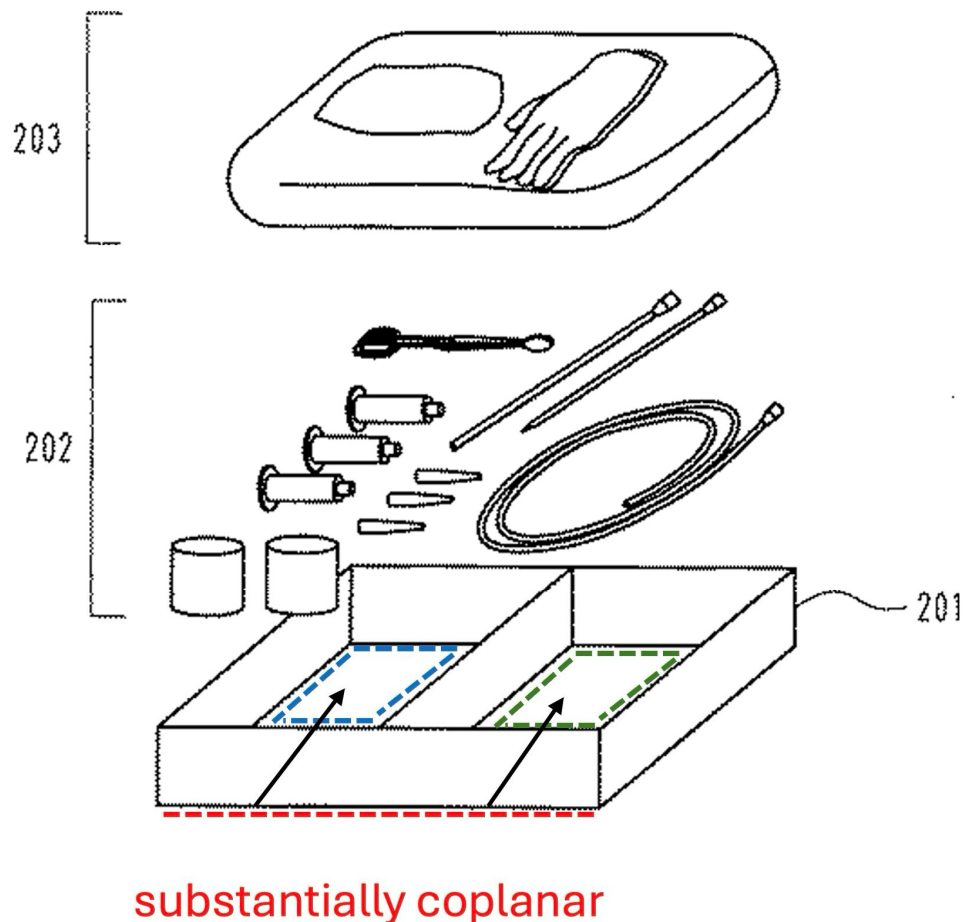


5. Claim 8

Numata discloses “*wherein a portion of the first base member and another portion of the second base member are substantially coplanar.*” (EX1002.¶358-59.)

As shown in annotated Figure 4, Numata discloses a tray with a flat bottom surface with the base member of both compartments lying in the same plane:

(FIG. 4)



substantially coplanar

D. Ground 4: Obviousness Over Numata, Serany, Disston and Beddow

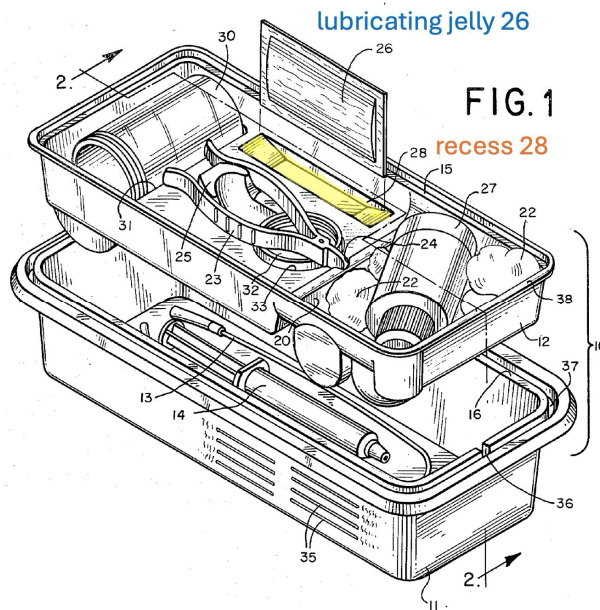
As discussed below, the combination of Numata, Serany, Disston and Beddow renders claims 3 and 4 obvious. (EX1002.¶¶361-84.)

1. Claim 3

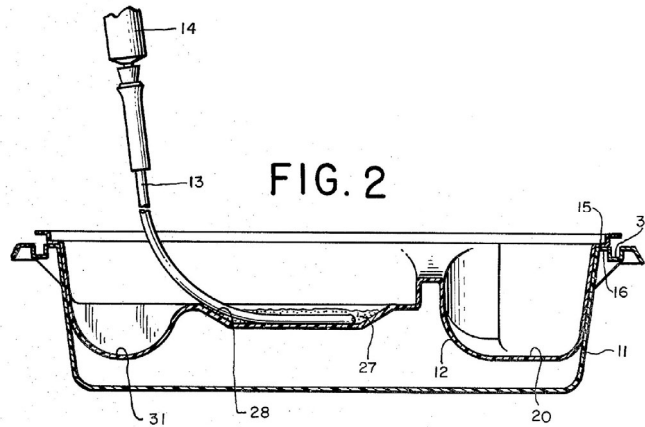
Numata and Beddow render “the first compartment defining a lubricating jelly application compartment” obvious. (EX1002.¶¶361-81.)

Beddow teaches using the compartment that stores the lubricant as a lubricating jelly application compartment to receive lubricating jelly: “To provide for lubrication of the catheter, the catheterization package 10 includes an individually sealed foil container 26 of lubricating jelly 27 packed within an elongated rectangular recess 28. In use, this container is removed from recess 27 [sic] and torn open, and the lubricating jelly contained therein is deposited in the recess.” (EX1010.3:11-16, Fig. 1; EX1002.¶¶362-65.)

As shown in Figure 1 of Beddow below, the lubricating jelly is stored in recess 28 (a first compartment of the tray) where the lubricant is also dispensed.



Once the lubricant is dispensed, the catheter is passed into the first compartment of Beddow (recess 28) to lubricate the catheter. (EX1010.3:18-22, Fig. 2.)



Thus, it was known in the art to lubricate the catheter in the compartment where the lubricant is stored because “clinicians find it convenient to pick up a lubricant syringe and squirt the lubricant into the same compartment where the syringe is stored.” (EX1003.¶¶127,128-41.)

In view of Beddow, a POSA would have been motivated to use the first compartment of Numata as a lubricating jelly application compartment and had a reasonable expectation of success in doing so because the first compartment would also store the lubricant (as discussed at limitation 1[d]). (EX1002.¶365.) This applies a known technique (the dual-use of a compartment to store lubricant and receive lubricant) to a known device (a catheter tray) to yield predictable results.

Lubrication compartments were ubiquitous in the prior art, but varied with respect to shape, size, and location in the tray. (EX1002.¶¶362-65; EX1003.¶¶128-141.) A POSA would have also understood that the first compartment of Numata is well-suited for lubrication, and thus meets any functional or structural requirements

of this claim. (EX1002.¶¶366-69; EX1003.¶¶133-40.) First, there is ample space in the first compartment to lubricate up to five inches of the catheter, which is the maximum length that is typically lubricated. (EX1002.¶367; EX1003.¶¶134.)

Second, the compartment is easily accessible because the tray has an open top, is not particularly deep, and the “single tray” nature of Numata means that the Foley catheter is stored in an adjacent compartment, which helps “prevent usage errors and preparation errors.” (EX1002.¶368.) Third, the tray is sterile. (EX.1007.0030; EX1002.¶368.) Fourth, Numata’s tray (made of hard plastic) is a smooth surface to easily run the catheter through the lubricant. (EX1007.0031; EX1002.¶368; EX1003.¶139.)

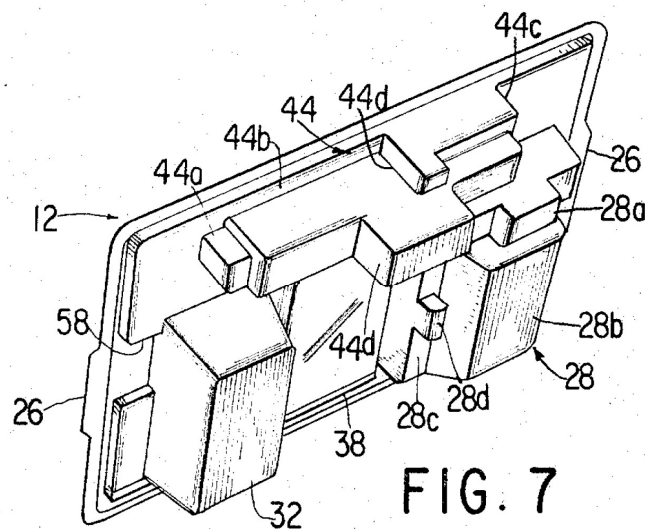
Finally, Numata only teaches two compartments. Thus, it would have been obvious to try using the first compartment as a lubrication compartment given the finite number of options where the catheter could be lubricated within the tray. (EX1002.¶369.)

To the extent this claim is deemed to require a specific structure that is not otherwise disclosed by Numata, it would have been obvious to add contouring such as a depression to the first compartment of Numata in view of Serany to accommodate the lubricant and water syringes to prevent movement during shipping. (EX1002.¶¶370-81.) This depression would perform the dual-function of serving as a shallow lubrication channel within the first compartment allowing the

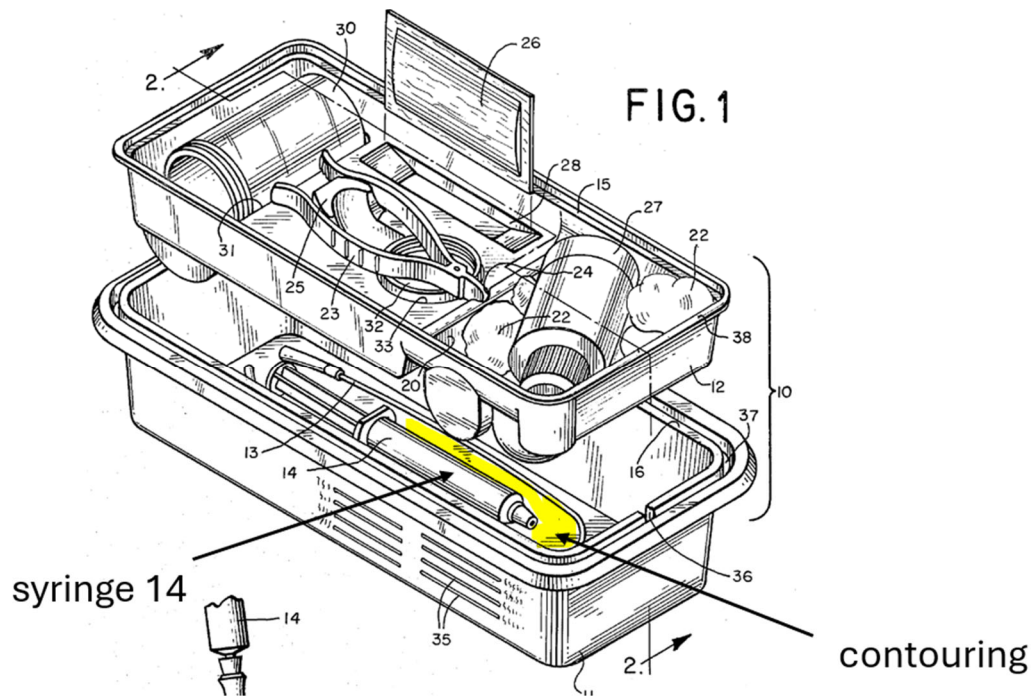
lubricant to pool in an enclosed space that is sufficient in size to lubricate an appropriate amount of the catheter. (EX1002.¶380.)

The tray of Numata does not provide any specific mechanism to hold the syringes in place within the first compartment of tray 201. Accordingly, the syringes could move during shipment of the tray, which could risk damaging the syringes. (EX1002.¶¶371.)

A known technique to prevent syringes from moving during shipping is to contour a compartment to accommodate a syringe and its flange via a depression. (EX1002.¶372.) As taught by Serany, such contouring both “hold[s] the syringe against lateral movement in its stored condition” and makes it “easily grasped.” (EX.1009.3:6-22, Fig. 7.) Both Serany and Beddow teach contouring to hold a syringe in place using known manufacturing methods:



(EX.1009.3:6-22, Fig. 7; EX.1002.¶¶372-79.)



(EX.1010, Fig. 1, 2:46-52, 4:14-17; EX.1002.¶¶373-79.)

Adding such contouring to Numata merely applies a known technique using known manufacturing methods (a contoured depression to hold a syringe flange) to a known device (a catheter kit with syringes) to yield predictable results (preventing movement of the syringes during shipping and allow for easy grasping of the syringes.) (EX1002.¶¶375-81.)

Further, adding a depression to accommodate the syringes would form a lubrication channel within the first compartment by allowing the lubricant to pool in a depression around the same length as five inches of the catheter that ideally should be lubricated. (EX1003.¶141.) Indeed, Male Catheter Insertion discloses

lubricating the catheter in the depression where the lubricant syringe is stored.
(EX1003.¶127 (citing EX1020.2:43-49,4:48-55).)



2. Claim 4

For the reasons in claim 3, Numata and Beddow render “*the lubricating jelly application compartment configured to receive lubricating jelly from the one of the first syringe or the second syringe to lubricate at least some of the Foley catheter when the Foley catheter is passed into the first compartment*” obvious.
(EX1002.¶¶382-84.)

Specifically, the first compartment of Numata would receive lubricating jelly from the lubricant syringe to lubricate at least some of the Foley catheter (e.g., the tip) when the Foley catheter is passed into the first compartment. (EX1002.¶¶383-84; EX1003.¶¶138-40.)

E. Ground 5: Obviousness Over Numata, Serany, Disston, Salvadori

As discussed below, the combination of Numata, Serany, Disston and Salvadori discloses each element of claims 6, 10, 11, 13, and thus renders them obvious. (EX1002.¶¶385-420.)

1. Claim 6

Numata and Salvadori render “*a specimen jar disposed within the single layer tray*” obvious. When customizing the kit of Numata to include urinary catheter equipment (*see* limitation 1[c]), it would have been obvious to add a specimen jar. (EX1002.¶¶385-90.)

Specimen jars were common in prior art catheter trays. (EX1010.1:21-25; EX1013.3:8). They are used to take a specimen of urine “if there is a clinical need.” (EX1019.51; EX1002.¶387.) Salvadori discloses “*a specimen jar*,” i.e., “specimen bottle 68.” (EX1009.1:12-16,3:8.)

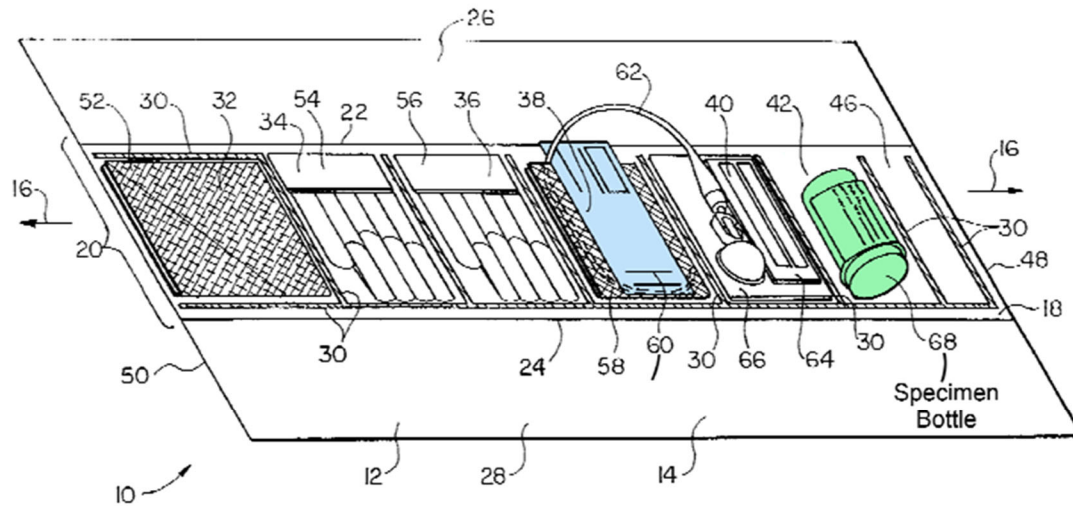


FIG. 1

In view of Salvadori, a POSA would have been motivated to include a speciman jar in the catheterization kit of Numata to allow a practitioner to take a urine sample. (EX1002.¶388.)

This involves the use of a known technique (provision of a speciman jar) to a known device (a Foley catheter kit) to yield predictable results (providing a speciman jar so that the practitioner can take a urine specimen). (EX1002.¶¶389-90.).

2. Claim 10

For the reasons in claim 2, Numata discloses “an outer packaging disposed about the single layer tray.”

Numata and Serany render “*a Foley catheter securement device disposed within the single layer tray*” obvious. (EX1002.¶¶391-97.) When customizing the kit of Numata to include urinary catheter equipment (*see* limitation 1[c]), it would have been obvious to add a Foley catheter securement device.

Serany discloses “*a Foley catheter securement device.*” Serany discloses a tray that includes a “safety pin 41” and “rubber band 42” that are “ready for use” and serve as a catheter securement device. (EX1009.3:1-5,3:23-26,3:55-58.) *See also* discussion at Ground 2, limitation 10[b].

In view of Serany, a POSA would have been motivated to include a Foley catheter securement device in the catheterization kit of Numata to allow for the Foley catheter to be properly secured when inserted. Furthermore, the inclusion of a Foley catheter securement device in the catheterization kit of Numata involves the use of a known technique (application of a securement device during a catheterization procedure) to a known device (a Foley catheter kit) to yield predictable results (providing a securement device in the tray so that the practitioner can secure the catheter after it inserted in the patient). (EX1002.¶¶393-97.)

The combination of Numata and Salvadori render “*one or more swabsticks disposed within the single layer tray*” obvious. (EX1002.¶¶398-406.) When customizing the kit of Numata to include urinary catheter equipment (*see* limitation 1[c]), it would have been obvious to add swabsticks to the kit of Numata. As

discussed at Ground 2, limitation 10[c], it is necessary to clean the patient’s genitalia prior to inserting a Foley catheter and swabsticks were a known device for performing this task. (EX1003.¶¶142-48.) Salvadori teaches a “urethral catheter kit or tray” that includes “swab sticks 60.” (EX1009.1:12-16,3:4.) In view of Salvadori, a POSA would have been motivated to include swabsticks in the catheterization kit of Numata to allow a practitioner to cleanse the patient’s genitalia prior to insertion of the catheter. (EX1002.¶475.)

Furthermore, the inclusion of swabsticks in the catheterization kit of Numata involves the use of a known technique (provision of swab sticks) to a known device (a Foley catheter kit) to yield predictable results. (EX1002.¶¶403-06.)

3. Claim 11

Numata and Serany render “*an underbuttocks drape disposed within the outer packaging; and a fenestrated drape disposed within the outer packaging*” obvious. (EX1002.¶¶407-14.)

Numata discloses includes “a drape” with an outer packaging. (EX1007.¶0031-33.)

When customizing the kit of Numata for a urinary catheterization procedure (see limitation 1[c]), it would have been obvious to substitute Numata’s “drape” with an “underbuttocks drape” and a “fenestrated drape,” which were well-known drapes used when performing a Foley catheterization procedure as taught by Serany.

(EX1009.2:21-33, Fig. 5.) This is a simple substitution of one known element (a drape) for another (an underbuttocks and fenestrated drape) to yield predictable results. This also involves the use of a known technique (providing an underbuttocks and a fenestrated drape) to a known device (a catheter kit) to yield predictable results. (EX1002.¶¶407-14.)

4. Claim 13

For the reasons in claim 2, Numata discloses “*an outer packaging disposed about the single layer tray.*” (EX1002.¶415.)

For the reasons in claim 10, Numata and Serany render “*a Foley catheter securement device disposed within the single layer tray*” obvious. (EX1002.¶416.)

For the reasons in claims 6 and 10, Solazzo and Salvadori render “*one or more swabsticks disposed within the single layer tray*” and “*a specimen jar disposed within the single layer tray*” obvious. (EX1002.¶¶417-20.)

F. Ground 6: Obviousness Over Numata, Serany, Disston, Imai

As discussed below, the combination of Numata, Serany, Disston and Imai renders claims 14 and 17 obvious. (EX1002.¶¶421-36.)

(a) Limitation 14[a]

For the reasons in limitation 1[a], Numata discloses “*A medical procedure kit, comprising: a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly.*” (EX1002.¶421.)

(b) Limitation 14[b]

For the reasons in limitation 1[b], Numata discloses “*a first syringe and a second syringe disposed within the first compartment.*” (EX1002.¶422.)

(c) Limitation 14[c]

For the reasons in claim 1[c], Numata, Serany and Disston disclose “*the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter.*” (EX1002.¶423.)

(d) Limitation 14[d]

For the reasons in claim 1[d], Numata and Serany render “*wherein: one of the first syringe or the second syringe contains lubricating jelly and another of the first syringe or the second syringe contains water*” obvious. (EX1002.¶424.)

(e) Limitation 14[e]

For the reasons in claim 1[e], Numata discloses “*the first compartment and the second compartment are adjacent and separated by a barrier.*” (EX1002.¶425.)

(f) Limitation 14[f]

Numata and Serany render “*the first syringe and the second syringe are ordered within the single layer tray in accordance with their use during a catheterization procedure*” obvious. (EX1002.¶¶426-31.)

Numata’s kit includes multiple syringes in a first compartment, though it does not specify a particular order of use of the syringes. It was well-known in the art to

arrange components in a catheterization kit in their order of use. (EX1002.¶427.) Specifically, Serany teaches a Foley catheter kit where “everything is available in the proper order of use” and “packaged in their order of use.” (EX1009.1:9-12,1:23-35.) Disston has a similar teaching. (EX1012.2:15-19.)

For the reasons in limitation 1[d], it would have been obvious to customize the contents of Numata’s syringes with sterile water and lubricant. In view of Serany, it would have been obvious to organize those syringes in the first compartment consistent with their order of use. (EX1002.¶¶427-30.) For example, the lubricant syringe could be positioned above the water syringe because the lubricant step is performed before the Foley catheter is inflated with the water syringe. (EX1002.¶236.) Alternatively, this order could be reversed if a test balloon step is performed as that requires using the water syringe first.

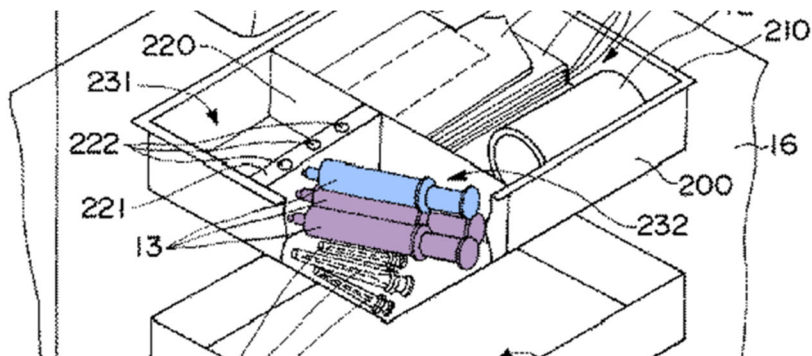
A POSA would have been motivated to arrange the syringes in their order of use in the kit of Numata. (EX1002.¶431.) Serany provides such motivation by teaching components that are “arranged in logical step-by-step order to facilitate the nurse’s or physician’s task.” (EX1009.1:9-35.) Arranging items in their order of use makes it more likely that the user will perform operations in the correct order as well as quicker to retrieve the correct device. (EX1002.¶431.) Indeed, it was well-known to include affordances to aid a user in performing operations in the correct order. (EX1002.¶428-31.) Finally, this applies a known technique (arranging components

in their order of use) to a known device (a catheter kit) to yield predictable results (arranging items in “a logical step-by-step order to facilitate the nurses or physicians task”).

(g) Limitation 14[g]

For the reasons in limitation 14[f], Numata and Imai render “*the first compartment supports the first syringe and the second syringe at different heights*” obvious. (EX1002.¶¶432-36.)

As discussed for limitation 14[f], it would have been obvious to arrange syringes in their order of use. It would have been obvious to try arranging them at different heights given the finite number of options available to arrange the syringes (by height versus left-to-right). Indeed, Imai discloses stacking syringes in a catheter tray at different heights:



(EX1012.Fig.1,¶¶0028-31.)

In view of Imai, a POSA would have been motivated to arrange the syringes at different heights based on their order of use and have a reasonable expectation of success in doing so. (EX1002.¶¶433-36.)

G. Ground 7: Obviousness Over Numata, Serany, Disston, Imai, Salvadori

As discussed below, the combination of Numata, Serany, Disston, Imai, and Salvadori renders claims 15, 16, 18, and 19 obvious. (EX1002.¶¶437-41.)

1. Claims 15 and 16

For the reasons in claim 2, Numata discloses “*an outer packaging disposed about the single layer tray.*” (EX1002.¶¶437-38.)

For the reasons in claims 10 and 11, Numata and Serany render “*a Foley catheter securement device disposed within the single layer tray*” and “*an underbuttocks drape disposed within the outer packaging,*” and “*a fenestrated drape disposed within the outer packaging*” obvious. (EX1002.¶¶439,441.)

For the reasons in claims 6 and 10, Numata and Salvadori render “*one or more swabsticks disposed within the single layer tray*” obvious. (EX1002.¶¶440.)

H. Ground 8: Obviousness Over Numata, Serany, Disston, Imai, Salvadori, and Beddow

As discussed below, Numata, Serany, Disston, Imai, Salvadori, and Beddow render claims 17-20 obvious. (EX1002.¶¶442-73.)

1. Independent Claim 17

(a) Limitations 17[p] and 17[a]

Claim 17 requires “*A medical procedure kit, comprising: a surface defining a single layer tray having a first compartment adjacent to and separated by a barrier*

from, a second compartment configured for receiving a Foley catheter, a coiled tubing, and a fluid drain bag.”

For the reasons in limitations 1[a] and [e], Numata discloses a single layer tray having a first compartment separated by a barrier from, a second compartment.” (EX1002.¶¶442-51.)

Numata renders obvious “***a surface defining a single layer tray having a first compartment separated by a barrier from, a second compartment.***” (EX1002.¶444.)

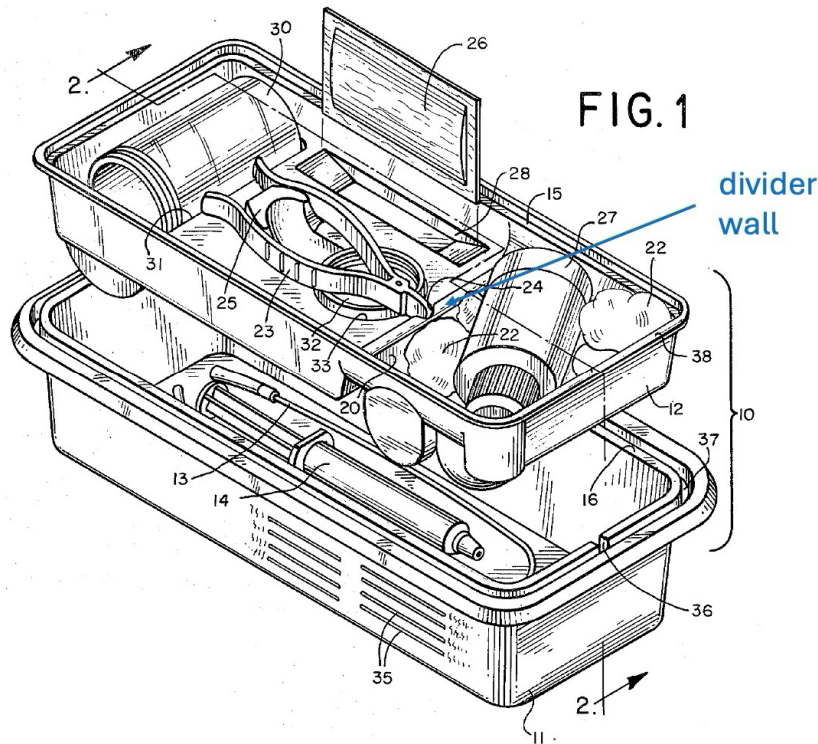
As noted above, the Board previously interpreted similar claim language as requiring a single surface, i.e. that the barrier is integrally formed. Numata discloses that “tray 201 [is] ***molded*** from hard plastic or the like.” (EX1007.¶0031 (emphasis added).)

A POSA would understand that injection molding is one form of molding and could be used to make the tray depicted in Numata with an integrally formed barrier. (EX1002.¶445-50.) Injection molding was a well-known manufacturing technique before 2009 that allows a tray (including its internal divider walls) to be formed from a single contoured surface. (EX1002.¶445-50.) Indeed, the ’347 patent confirms that injection molding can be used to form a tray that has at least two compartments separated by an integrally formed barrier. (EX1001.4:39-50.) And, the Board similarly determined that injection molding could be used to make a tray that meets this limitation. (EX1015.0030-35.)

A POSA would have strong motivations to use injection molding to manufacture the single level tray of Numata with “a surface defining a single layer tray having a first compartment separated by a barrier from, a second compartment” and had a reasonable expectation of success in doing so. (EX1002.¶¶445-51.) Manufacturing a tray with an integrally formed barrier strengthens the tray by providing additional rigidity and simplifies the manufacturing process by eliminating the need to assemble separate plastic components. Moreover, using injection molding to manufacture a tray as depicted in Numata would have been well within the skillset of a POSA. Injection molding, including the use of injection molding to form an integral barrier, was well-known in the medical industry prior to 2009. For example, as the Board recognized in the Previous IPRs, Medline’s expert “testified that a different prior art single layer tray [Rauschenberger from 1977] was formed by injection molding depicted a molded surface defining multiple compartments separated by a barrier.” (EX1015.0034; EX1002.¶¶449; EX1021.)

Alternatively, it would have been obvious to form the tray of Numata using thermoforming, a different form of molding, instead of injection molding. (EX1002.¶¶446-448.) Thermoforming was also a well-known manufacturing technique before 2009 and thermoformed catheter trays were also well-known. (EX1002.¶¶445-50.) For example, Beddow discloses trays that are “thermoformed

by conventional methods.” (EX1010.2:55-57.) As shown in Figure 1, the trays of Beddow have an integrally formed divider wall:



(EX1010.Fig.1; EX1002.¶¶447.) Again, a POSA would recognize that using thermoforming to make a tray with an integrally formed barrier provides several advantages including increased rigidity and manufacturing simplicity. Moreover, the '347 patent also acknowledges that thermoforming can be used to make the trays depicted in the patent, which have integrally formed barriers. (EX1001.4:39-50.)

In view of Beddow, a POSA would have been motivated to manufacture the tray of Numata using thermoforming and has a reasonable expectation of success in doing so. (EX1002.¶¶448,450.) This applies a known technique (forming a single level tray as a part of a single surface using thermoforming) to a known device (a

catheter tray) to yield predictable results (strengthening the tray while utilizing a manufacturing technique that is cheaper and faster). (EX1002.¶¶446.)

(b) Limitation 17[b]

For the reasons in claim 1[a] and [b], Numata discloses “*a first syringe and a second syringe disposed within the first compartment.*” (EX1002.¶¶452-53.)

For the reasons in limitation 1[d], Numata, Serany, and Disston render “*the first syringe containing lubricating jelly and the second syringe containing water*” obvious. (EX1002.¶454.)

For the reasons at limitations 14[f-g], Numata, Serany and Imai render “*wherein the first syringe and the second syringe are arranged at different heights within the first compartment in accordance with their use during a Foley catheterization procedure*” obvious. (EX1002.¶455.)

(c) Limitation 17[c]

For the reasons in limitation 1[c], Numata, Serany and Disston render “*the Foley catheter, the coiled tubing, and the fluid drain bag situated in the second compartment*” obvious. (EX1002.¶456-57.)

Numata, Serany and Disston further disclose “*with the coiled tubing positioned between the Foley catheter and the fluid drain bag.*” (EX1002.¶¶458-59.) The coiled tubing of Serany and Disston is “positioned between” the catheter and bag because it connects them. (EX1009.3:32-35; EX1008.2:19-23.) If this

claim requires the tubing be positioned in the compartment between the catheter and bag, it would have been obvious to do so because that is the order in which those components are used. (EX1002.¶¶460-66.) This applies a known technique (arranging items in their order of use) to a known device (a catheter kit) to yield predictable results. (EX1002.¶¶460-66.)

2. Claim 18

For the reasons in claims 10 and 11, Numata and Serany render “*a Foley catheter securement device disposed within the single layer tray*” obvious. (EX1002.¶¶467,469.)

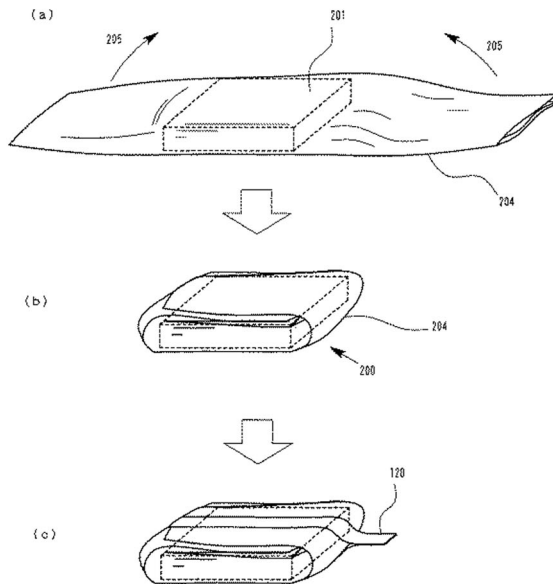
For the reasons in claims 6 and 10, Numata and Salvadori render “*one or more swabsticks disposed within the single layer tray*” and “*a specimen jar disposed within the single layer tray*” obvious. (EX1002.¶¶468,470.)

3. Claim 19

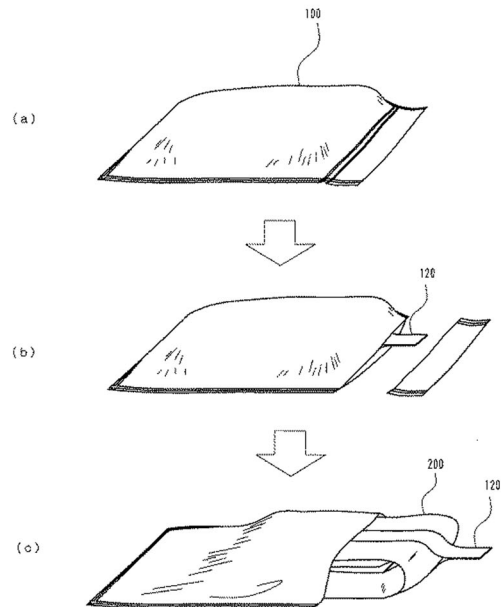
Numata discloses “*one or more layers of wrap material enclosing the single layer tray within one or more folds of the one or more layers of wrap material and an outer packaging disposed about the one or more folds of the one or more layers of wrap material.*” (EX1002.¶¶471-72.)

Numata discloses a single layer tray wrapped in the one or more layers of cover cloth 204 as shown in Figure 5 and sealed in an outer packaging 100 as shown in Figure 7:

(FIG. 5)



(FIG. 7)



(EX1007.¶¶0022-25,0031-32.)

4. Claim 20

For the reasons in claim 3, Numata and Beddow render “*the first compartment defining a lubricating jelly application compartment*” for patenting.

(EX1002.¶473.)

I. No Secondary Considerations of Nonobviousness

In the Previous IPRs, Medline raised several secondary consideration factors, including long-felt need, copying and praise, failure by others and commercial success. But the Board rejected Medline’s evidence. **First**, the Board recognized that the critical claimed features (a single-layer tray and syringes arranged in their order of use, which Medline itself had identified) were in the prior art—meaning Medline “fail[ed] to prove that it is entitled to a presumption of nexus.”

(EX1014.0057-63.) **Second**, the Board addressed the evidence Medline presented for each factor and rejected nearly all of it. (EX1014.0063-76.). Only for copying and praise, the Board determined “that the evidence of copying and praise *slightly* favors a finding of nonobviousness” and that this evidence “does not weigh significantly against a conclusion of obviousness for any claim at issue.” (EX1014.0069,76.) For similar reasons here, there are no significant secondary considerations weighing against a finding of obviousness. (EX1002.¶¶474-78.) Petitioner reserves its right to respond to any assertion of secondary considerations advanced by Medline.

XI. 35 U.S.C. § 325(d) DOES NOT FAVOR DENIAL

The Board uses a two-part framework to analyze whether denial under § 325(d) is proper. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7 (PTAB Feb. 13, 2020). The Board considers several nonexclusive factors (“*Becton Dickinson* factors”) within this framework to provide useful insight into how to apply each prong, each of which is discussed below. *Id.* at 4; *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, 17-18 (Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph) (“*Becton, Dickinson*”).

Becton Dickinson factors (a), (b), and (d) relate to whether the art or arguments presented in the Petition are the same or substantially the same as those

previously presented to the Office. *Advanced Bionics* at 10. Factors (c), (e), and (f) are only considered if the same or substantially the same art or arguments were previously presented to the Office. *Id.*

A. *Becton Dickinson* Factors (a), (b), and (d)

Petitioner’s arguments and prior art here are neither the same nor substantially the same art or arguments previously before the Office during prosecution of the ’347 patent. For example, Petitioner asserts the Numata reference, which was not previously before the Office. Numata is the primary reference asserted by Petitioner in Grounds 3-8. And while Petitioner’s other primary reference, Solazzo, was previously before the Office, the Board’s remand FWDs IPR2019-00035 and IPR-00036 were not before the Office nor was Medline’s subsequent abandonment of its appeals of those FWDs and the ultimate cancellation of most ’088 claims. The remand FWDs combine Solazzo with several secondary references to find substantively identical limitations in the ’088 patent unpatentable. Yet, Solazzo was not substantively discussed by the Examiner. These factors weigh against discretionary denial.

B. *Becton Dickinson* Factors (c), (e), and (f)

These factors also weigh against discretionary denial because the Office materially erred by failing to consider the remand FWDs in IPR2019-00035 and IPR-00036, which found numerous claims of the related ’088 patent invalid. “[I]f

the record of the Office’s previous consideration of the art is not well developed or silent, then a petitioner may show the Office erred by overlooking something persuasive under factors (e) and (f).” *Advanced Bionics* at 10; *see also Hamilton Technologies LLC v Tehrani*, IPR2020-01199, 2021 WL 54761, at *10 (P.T.A.B. Jan. 6, 2021).

As mentioned above in § IV.B, the applicant submitted to the Office an IDS disclosing the April 9, 2020 FWDs in IPR2019-00035 and IPR2019-00036. The applicant also submitted in another IDS the Federal Circuit decision vacating and remanding the April 9, 2020 FWDs. The applicant did **not** submit, however, the remand FWDs that invalidated the ’088 patent claims described above. These remand FWDs invalidated most claims of the ’088 patent as obvious over Solazzo and Serany. That the Examiner did not have the benefit of these FWDs is material to patentability, as both Solazzo and Serany were before the Examiner and the invalidated claims of the ’088 patent are substantially similar to the issued claims of the ’347 patent. *Compare* ’088 patent claims 1, 25, 37 *with* ’347 patent claims 1, 14, 17.

XII. 35 U.S.C. § 314(a) DOES NOT FAVOR DENIAL

The *Fintiv* Factors weigh in favor of institution.

A. *Fintiv* Factor 1: Whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted

The Court has not granted a stay. Accordingly, this factor is neutral.

B. *Fintiv* Factor 2: Proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision

Fact discovery in the District Court litigation is ongoing and no depositions have taken place. A *Markman* hearing has not been scheduled and fact discovery will not close until 45 days after the Court issues its *Markman* order. Thereafter, expert discovery will take several additional months followed by *Daubert* and dispositive motions. A trial date will not be set until after resolution of dispositive motions. Moreover, the Court recently appointed a Special Master who will first issue a report and recommendation on claim construction that must then be adopted or modified by the Court. The projected date for a final written decision is July 2026, and the Court in the District Court litigation has not set a trial date. The Board has stated “where a trial date as not be scheduled in a related district court proceeding, we will not speculate as to the timing of events that may occur in that proceeding.” *Church & Dwight Co., Inc. v. Batinkoff*, No. IPR2020-00168, 2020 WL 2511248, at *6 (P.T.A.B. May 15, 2020). This factor weighs against discretionary denial.

C. *Fintiv* Factor 3: Investments in the parallel proceeding by the court and the parties

The district court litigation is not in an advanced stage. Written discovery has taken place, but no depositions have occurred, and there have been no significant investments by the Court or the parties in this case related to invalidity. A claim

construction hearing has not been scheduled. Moreover, the Court recently appointed a Special Master who will first issue a report and recommendation on claim construction that must then be adopted or modified by the Court. Therefore, a claim construction order is unlikely to issue until after the expected institution date (June 2025), this factor weighs against discretionary denial. *Med-El Elektromedizinische Geräte Ges.m.b.H. v. Advanced Bionics AG*, No. IPR2020-00190, 2020 WL 3033320, at *5 (P.T.A.B. June 3, 2020) (weighing factor 3 in favor of institution where “a claim construction order will not have issued” at the time of the institution decision); *Facebook, Inc. v. USC IP P’ship, L.P.*, No. IPR2021-00033, 2021 WL 1718801, at *5 (P.T.A.B. Apr. 30, 2021) (weighing in factor 3 in favor of institution where “[t]he district court proceeding is still at a relatively early stage”).

D. *Fintiv* Factor 4: Overlap between issues raised in the petition and the parallel proceeding

Petitioner agrees that, if this petition is instituted, it will not assert invalidity grounds in the litigation that are included in this petition. Petitioner’s agreement not to use the same grounds if institution is granted reduces the risk of duplicative efforts across proceedings. Thus, this factor weighs in favor of institution. *See, e.g., Sand Revolution II, LLC v. Continental Intermodal Grp.-Trucking LLC*, IPR2019-01393, Paper 24 at 11-12 (PTAB June 16, 2020) (informative) (finding Petitioner’s stipulation not to pursue the same grounds in the district court weighed in favor of institution); *Google LLC et al v. Parus Holdings, Inc.*, IPR2020-00846, Paper 9 at

22 (PTAB October 21, 2020) (“Petitioner has stipulated that it will not pursue the same grounds in the Texas court as it pursues here, which will further lessen the possibility of duplication and inconsistent results between the two forums.”).

E. *Fintiv* Factor 5: Whether the petitioner and the defendant in the parallel proceeding are the same party

The Petitioner here is the same party as the defendant in the district court case. Although this factor may weigh slightly in favor of discretionary denial, it does not outweigh the other factors discussed above.

F. *Fintiv* Factor 6: Other circumstances that impact the Board’s exercise of its discretion, including the merits

The merits of the petition also support institution. As discussed in detail above, there is no novel aspect of the ’347 patent. Every aspect of the claimed invention was already known in the art, and the Examiner failed to consider the remand FWDs in IPR2019-00035 and IPR2019-00036, which found that claims substantially similar to those in the ’347 patent were invalidated by references before the Office. Accordingly, the merits of the petition weigh strongly in favor of institution.

XIII. CONCLUSION

For the foregoing reasons, Petitioner has established a reasonable likelihood that the Challenged Claims are unpatentable. Petitioner therefore respectfully requests that *inter partes* review of the ’347 patent be granted.

DATED: January 3, 2025

Respectfully submitted,

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Attorney for Petitioner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(a) and (d), the undersigned hereby certify that the **PETITION FOR INTER PARTES REVIEW** complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(i) and (b)(i) permitting a petition of up to 14,000 words because, exclusive of the exempted portions, it contains 13,791 words as counted by the word processing program used to prepare the paper.

Date: January 3, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

In accordance with 37 C.F.R. §§ 42.6(e) and 42.105, I hereby certify that true and correct copies of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 11,684,347 and supporting exhibits were served on January 3, 2025 via USPS Priority Mail Express to the following correspondence address of the attorneys of record for U.S. Patent No. 11,684,347 as evidenced on the Patent Office’s public Patent Center system:

Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC
222 12th Street NE
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Courtesy copies of the same documents were also sent to: Gabrielle LaHatte (gabrielle.lahatte@lw.com), Brett Sandford (brett.sandford@lw.com), Gregory K. Sobolski (Greg.Sobolski@lw.com), Terra Reynolds (terra.reynolds@lw.com), and Brent T. Watson (thomas.watson@lw.com), counsel for Plaintiffs in *Medline Industries, LP v. C.R. Bard, Inc.*, 1:23-cv-5827-JPB (N.D. Ga.).

Date: January 3, 2025

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