

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 IPR2025-00401

U.S. Patent No. 11,661,219

**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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Ex.	Description	Document Name
1001	U.S. Patent No. 11,661,219	'219 patent
1002	Declaration of Karl Leinsing	Leinsing Decl.
1003	Declaration of Dr. Edward Yun	Yun Decl.
1004	Prosecution History of 11,661,219	'219 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) ('088 Patent)	IPR2019-00035 Remand Decision
1015	Final Written Decision on Remand (Paper 102), IPR2019-00036	IPR2019-00036 Remand Decision

Ex.	Description	Document Name
	(November 23, 2022) (’088 Patent)	
1016	Final Written Decision on Remand (Paper 87), IPR2019-00223 (November 23, 2022) (’596 Patent)	IPR2019-00223 Remand Decision
1017	Inter Partes Review Certificate for ’088 Patent	’088 IPR Certificate
1018	Inter Partes Review Certificate for ’596 Patent	’596 IPR Certificate
1019	Madeo, M. and Roodhouse, A.J., Reducing the risks associated with urinary catheters, Nursing Standard, Vol. 23, No. 29, 47-55 (2009)	Nursing Standard
1020	Male Catheter Insertion Video, uploaded to YouTube on February 7, 2008, available at https://www.youtube.com/watch?v=ISBAya_5cIM	<i>Catheterization Video</i>
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	CAUTI Guide

Ex.	Description	Document Name
	Facility-Based Prevention Interventions in Acute and Long-Term Care Settings, Association for Professionals in Infection Control and Epidemiology (2008)	
1028	U.S. Patent No. 6,158,437 to Vagley	Vagley
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. 11,661,219 (“the ’219 patent”), assigned to Medline Industries, LP, and cancellation of claims 1-7 and 9-16 (“Challenged Claims”). As explained by Mr. Leinsing and Dr. Yun,¹ those claims are unpatentable as obvious in view of the prior art references described below. All claims are challenged based on Numata, which was not submitted during prosecution. The Petition also includes grounds based on Solazzo (which the Board previously relied upon in cancelling numerous related claims) and Rauschenberger.

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.

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

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.

asserted the '219 patent. Patent Owner also asserts U.S. Patent Nos. 11,684,347 (“the '347 patent”), and 11,661,220 (“the '220 patent”). The '219 patent claims priority to common priority applications as the '347 and '220 patents and has a specification with overlapping disclosures as the '347 and '220 patent.

Petitioner concurrently is filing a petition challenging the asserted claims of the '347 patent, and '220 patent and thus lists: Petitions for *Inter Partes* Review of U.S. Patent Nos. 11,684,347, 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 1-7 and 9-16 of the '219 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 certify that the '219 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.

IV. IDENTIFICATION OF CHALLENGE AND RELIEF REQUESTED

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

Petitioner requests IPR of claims 1-7 and 9-16 of the '219 patent and that the PTAB cancel those claims as unpatentable.

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

Petitioners respectfully request 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, 3-7, 9-14	Numata, Serany, Disston, and Beddow
2	103(a)	2	Numata, Serany, Disston, and Beddow, and Salvadori
3	103(a)	15-16	Numata, Serany, Disston, Beddow, Salvadori, and Imai
4	103(a)	13-14	Rauschenberger, Serany
5	103(a)	15-16	Rauschenberger, Serany, Salvadori
6	103(a)	13-14	Solazzo, Serany, Disston, Imai,
7	103(a)	15-16	Solazzo, Serany, Disston, Imai, and Salvadori

V. THE '219 PATENT

A. Overview

The '219 patent is directed to “a storage container” for “a catheter, and related medical devices.” (EX1001.1:43–47; EX1002.¶¶31-34.) Figure 7 (annotated) depicts tray 100:

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

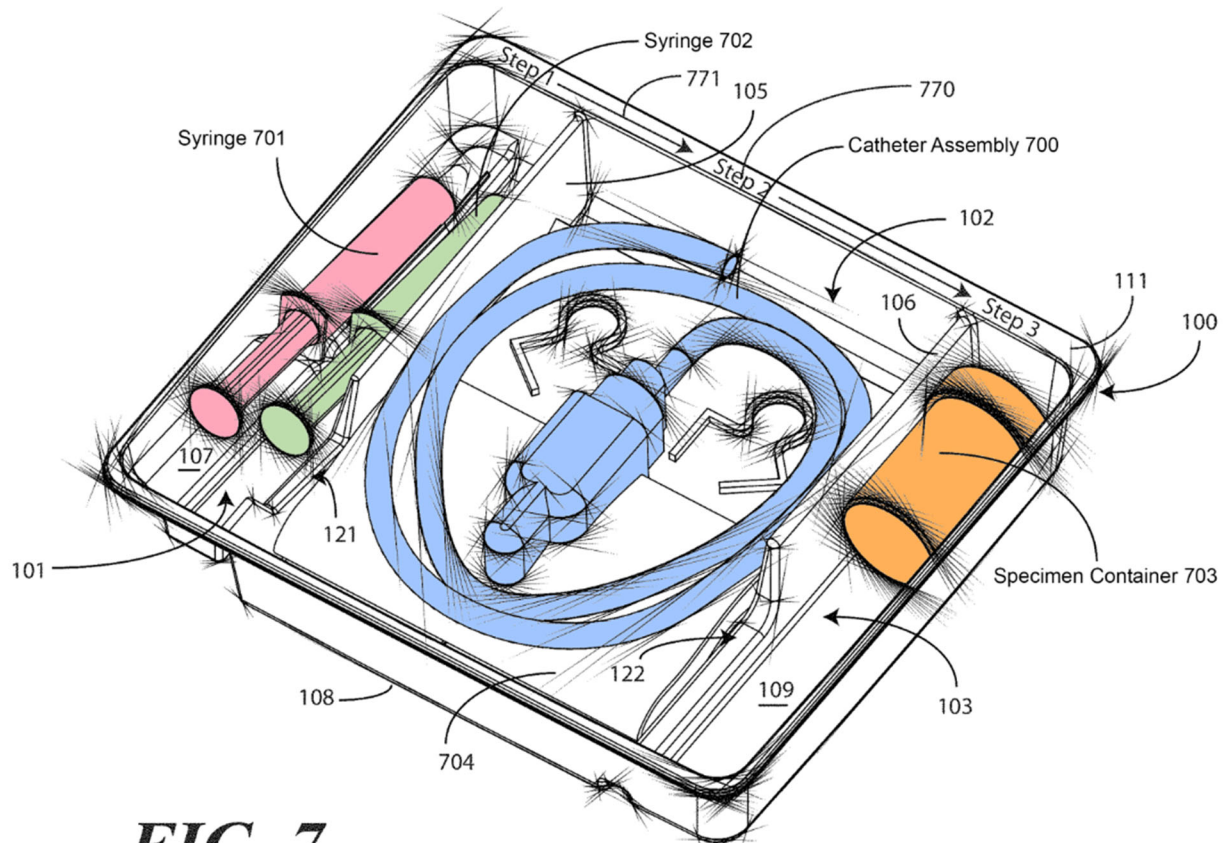


FIG. 7

(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. (EX1001.11:64-67,21:59-63, Fig.10.) Tray 100 includes three compartments 101, 102, 103 adapted to receive various items used in a catheterization procedure. (EX1001.5:23-25.) First compartment 101 accommodates syringes 701, 702 (red, green) containing sterile water or lubricants. (EX1001.9:36-37,10:1.) Second compartment 102 accommodates catheter assembly 700 (blue). (EX1001.9:37-39,46-47.) Third compartment 103 accommodates

specimen container 703 (orange). (EX1001.9:39-41.) Additional objects can be included with the tray, including swab sticks. (EX1001.5:56-61.)

The '219 patent claims priority to several provisional and non-provisional applications, the earliest of which was filed on June 3, 2009. Solely for purposes of this petition, Petitioner uses the June 3, 2009 date .

B. The Challenged Claims

Among the Challenged Claims, claims 1 and 13 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 comprising a compartment separated by a wall from a lubricating jelly application chamber;
1.b	a container of lubricating jelly disposed within the single layer tray; and
1.c	a coiled tubing coupled between a Foley catheter and a drain bag, wherein the coiled tubing, the drain bag, and the Foley catheter are disposed within the medical procedure kit;
1.d	wherein the lubricating jelly application chamber is configured to receive lubricating jelly from the container of lubricating jelly for lubricating at least a portion of the Foley catheter with the lubricating jelly;
1.e	the container of lubricating jelly comprising a syringe containing the lubricating jelly; and
1.f	the syringe situated within the lubricating jelly application chamber.

Claim 13	
13.p	A medical procedure kit, comprising:
13.a	a first syringe and a second syringe;
13.b	a medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter;
13.c	a single layer tray comprising a first compartment for receiving the first syringe and the second syringe and a second compartment for receiving at least a portion of the medical assembly,
13.d	the medical procedure kit allowing passage of at least some of the Foley catheter into a lubricating jelly application chamber; and
13.e	an outer packaging disposed about the single layer tray; wherein:
13.f	one of the first syringe or the second syringe contains lubricating jelly;
13.g	another of the first syringe or the second syringe contains water;
13.h	the first syringe and the second syringe are ordered within the single layer tray in accordance an order with which they are drawn out of the single layer tray during a Foley catheterization procedure; and
13.i	the first compartment defines one or more contours for accommodating one or more of the first syringe or the second syringe.

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 6 and 7. (EXS1014-16;

EX1002.¶¶40-49.)³ Indeed, several limitations of the Challenged Claims are substantively identical to ones at issue in the Prior IPRs.

In the Prior IPRs, the Board issued FWDs finding that all claims were not unpatentable. 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.

On remand, the Board found the vast majority of the challenged claims obvious. In doing so, the Board found, *inter alia*, that the prior art discloses or renders obvious, *inter alia*, a single layer tray, water and lubricant syringes, and swabsticks. (EX1015.15-40.) 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. (EX1015.29-58.) The Board found this evidence “does not weigh significantly against a conclusion of obviousness for any claim at issue on remand.” (EX1015.57.) Medline initially

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

appealed the remand FWDs, but then 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, respectively, were issued. (EXS1017-18.)

D. Prosecution History

The '219 patent issued from the '575 application, which was filed on March 28, 2020. (EX1002.¶¶50-59.) On July 14, 2020, Medline submitted an IDS that included the Board's *initial* Final Written Decisions ("Initial FWDs") in the Prior IPRs. (EX1004.0209-10.) On September 13, 2022, the examiner issued an office action, rejecting most pending claims under nonstatutory double patenting in view of the '088 and '596 patents. (EX1004.0276-85.) Medline filed a terminal disclaimer on February 13, 2023. (EX1004.0585-86.)

Medline never submitted the Remand FWDs during the prosecution of the '219 patent despite submitting several IDSs following their September 30, 2022 issuance. (EX1004.0475-78,0672-75,0760-61.)

Thus, the Examiner did not have the benefit of the Remand FWDs when he issued Notices of Allowance in February and April 2023. (EX1004.0686-91,0764-73.) While the Examiner discussed Solazzo in the Notice of Allowance, he did so while having considered the Initial FWDs without considering the Remand FWDs.

(EX1004.0686-91,0764-73.) The Notice of Allowance also did not discuss Numata (which was not submitted) nor Rauschenberger. (EX1004.0686-91,0764-73.)

VI. 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.)

VII. CONSTRUCTION OF THE CHALLENGED CLAIMS⁴

A petition must 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).

Bard proposes that the claim terms in the ’219 patent are given their plain and ordinary meaning.

⁴ Petitioners reserve the right to pursue different claim constructions during this and related proceedings as well as in any district court litigation.

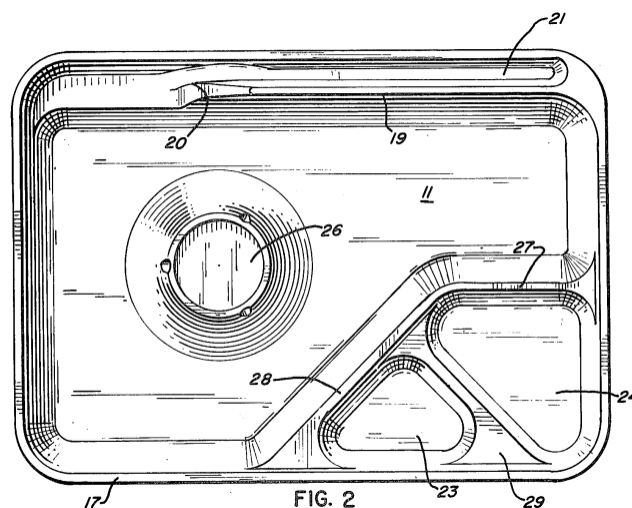
VIII. THE PRIOR ART

The packaging of medical assemblies, including Foley catheters, was extremely well-developed by 2009. (EX1002.¶¶61-131; EX1003.¶¶27-60.)

A. Rauschenberger

Rauschenberger issued on July 10, 1979, making it prior art under Section 102(b). Rauschenberger is directed to a urethral catheterization tray providing a sterile, self-contained catheterization package and work area. (EX1021.Abstract; EX1002.¶¶106-11; EX1003.¶¶39-42.) Rauschenberger notes that in the prior art certain steps of the catheterization procedure were performed on a CSR wrap, which increased the odds of contamination or soiling of the work area. (EX1021.1:7-42.) Thus, Rauschenberger provides a single-layer tray with compartments to perform such steps, such as lubricating the catheter. (EX1021.1:43-2:63.)

Fig. 2 shows a single layer tray, with multiple compartments. Channel 21 is adapted to receive a conventional urethral catheter. (EX1012.1:62-63.)



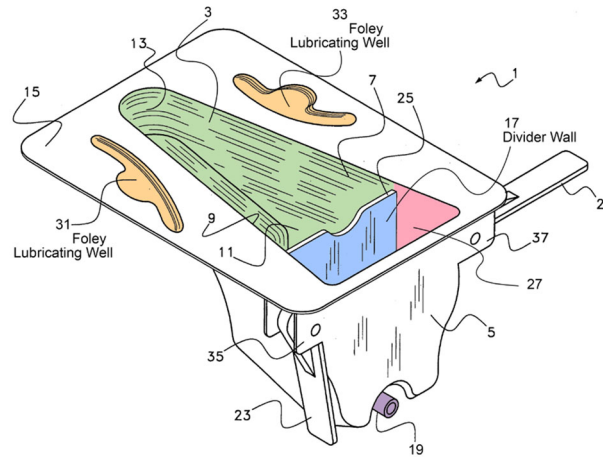
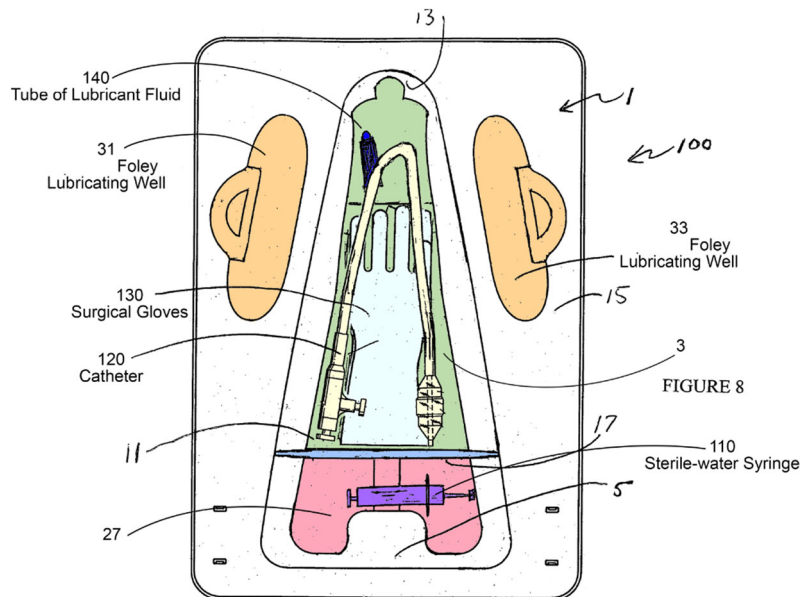


Fig. 1

Compartments 3 and 27 store medical devices, including a Foley catheter, lubricant, gloves, inflation syringe, irrigation syringe, evacuation tubing, and antiseptic solutions. (EX1005.3:14-24,4:1-8, Fig. 8.) 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.)



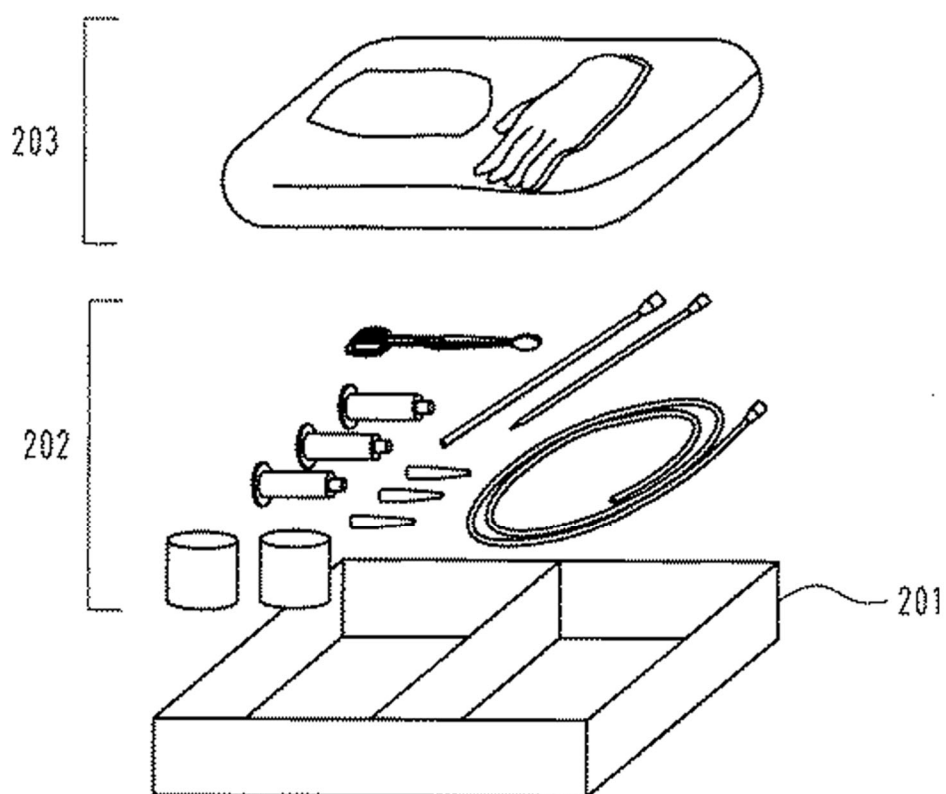
In use, recessed area 3 and compartment 27 fit between the legs of “[a] patient requiring a urological procedure.” (EX1005.1:8-12,3:66-4:10,4:26,4:32-33, Fig. 1.)

C. Numata

Numata is a Japanese patent application that was published on May 25, 2006, making it prior art under Section 102(b). Numata is directed to a package 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.¶¶70-78; 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).)

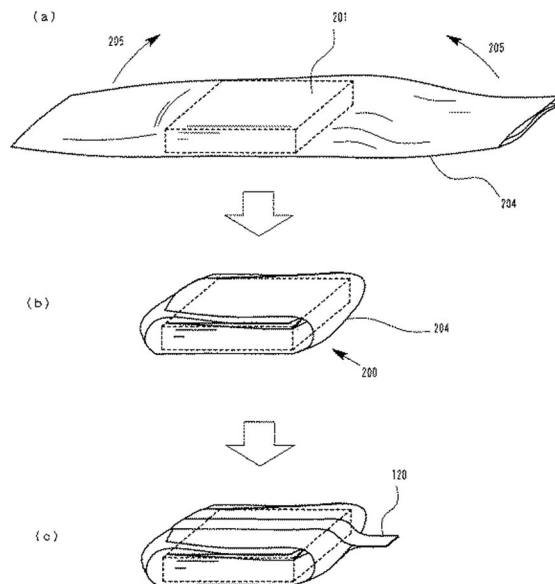
Figure 4 shows a multi-compartmented single layer “tray 201” that stores “medical instruments 202 such as catheters, syringes, injection needles, forceps and degreasing cotton.” (EX1007.¶0031.) Items 203, which are placed above the medical instruments, include “gloves,” “a drape,” etc. (EX1007.¶0031.)

(FIG. 4)

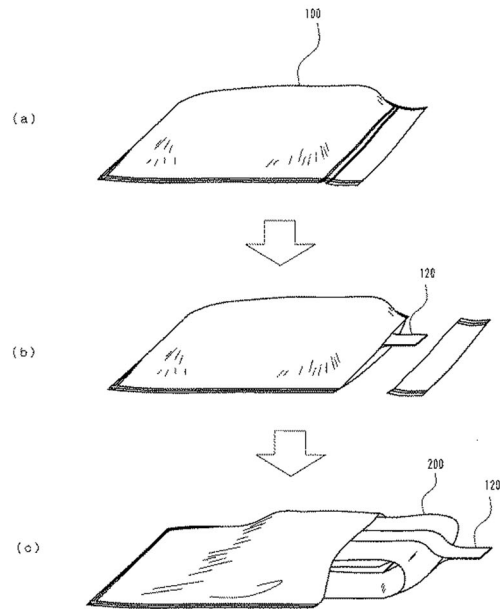


The tray is wrapped in a cover cloth 204 and sealed inside a packaging body 100 as shown in Figures 5 and 7:

(FIG. 5)



(FIG. 7)

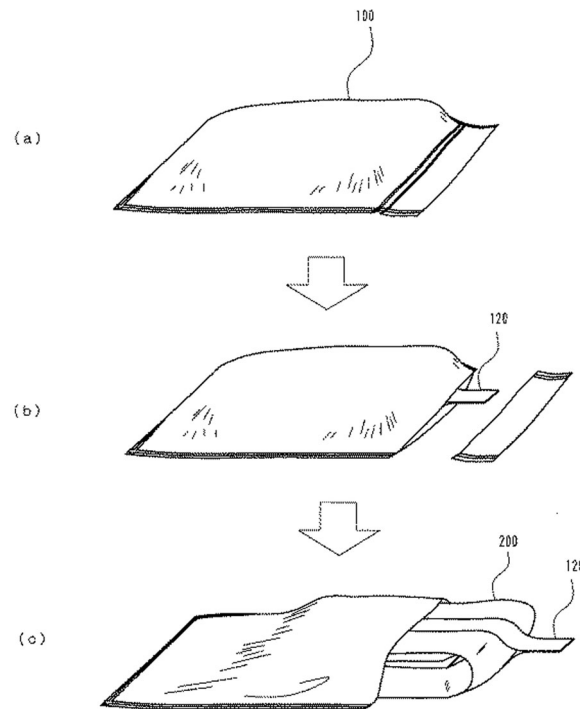


Numata is directed to a “package body for storing medical instruments” for procedures “employing disposable medical instruments such as catheters.” (EX1007.¶0001.) The exemplary embodiment of Numata stores “medical instruments used for surgery, such as catheters for introduction into blood vessels and 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.)

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.) To solve this problem, Numata allows for the removal of the medical instruments from the packaging bag without touching them. (EX1007.¶0009.) “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”:

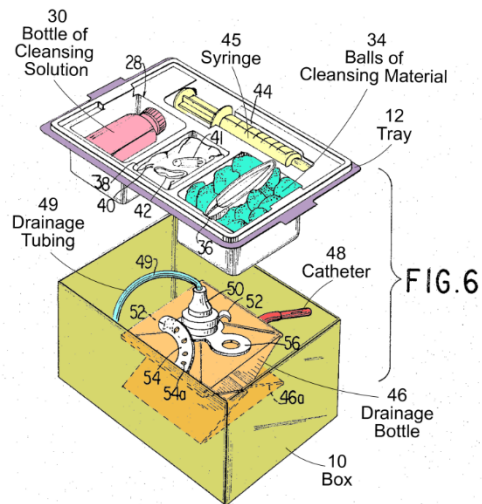
(FIG. 7)



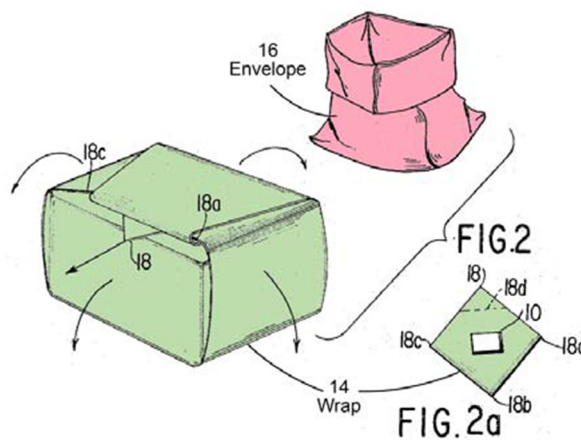
D. Serany

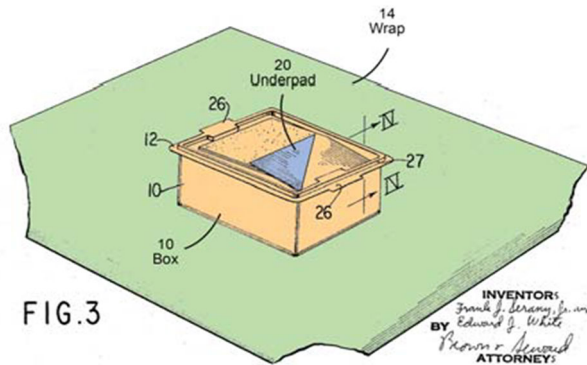
Serany is a U.S. patent issued on July 4, 1967, making it prior art under Section 102(b).

Serany discloses a Foley catheter kit as shown in Figure 6:



(EX1009.Fig.6; EX1002.¶¶79-85; EX1003.¶35.) The kit includes a closed-system Foley catheter with a “catheter and drainage tube preconnected to [a collapsible drainage] bottle.” The tray of Serany is enclosed in a “wrap 14” and provided in “plastic bag 16”:





The wrap is “folded about said box and adapted to be unfolded to provide a sterile field as said components are removed from the package and used.” (EX1009.4:49-52.)

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 (emphases added).) Serany’s package includes an underpad 20, gloves 22, cleansing solution bottle 30, rayon balls 34, forceps 36, and lubricating jelly pouch 40.

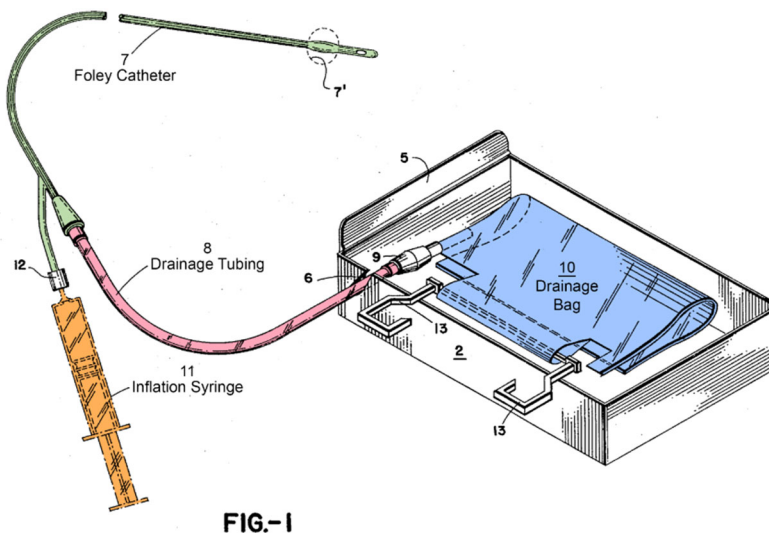
E. Disston

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

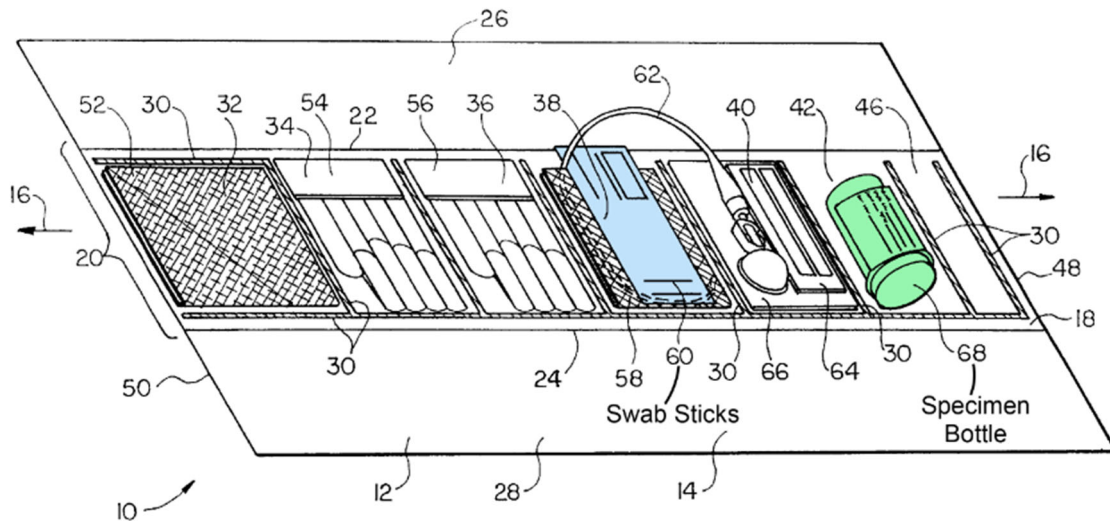
Disston discloses “a complete, properly organized, conveniently arranged, sterile set of equipment for catheterization, the entire drainage system being pre-assembled.” (EX1008.1:59-67,2:60-63,Figs.2-3; EX1002.¶¶86-90; EX1003.¶35.) The single tray contains catheterization devices “arranged in such order and position as to be most conveniently available when the container is opened.” (EX1008.2:15-23.)

When opened, the tray presents contents including gloves, cleansing solution, underpad, lubricant, sterile water packet, syringe, and “a pre-assembled catheter-drainage tube-drip chamber-drainage bag and hanger, assembly, sterile and ready for use immediately.” (EX1008.1:26-35,2:41-52,Fig.1.)

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



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 below:

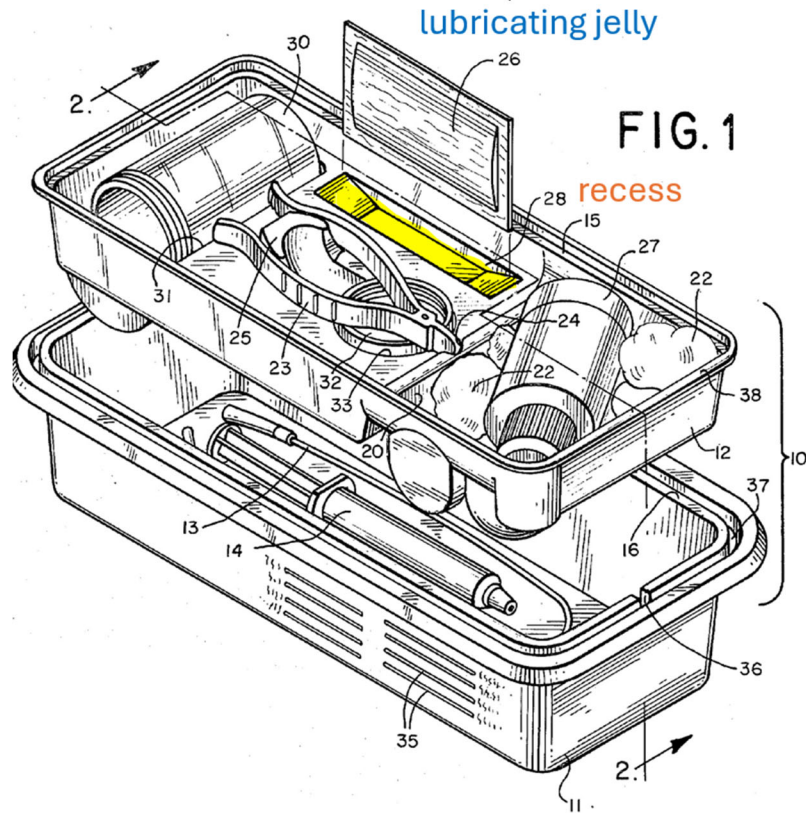


(EX1013.1:25-31,1:44-49,2:66-3:8,FIG.1; EX1002.¶¶98-100; EX1003.¶¶144,147-48.)

H. Beddow

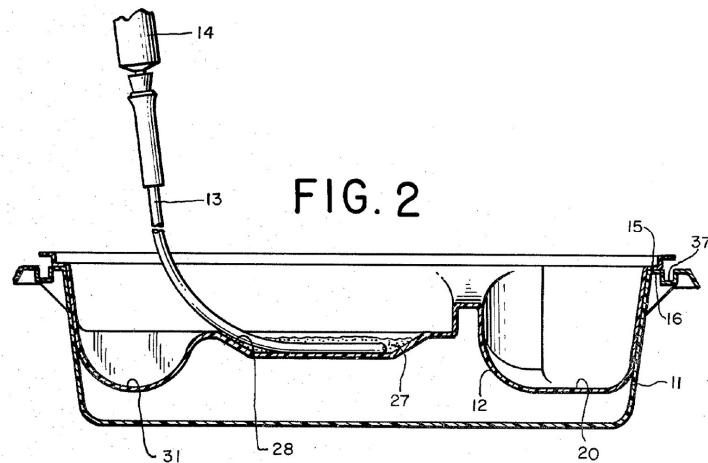
Beddow is a U.S. patent that issued on October 7, 1980, making it prior art under Section 102(b).

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.¶¶101-05; EX1003.¶128.)



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

Figure 2:



(EX1010.3:18-22.)

I. State of the Art

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 Section 102(a). Nursing Standard describes an “all-in-one Foley tray” and states that closed-system Foley catheters reduce infection rates. (EX1019.51-55; EX.1002¶¶112-18.)

A Nursing Lab: Take Two Male Catheter Insertion video uploaded to YouTube on February 7, 2008 is prior art under Section 102(b) (“Catheterization Video”). It demonstrates a Foley catheter procedure and shows the compartment where a lubricant syringe had been stored being used to lubricate the catheter. (EX1020.2:43-2:50; EX1002¶¶119-25.)

IX. DETAILED EXPLANATION OF GROUNDS FOR INVALIDITY

A. Ground 1: Obviousness Over Numata, Serany, Disston, and Beddow

Numata, Serany, Disston, and Beddow render claims 1, 3-7, 9-14 obvious. (EX1002.¶¶135-229.)

1. Independent Claim 13

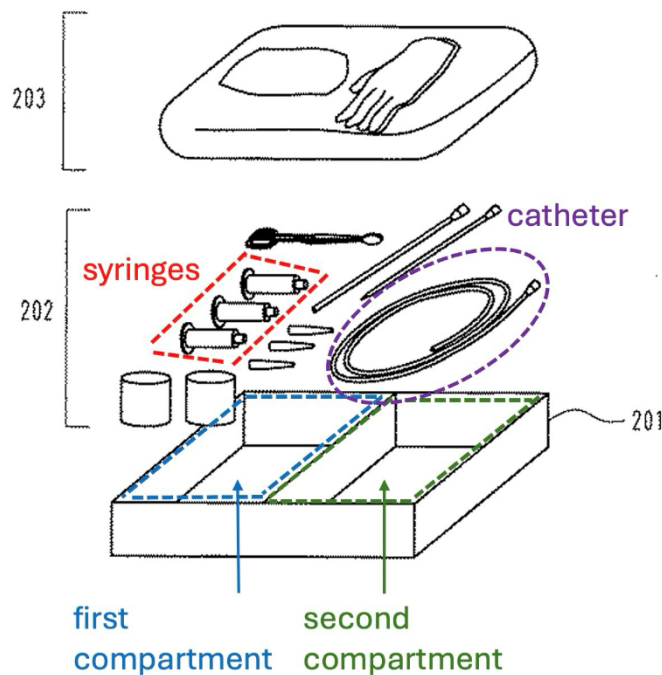
(a) Limitations 13[p] and 13[a]

Numata discloses “*A medical procedure kit, comprising: a first syringe and a second syringe.*” (EX1002.¶¶135-40.)

Numata discloses a “medical procedure kit”: “a package body for storing medical instruments for use in surgical procedures...., 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.” (EX1007.¶5, 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:

(FIG. 4)



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

(b) Limitation 13[b]

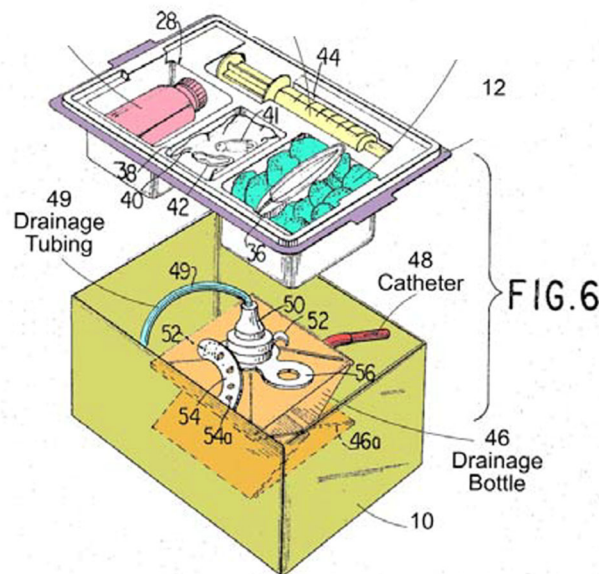
Numata, Serany, and Disston render “*the medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter*” obvious. (EX1002.¶¶141-60.)

For the reasons in 13[a], Numata discloses a medical assembly (a catheter) in a second compartment. (EX1007.Fig.4,¶0031.) 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 a closed-system Foley catheter to the kit of Numata. (EX1002.¶¶141-60; EX1003.¶¶95-126.) And it would have been obvious to place this catheter in the second compartment of Numata to replace Numata’s 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.

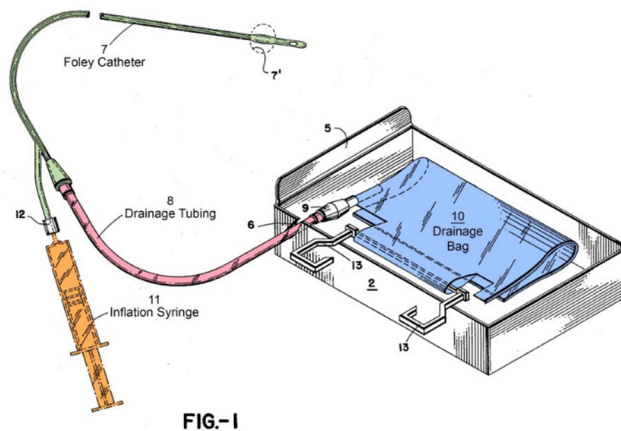
The exemplary embodiment of Numata describes “catheters for introduction into blood vessels and their accessories.” (EX1007.¶0037.) “However, the invention is also applicable to any other medical products... which are sold sealed within packaging material in a sterilized state.” (EX1007.¶0037.)

A closed-system Foley catheter is a medical product that is sold sealed within packaging material in a sterilized state. (EX1003¶31.) 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.¶144.) The tubing 49 is “coiled.” (*Id.*)



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. (EX1009.3:26-32, Fig. 6.) A POSA would understand Serany to teach a fluid bag because a collapsible drainage receptacle made of a flexible plastic material would be considered a bag. (EX1002.¶145.) If Medline argues that Serany does not teach a bag, it would have 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:



(EX1008.Fig.1,2:19-23.) Doing so would involve a simple substitution of one container (a “bottle”) for another known type of container (a “bag”) to produce predictable results. (EX1002.¶146.)

Based on 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.¶146.)

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.¶147.)

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 ’219 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 POSA would have been motivated to use the tray of Numata to accommodate Foley catheter equipment to “prevent usage errors and preparation errors.” (EX1002.¶148-49.)

Third, a POSA would have been motivated to add a Foley catheter to the kit of Numata because several pieces of equipment stored in the kit Numata, such as syringes, gloves, cotton balls and forceps, and drapes were also commonly included in Foley catheter kits. (EX1007.¶0037, Fig. 4; EX1009.2:21-3:45, Fig. 6; EX1008.2:15-72, Fig. 1; EX1002.¶150.) Thus, a POSA would understand that the kit of Numata is well-suited for use with a Foley catheter.

Fourth, 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.¶¶151-54.) 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 to reduce CAUTI would have turned to Numata. The kit of Numata when provided with Foley catheter equipment would be useful in both surgical and non-surgical settings. (EX1003.¶¶106-126.) Numata’s invention would eliminate or reduce the risk of contamination via the outer packaging. (EX1003.¶¶106-123.) Thus, a POSA would have been further motivated to add Foley catheter equipment to Numata’s tray to utilize Numata’s packaging solution to perform Foley catheterization procedures to reduce the risk of CAUTI. (EX1002.¶¶151-54.)

Finally, there would be a reasonable expectation of success in combining Numata with the sterile catheter equipment of Serany and Disston. (EX1002.¶.155.) The kits contain much of the same equipment as discussed above. (*Id.*) There is also ample space within Numata to accommodate Foley catheter equipment given the dimensions that Numata provides. (EX1002.¶¶156-60; 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.¶¶156-60.)

(c) Limitation 13[c]

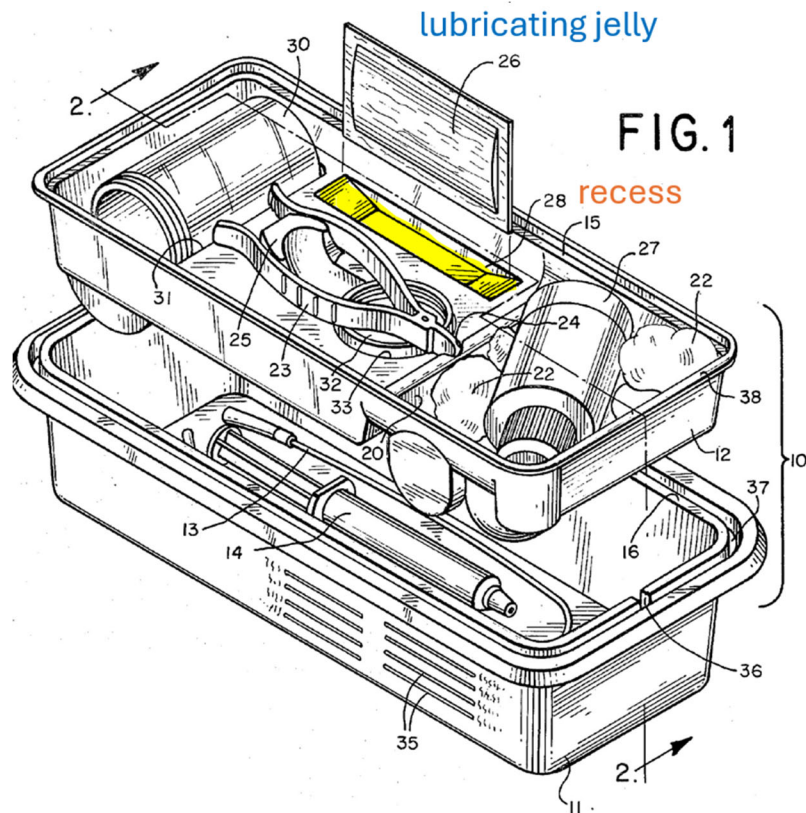
For the reasons at 13[a] and 13[b], Numata, Serany and Disston render “*a single layer tray comprising a first compartment for receiving the first syringe and the second syringe and a second compartment for receiving at least a portion of the medical assembly*” obvious. (EX1002.¶161.)

(d) Limitation 13[d]

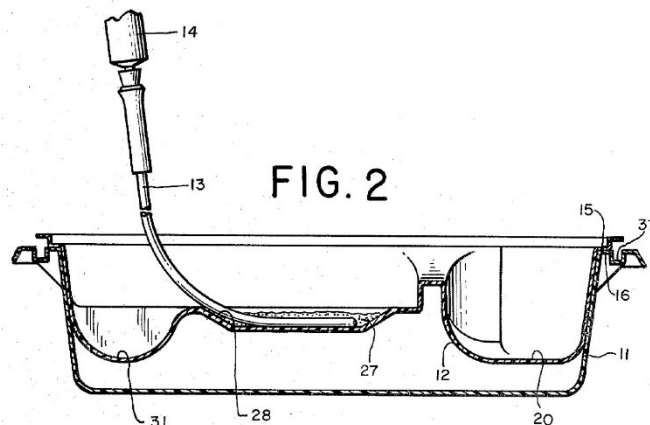
Numata and Beddow render “*the medical procedure kit allowing passage of at least some of the Foley catheter into a lubricating jelly application chamber*” obvious. (EX1002.¶¶162-75.)

Beddow discloses a lubricating jelly application chamber that allows passage of at least some of the Foley catheter into the chamber. Beddow further teaches using the compartment that stores the lubricant as a lubricating jelly application compartment to receive lubricating jelly. (EX1010.3:11-16; EX1002.¶¶164-66.)

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:



Once the lubricant is dispensed, the catheter is passed into the first compartment (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.) As discussed at 13[a] and 13[f], Numata discloses multiple syringes in a first compartment and it would have been obvious to fill one of the syringes with lubricating jelly when customizing the kit of Numata to perform a Foley catheterization procedure.

Based on Beddow, a POSA would have been motivated to use the first compartment of Numata as a lubricating jelly application chamber because the first compartment would also store the lubricant. (EX1002.¶¶167.) 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 chambers were ubiquitous in the prior art, but varied with respect to shape, size, and location in the tray. (EX1002.¶¶164-67; EX1003.¶¶128-141.) A POSA would have understood that the first compartment of Numata is well-suited for lubrication, and meets any functional or structural requirements of this claim. (EX1002.¶¶168.) 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.¶¶169; 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.¶170) Thus, a POSA would understand that the Foley catheter can be passed from the second compartment of Numata to the first compartment by passing it over the internal wall because the tray has an open top. (EX1007.Fig.4; EX.1002.¶170.) This approach has the advantage of allowing for the lubrication of the catheter while the catheter remains within Numata’s single tray.

Third, the tray is sterile. (EX.1007.¶¶0030; EX1002.¶171.) Fourth, Numata’s tray (made of hard plastic) is a smooth surface to easily run the catheter through the lubricant; (EX1007.¶¶0031; EX1002.¶171.) Finally, given that Numata teaches only two compartments, it would have been obvious to try using the first compartment as a lubrication compartment. (EX1002.¶172.)

If this claim is deemed to require a specific structure beyond what Numata discloses, it would have been obvious to add a shallow depression to the bottom surface of the first compartment of Numata in view of Serany and Beddow to accommodate the lubricant and water syringes to prevent movement during shipping for the reasons at limitation 13[i]. (EX1002.¶¶173-75.) This depression would perform the dual-function of serving as a shallow lubrication channel allowing the lubricant to pool in an enclosed space that is sufficient in size to lubricate an appropriate amount of the catheter (at least five inches).

By adding a depression to accommodate the syringes, this would form a lubrication channel within the first compartment by allowing the lubricant to pool in

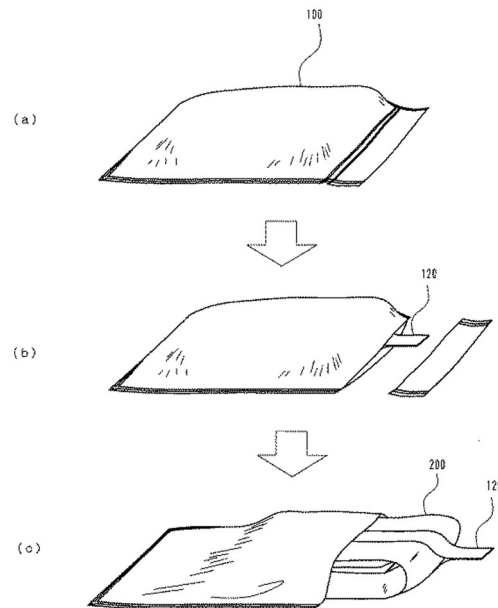
a depression around the same length as five inches of the catheter that ideally should be lubricated. (EX1002.¶¶174; EX1003.¶¶75.) Indeed, the Catheterization Video discloses lubricating the catheter in the depression where the lubricant syringe is stored. (EX1002.¶¶174; EX1003.¶¶127 (citing EX1020.2:43-49,4:48-55).)



(e) Limitation 13[e]

Numata discloses “*an outer packaging disposed about the single layer tray.*” (EX1002.¶¶176-78.) Numata discloses a “packaging bag 100 for sealing the medical product 200” (i.e. by disposing it about tray 201) as shown in Figure 7:

(FIG. 7)



(EX1007.¶¶0022-25,0031-32,Fig.7.)

(f) Limitations 13[f] and 13[g]

Numata, Serany and Disston render “*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.¶¶179-85.)

Numata discloses syringes disposed within the first compartment of tray 201, but does not disclose the contents of the syringes. (EX1021.Fig.4,¶0031.) When customizing the kit of Numata for a Foley catheterization procedure, it would have been obvious to fill one syringe with sterile water and another syringe with lubricating jelly. This is a simple substitution of one element (syringes) with another (syringes filled with water and lubricating jelly) to yield predictable results.

A Foley catheter requires an inflation syringe (filled with sterile water) to inflate the retention balloon. 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.) Disston also teaches an inflation syringe. (EX1008.Fig.1,2:44-45.)

A POSA would understand that a Foley catheter also requires lubricant to lubricate the catheter. Beddow discloses a container 26 of lubricating jelly. (EX.1010.3:10-14.) Serany also discloses “lubricating jelly.” (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. Doing so would involve a simple substitution of one container (a foil container as taught by Beddow) 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.¶¶181-83; EX1003.¶49.)

(g) Limitation 13[h]

Numata, Serany, and Disston render “*the first syringe and the second syringe are ordered within the single layer tray in accordance an order with which they are drawn out of the single layer tray during a Foley catheterization procedure*” obvious. (EX1002.¶¶186-94.)

Numata discloses a medical kit with multiple syringes, though it does not specify a particular order of use or order of removal/drawing out of the syringes. It was well-known in the art to arrange components in a catheterization kit in their order of removal and use. (EX1002.¶¶187-88.) Arranging items in their order of removal and use prompts the user to perform operations in the correct order as well as allowing quicker retrieval of the correct device. Serany teaches a Foley catheter kit where “provides the convenience of having all the components arranged in logical step-by-step order to facilitate the nurse’s or physician’s task.” (EX1009.1:30-35.) Serany also discloses providing “components in their preferred order of use” and “proper order of use.” (EX1009.1:9-12,1:23-25.) A POSA would have understood that syringe are removed/drawn out from the tray in the same order in which they are used. Indeed, Disston notes that “contents of the tray portion,” including “lubricant, syringe and water packet **are removed and put to their respective intended uses.**” (EX1008.2:41-45 (emphasis added).)

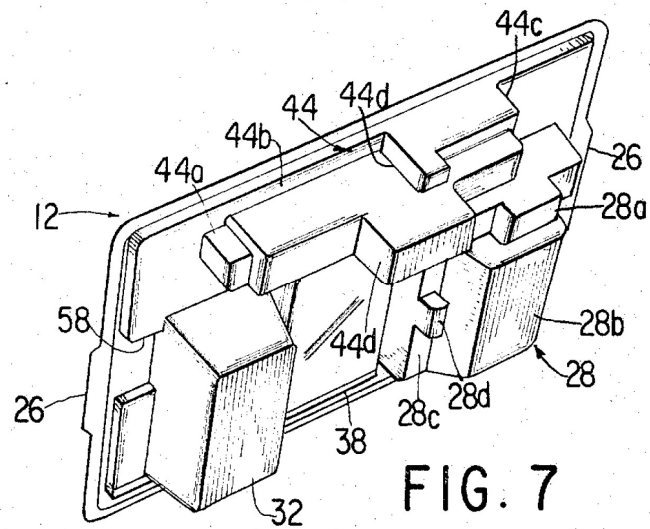
Ordering components with their order of removal and use during a catheterization procedure was well-known in the art and would have motivated a POSA to do so here with a reasonable expectation of success. It was well-known in the art of device design (including the design of medical trays) to include affordances to aid a user in performing operations in the correct order. (EX1002.¶¶189-90.) And arranging items in their order of use/removal aligns with Numata’s statement that

items in its kit are “packaged together in a single tray” to “prevent usage errors and preparation errors.” (EX1007.¶¶0005.) This applies a known technique (arranging components in their order of use/removal) 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”). For example, as discussed at claim 5, it would have been obvious to arrange syringes from left-to-right consistent with their order of use/removal. (EX1002.¶¶191-94.)

(h) Limitation 13[i]

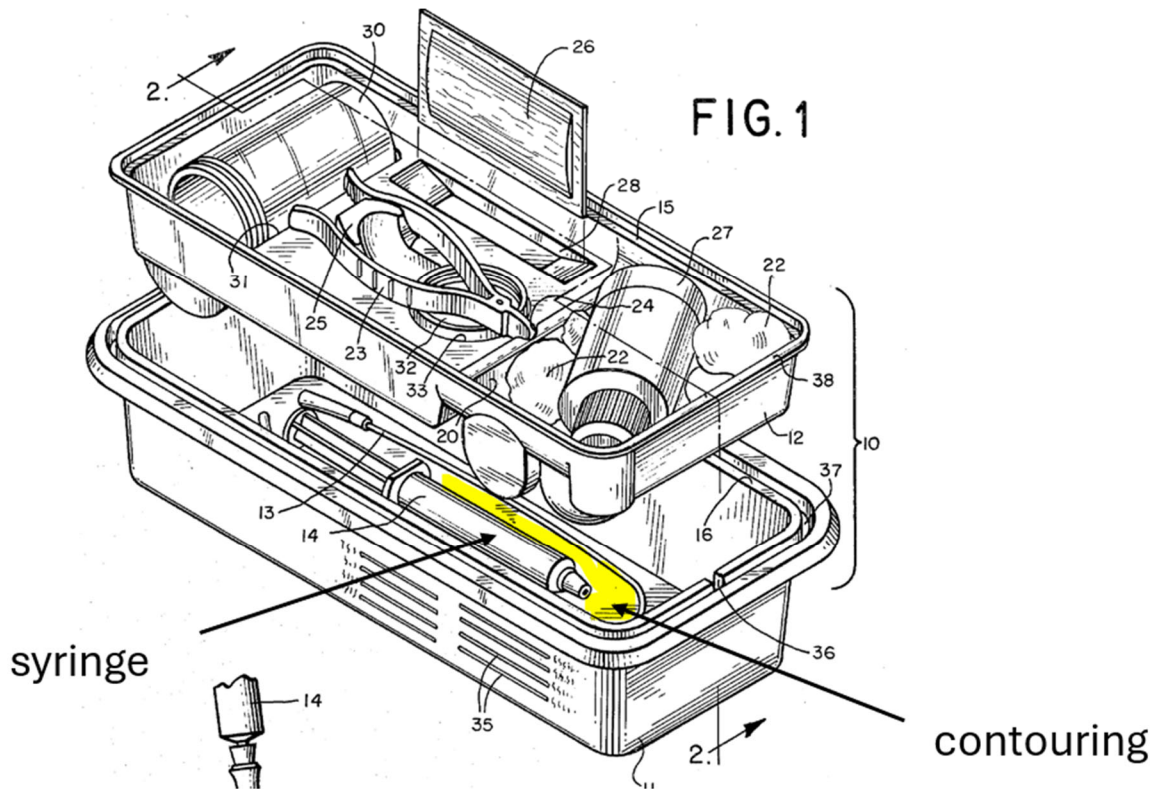
Numata, Serany and Beddow render “*the first compartment defines one or more contours for accommodating one or more of the first syringe or the second syringe*” obvious. (EX1002.¶¶195-206.)

Because Numata does not provide any specific mechanism to hold the syringes in place within the first compartment of tray 201, the syringes could move during shipment of the tray. A known technique to prevent syringes from moving during shipping is to define one or more contours of a compartment to accommodate a syringe and its flange—thus holding the syringe in place as well as making it easier to grasp the syringe. (EX1002.¶¶197-98.) Serany teaches that depression 44 holds a syringe and includes an upper portion 44c that is wider than the diameter of the syringe plunger handle 45a “so that it may be easily grasped,” and indentations 44d to accommodate the “flange or finger grip 45c of the syringe”:



(EX1009.3:6-22, Fig. 7.) Storing the syringe in this manner “hold[s] the syringe against lateral movement in its stored condition.” (EX1009.3:15-16.)

Beddow also teaches a tray that includes contouring for holding a syringe (including its flange) as shown in annotated Figure 1:



(EX1010.Fig.1,2:46-52,4:14-17.)

It would have been obvious in view of Serany and Beddow to add contours to the first compartment of Numata to hold the syringe flange of one or more of the first and second syringes such that they do not move during shipping and can more easily be grasped. (EX1002.¶¶199-200.) This applies a known technique (contours for accommodating a syringe flange) to a known device (a catheter kit with syringes) to yield predictable results (preventing movement of the syringes during shipping and allowing easy grasping of the syringes.) (EX1002.¶200.) A POSA would have understood that such contouring could easily be accomplished using known manufacturing techniques. (EX1002.¶¶201-06.).

2. Independent Claim 1

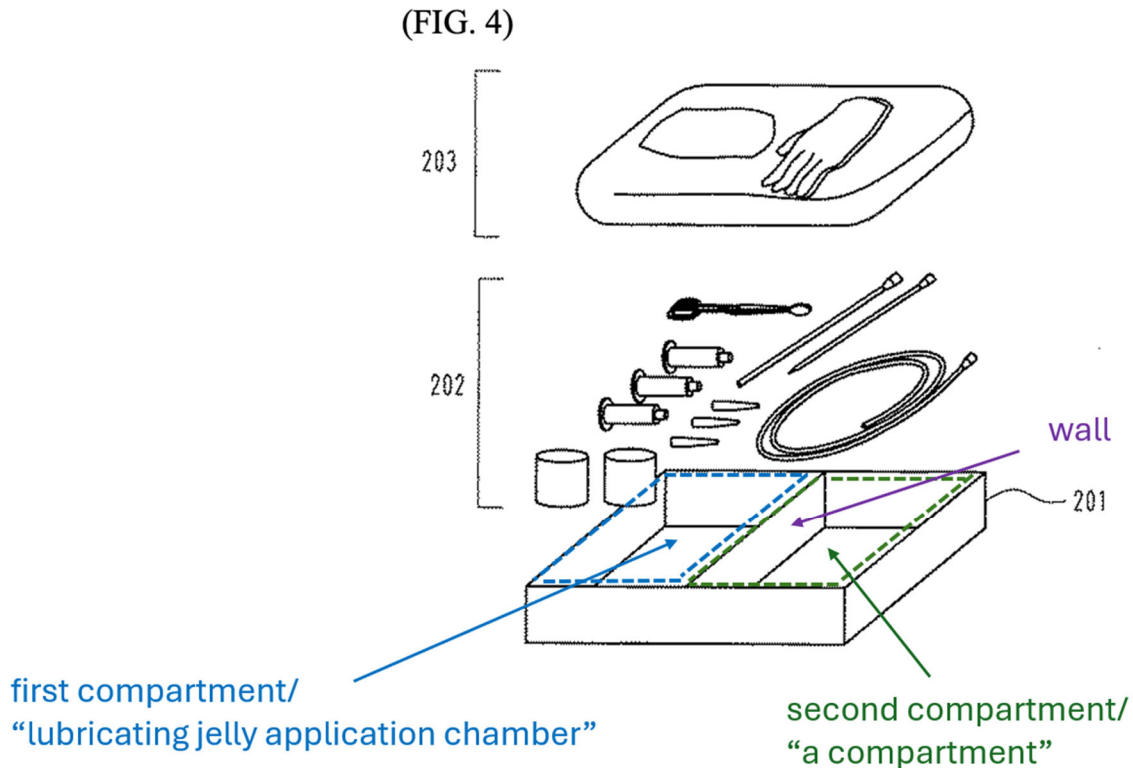
(a) Limitation 1[p]

For the reasons at 13[p], Numata discloses “*A medical procedure kit.*” (EX1002.¶207.)

(b) Limitations 1[a] and [d]

For the reasons at 13[a] and [d], Numata, Beddow and Serany render “*a single layer tray comprising a compartment separated by a wall from a lubricating jelly application chamber*” and “*the lubricating jelly application chamber is configured to receive lubricating jelly*” obvious. (EX1002.¶¶208-10.)

As shown in annotated Figure 4, the “lubricating jelly application chamber” of claim 1 and the “first compartment of claim 13” are both the left compartment of Numata and the “a compartment” of claim 1 and the “second compartment” of claim 13 are both the right compartment of Numata. These compartments are separated by a wall.



(c) Limitations 1[b], 1[e], 1[f]

For the reasons at 13[f], Numata, Serany and Beddow render “*a container of lubricating jelly disposed within the single layer tray,*” “*the container of lubricating jelly comprising a syringe containing the lubricating jelly,*” and *the syringe situated within the lubricating jelly application chamber*” obvious. (EX1002.¶211.)

(d) Limitation 1[c]

For the reasons at 13[b], Numata, Serany and Disston render “*a coiled tubing coupled between a Foley catheter and a drain bag, wherein the coiled tubing, the drain bag, and the Foley catheter are disposed within the medical procedure kit*” obvious. (EX1002.¶¶212-13.)

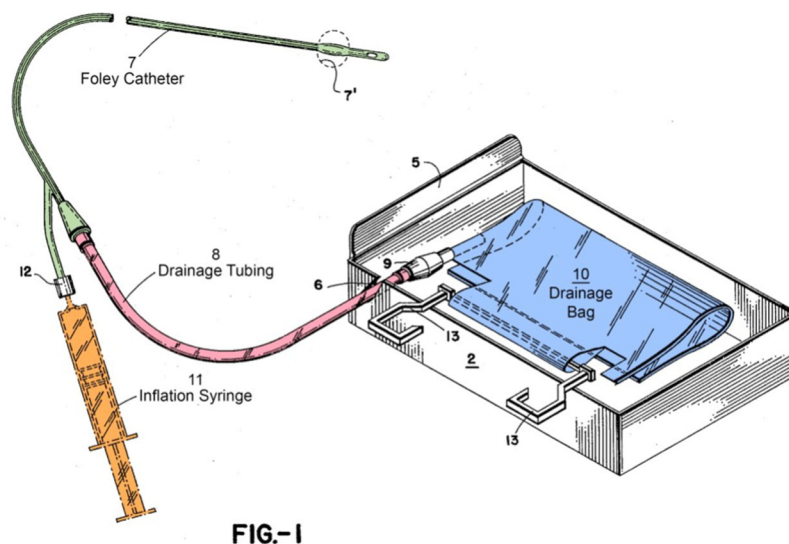
3. Claims 3 and 10

For the reasons at 13[g], Numata, Serany, and Disston render “a syringe containing water disposed within the single layer tray,” (claim 3) and “the second syringe contains water” (claim 10) obvious. (EX1002.¶¶214-15.)

4. Claims 9 and 14

Numata, Serany and Disston render “the second syringe is for attachment to the Foley Catheter,” (claim 9), and “the second syringe is attachable to the Foley catheter” (claim 14) obvious. (EX1002.¶¶216-18.)

For the reasons at 13[g], Numata, Serany and Disston render obvious an inflation syringe containing water. A POSA would understand that the inflation syringe functions by being attached to the inflation port of the Foley catheter as shown in Disston:



(EX1008.Fig.1,1:41-53.)

5. Claims 4, 5, and 11

For the reasons at 13[h], Numata, Serany and Disston render “*wherein the syringe containing the lubricating jelly and the syringe containing the water are arranged within the single layer tray in a left-to-right configuration*” (claim 4), “*wherein the left-to-right configuration comprises a left-to-right usage configuration*” (claim 5), and “*wherein the syringe and the second syringe are arranged in the single layer tray in accordance with an order of use during a Foley catheterization procedure*” (claim 11) obvious. (EX1002.¶¶219-25.)

As discussed at 13[h], it would have been obvious to arrange Numata’s syringes in their order of use/removal. One known (and obvious) way of doing so was to arrange items from left-to-right in their order of use. Serany discloses “removing the bottle of cleansing solution from compartment 28 [on the left], as previously described, and pouring it over the rayon balls 34 in their stored position in the depression 32 [on the right].” (EX1009.Fig.6,2:57-72; EX1002.¶¶220-22.) Thus, bottle 30 (stored on the left) is removed and used before balls 34 (stored on the right). This applies a known technique (arranging components in their order of use from left-to-right) 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”). And it would have been obvious to try arranging the syringes left-to-right consistent with their order of use because there were a finite number of identified,

predictable solutions (i.e., placing the water syringe to the left of the lubricating jelly syringe, or vice versa) with a reasonable expectation of success. (EX1002.¶¶223-25.)

6. Claims 6 and 7

For the reasons at 13[h] and claims 4 and 5, Numata, Serany and Disston render “*wherein the syringe containing the lubricating jelly and [the syringe containing the water (claim 6)/second syringe (claim 7)] are arranged within the single layer tray in accordance with an order with which the syringe containing the lubricating jelly and the [syringe containing the water/second syringe] are [removed (claim 6)/drawn out (claim 7)] from the single layer tray*” obvious. (EX1002.¶¶226-27.)

7. Claim 12

For the reasons at 13[i], Numata, Serany, and Beddow render “*the first compartment defines one or more contours for accommodating one or more of the first syringe or the second syringe*” obvious. (EX1002.¶¶228-29.)

B. Ground 2: Obviousness Over Numata, Serany, Disston, and Beddow and Salvadori

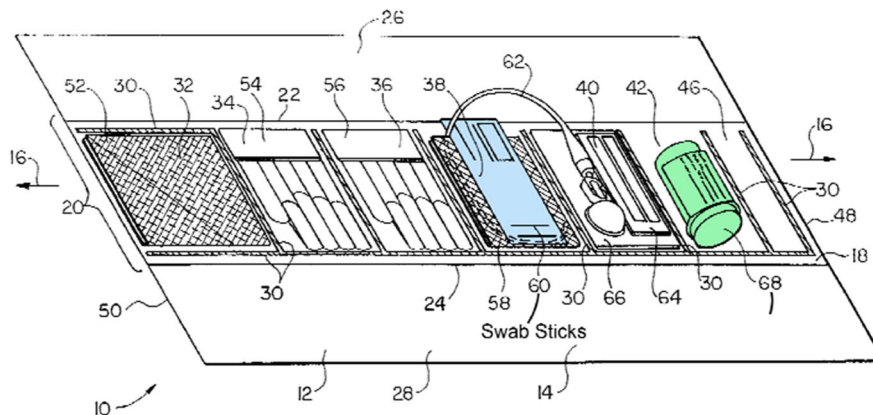
Numata, Serany, Disston, Beddow, and Salvadori render claims 2 obvious. (EX1002.¶¶230-37.)

1. Claim 2

Numata and Salvadori render “one or more swabsticks disposed within the single layer tray” obvious. (EX1002.¶¶230-37.)

It was well-known in the art to clean the patient’s genitals before catheter insertion and that the equipment available to do so was (1) forceps and absorbent material (such as cotton) or (2) swabsticks (i.e., an absorbent material with a handle). (EX.1003.¶¶142-48.)

Salvadori teaches a “urethral catheter kit or tray” that includes “swab sticks 60.” (EX1013.1:12-16,3:4,Fig.1.)



When customizing the kit of Numata to include urinary catheter equipment (see limitation 13[c]), it would have been obvious to substitute Numata’s forceps and cotton (EX.1007.0031, Fig.4) for Salvadori’s swabsticks. (EX1002.¶¶233-37.) A POSA would have been motivated to do so because swabsticks provide a handle,

which is easier to manipulate than forceps, making it less likely that the cotton is inadvertently dropped. (EX1003.¶146.) The inclusion of swabsticks in the catheterization kit of Numata involves the use of a known technique (providing swab sticks) to a known device (a catheter kit) to yield predictable results. (EX1002.¶234.)

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

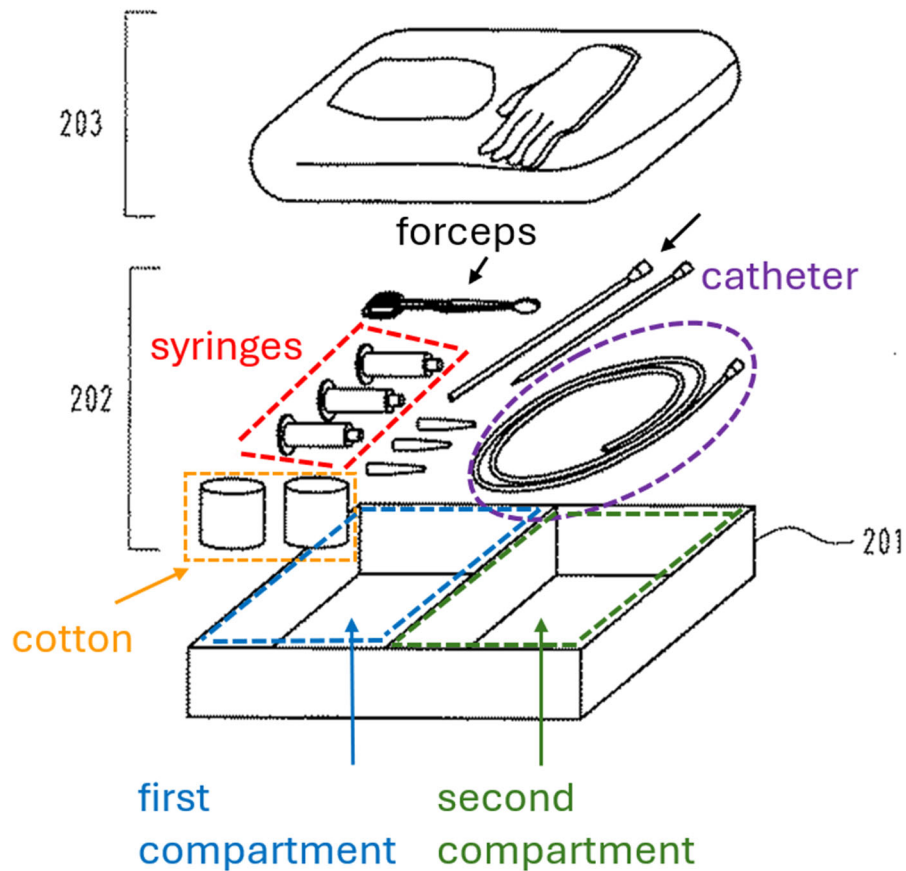
Numata, Serany, Disston, Beddow, and Salvadori render claims 15 and 16 obvious. (EX1002.¶¶238-49.)

1. Claim 15

Numata, Salvadori and Imai render “*wherein the single layer tray comprises a third compartment containing one or more swabsticks*” obvious. For the reasons at claim 2, it would have been obvious to add swabsticks to the kit of Numata by substituting Numata’s forceps and cotton for swabsticks. (EX1002.¶¶238-44.)

Numata’s “forceps” and “cotton” are stored in the left/first compartment of Numata:

(FIG. 4)



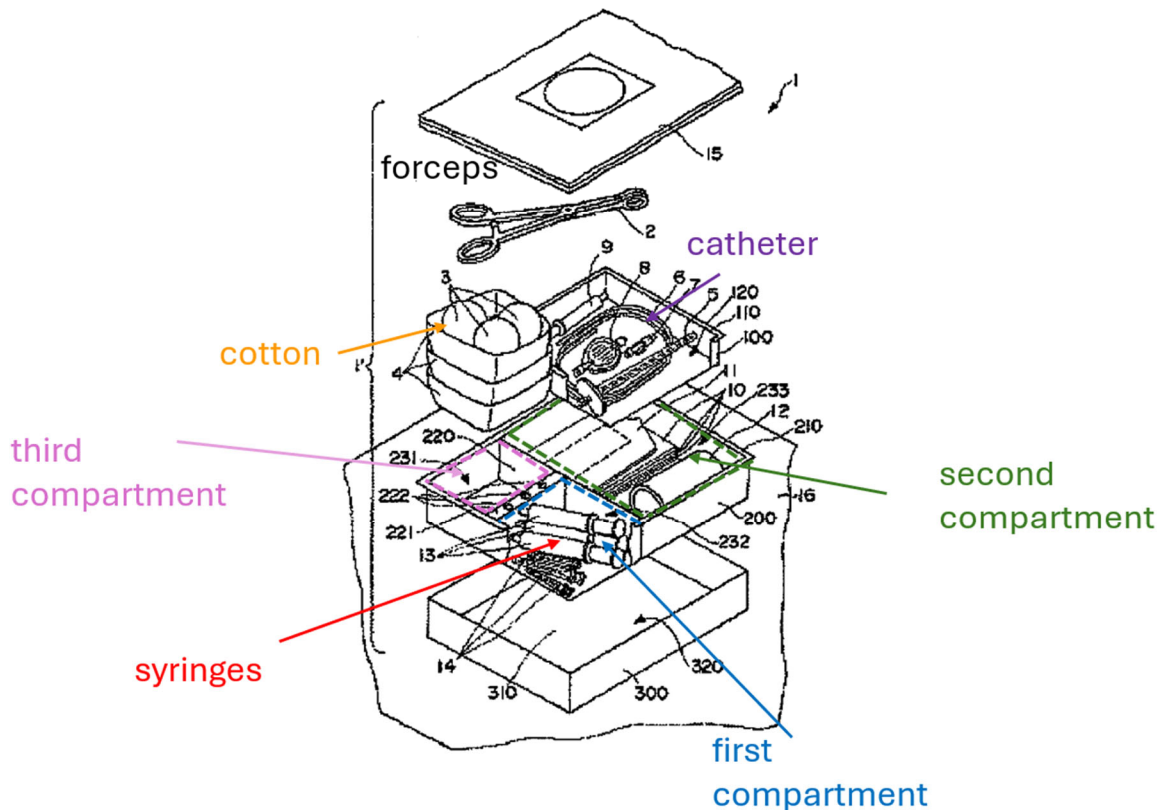
(EX1007.Fig.4,¶0031.)

Catheter kits with three compartments were well-known in the art. For example, Imai, Serany, and Beddow all disclose trays with at least three compartments for organizing the equipment stored in the kit. (EX1002¶239.)

It would have been obvious in view of Imai to add a third compartment to the tray of Numata to store the forceps and cotton (replaceable with swabsticks) separately from the other equipment stored in the first compartment. (EX1002.¶238-44.) Like Numata, Imai discloses a catheter kit with a catheter 6, syringes 13, forceps

2, and cotton balls 3 stored in a tray. Within tray 200, Imai includes “three storage cells 231 to 233” (i.e., three compartments) to store this equipment. (EX1012.Abstract, Fig. 1).

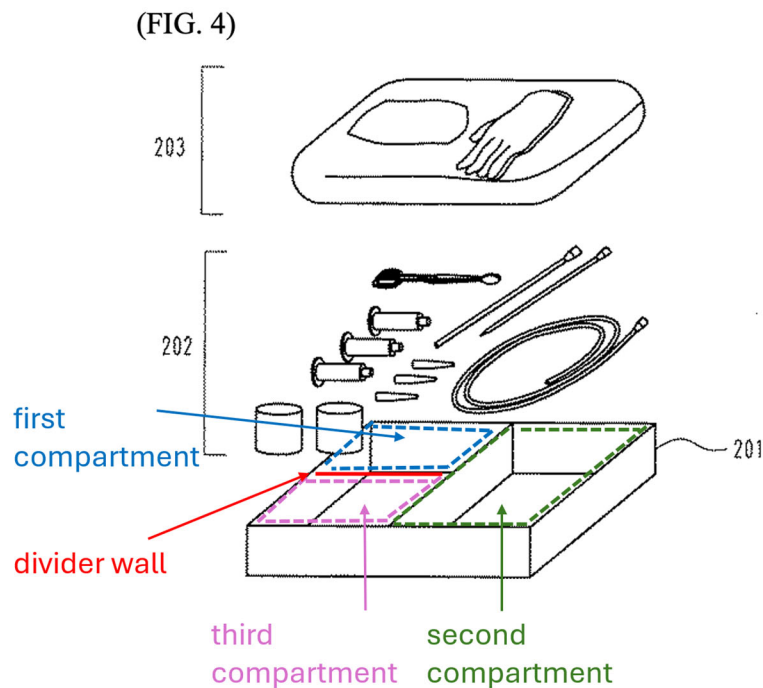
[Figure 1]



The syringes are stored in a first compartment (232), a catheter is stored in a second compartment (233), and cotton is stored in a third compartment (231). (EX1012.Fig.1, ¶¶ 0014, 0018-0021, 0028, 0045.) The tray is partitioned into these compartments via a divider wall 220. (EX1012.¶0019.) Imai notes that “partitioning member 220” “fortifie[s]” the strength of tray 200 and “functions as a movement-

restricting means to prevent the treatment tools housed within... from freely moving around.” (EX1012.¶0020.)

Nothing in Numata separates the cotton and forceps (replaceable with swabsticks) from the other equipment stored in the first compartment such as the syringe. Thus, in view of Imai, a POSA would have been motivated to add an additional divider wall to tray 201 of Numata thereby creating a third compartment to fortify the strength of the tray and “to prevent the treatment tools housed within... from freely moving around.” (EX1012.¶0020; EX1002.¶238-44.) For example, third compartment could be added as shown in Figure 4:



Numata already discloses a divider wall to separate the two compartments in tray 201 so adding a third compartment via an additional divider wall would be

within the knowledge and skill of a POSA. (EX1002.¶243.) Indeed, Imai’s “partitioning member 220” divides the tray into three compartments in the same manner proposed here (i.e., a large compartment on the right and two smaller compartments on the left.) Moreover, adding an additional divider wall to Numata would separate the same equipment (syringes and cotton) that partitioning member 220 separates in Imai. This applies a known technique (adding a third compartment via an additional divider wall) to a known device (a catheter kit) to yield predictable results (preventing equipment from moving around in the tray). (EX1002.¶243.) It also would have been obvious to try given the finite number of ways to store equipment in a catheter kit (together in a single compartment or in separate compartments).

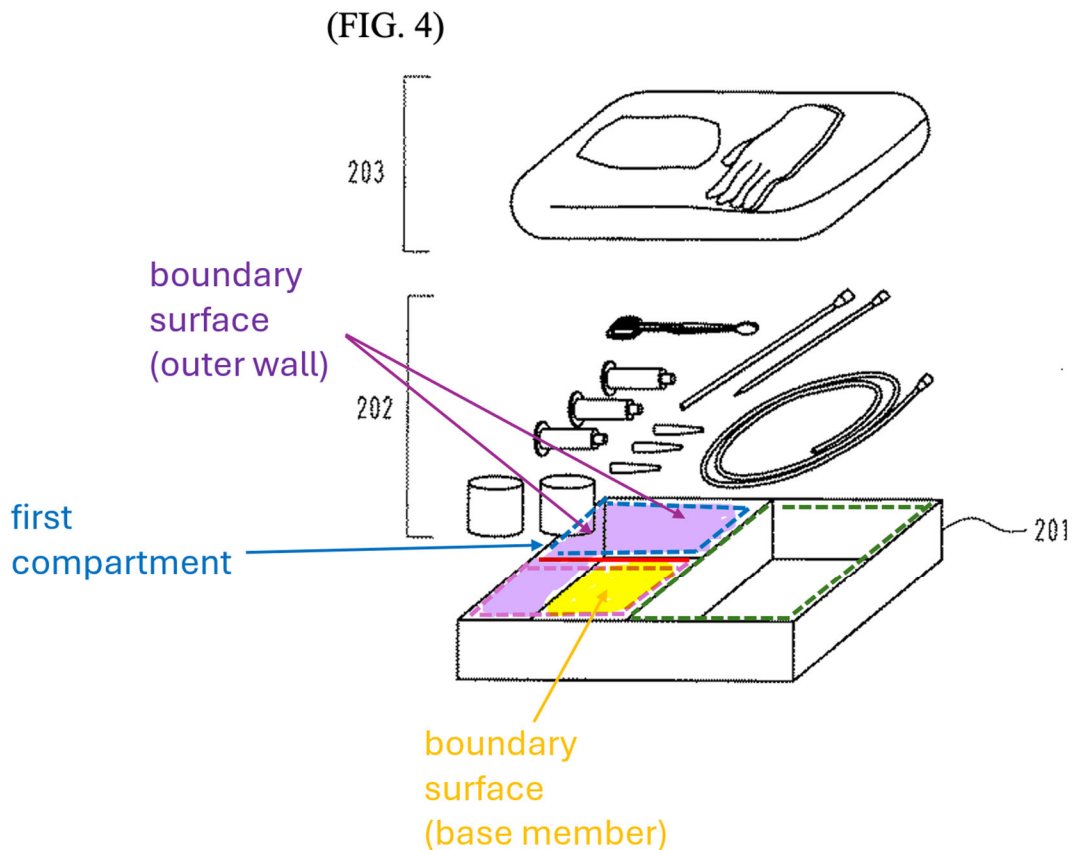
There would have been a reasonable expectation of success in combining Numata and Imai. (EX1002.¶244.) Both patents are directed to catheter kits with similar equipment stored in a tray that is covered in a wrap and outer bag. (EX1007.Abstract,Figs.4-6; EX1012.Fig.1,¶0014,0064-0072.) The tray of Numata is “molded” from a “hard plastic or the like” and tray 200 of Imai can be made from various plastics. (EX1007.¶0014; EX1012.¶0017.)

When modifying the left compartment Numata to have two smaller compartments of equal size, the new first compartment would have dimensions of 8

by 11 inches, which is sufficient to accommodate multiple syringes and lubricate the catheter (and could be made even smaller as discussed at 13[b]).

2. Claim 16

Numata and Beddow render “a boundary surface defines the lubricating jelly application chamber” obvious. (EX1002.¶¶245-49.) As discussed at limitation 1[a], the first compartment of Numata is a lubricating jelly application chamber. As shown in Figure 4, the first compartment/lubrication chamber (as modified in claim 15) is defined by boundary surfaces of the tray, including the base member of the tray and the outer walls of the tray. (EX1007.Fig.4.)



D. Ground 4: Obviousness Over Rauschenberger and Serany

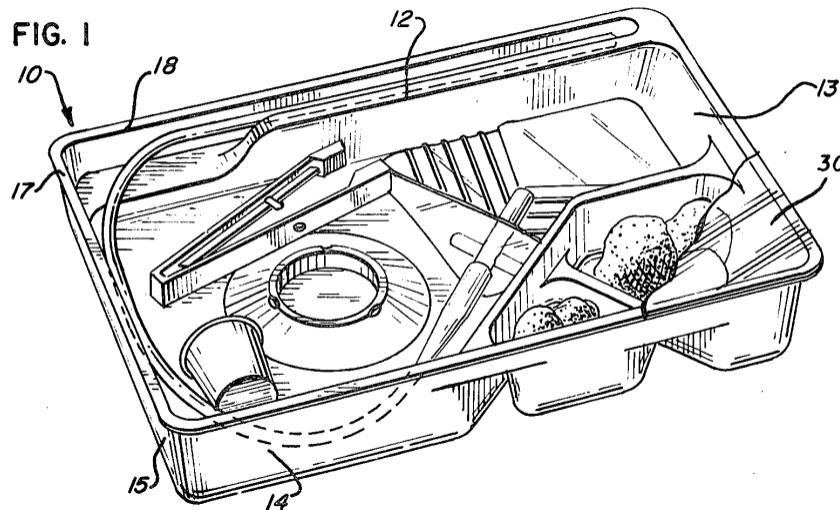
Rauschenberger and Serany render claims 13-14 obvious. (EX1002.¶¶250-305.)

1. Independent Claim 13

(a) Limitations 13[p] and 13[a]

Rauschenberger and Serany render “*A medical procedure kit, comprising: a first syringe and a second syringe*” obvious. (EX1002.¶¶250-305.)

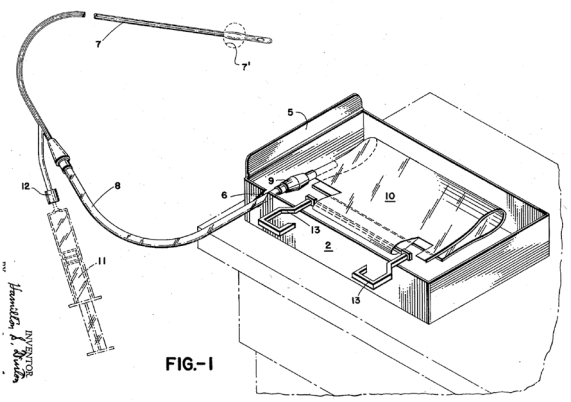
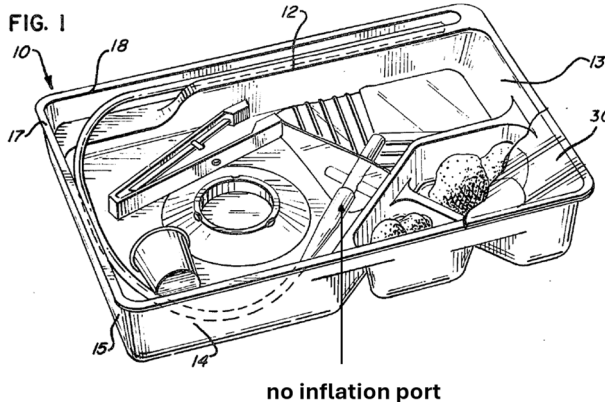
Rauschenberger discloses a “urethral catheterization tray” 10 which is a medical procedure kit. (EX1021.Abstract, Fig. 1.)



First/Lubricant Syringe. All-in-one urethral catheter kits (like Rauschenberger) include lubricant (which may come in the form of a syringe) to lubricate the catheter before insertion. (EX1021.2:22-2:26; EX1008.2:41-45; EX1009.3:1-5.) Rauschenberger discloses one of the components of the tray is a “lubricant packet.” (EX1021.2:22-3:33.) It would have been obvious to substitute

Rauschenberger's lubricant packet with a lubricant syringe. Doing so would merely involve a simple substitution of one container (a lubricant packet as taught by Rauschenberger) for another known type of container (a syringe) 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.¶¶252-53; EX1003.¶49.) The Board already found that Rauschenberger's lubricant packet could be substituted with a syringe.

Second/Water Syringe. There are two types of urethral catheters: an intermittent catheter and an indwelling Foley catheter. (EX1003.¶¶27-60.) Foley catheter kits include both lubricant and an inflation syringe (supplied with sterile water) to inflate the retention balloon. For example, Serany and Disston each include an inflation syringe. (EX1009.3:6-12; EX1008.Fig.1,2:44-45.) The urethral catheter of Rauschenberger is generically referred to as a "catheter." (EX1021.1:62:2-46,claims.1-2.) Rauschenberger does not expressly mention that the kit is provided with an inflation syringe. And the catheter of Rauschenberger is not depicted as including an inflation port unlike Disston:

Disston	Rauschenberger
 FIG. 1	 FIG. 1 no inflation port

Thus, a POSA would understand the “urethral catheter” of the preferred embodiment of Rauschenberger to likely be an intermittent catheter. (EX1002.¶¶254-55.)

It would have been obvious to provide a Foley catheter in the kit of Rauschenberger. Whether to insert an intermittent or a Foley catheter is a clinical determination based on the patients’ needs. (EX1003.¶30.) There would have been motivation to equip Rauschenberger with a Foley catheter to allow the invention of Rauschenberger to be used with the other common type of urethral catheter. (EX1002.¶256.)

When equipping Rauschenberger with a Foley catheter, it would have been obvious to add an inflation syringe to the kit of Rauschenberger so that its retention balloon can be inflated. Thus, there would have been a motivation to include an

inflation syringe (such as the inflation syringe provided by Serany) with the kit of Rauschenberger to allow for a Foley catheterization procedure to be completed, which requires an inflation syringe. This applies a known technique (provision of an inflation syringe) to a known device (a urethral catheter kit) to yield predictable results. (EX1002.¶257.)

There would have been a reasonable expectation of success in combining Rauschenberger with Serany—both of which are directed to all-in-one urethral catheter kits. All three references disclose equipment to perform urethral catheter procedures, such as a urethral catheter, drainage bag, fenestrated drape, lubricant, forceps, and gloves. (EX1009.2:21-3:45; EX1021.2:15-27.) Thus, this combination merely requires substituting Rauschenberger’s closed-system intermittent catheter with Serany’s closed-system Foley catheter and to add an inflation syringe. (EX1002.¶¶258-59.)

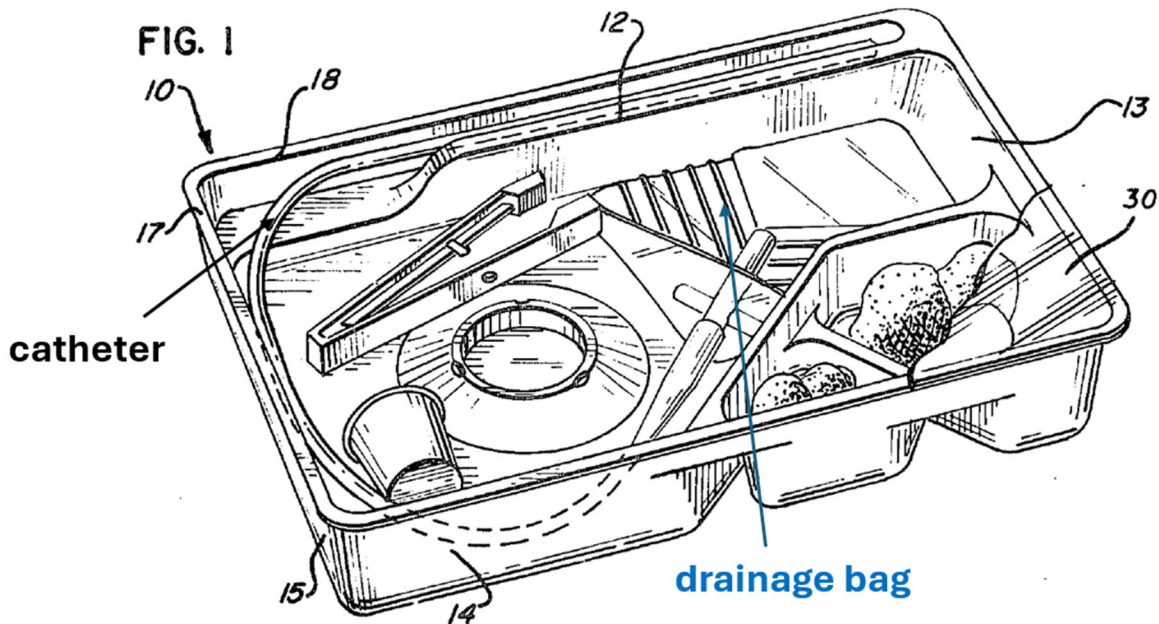
The benefit of Rauschenberger’s invention applies equally to intermittent and Foley catheters, which adds motivation to customize Rauschenberger’s kit with a Foley catheter. Rauschenberger states that with “prior art devices,” the clinician would “place[] an amount of lubricant on the CSR wrap” to lubricate the catheter. (EX1021.1:7-43.) This was “less than ideal” because the lubricant could “contact” the patient or clinician. (EX1021.1:7-43.) Thus, Rauschenberger provides a tray where catheterization procedure steps, such as lubricating the catheter, can be

performed. (EX1021.1:44-2:43.) This advantage applies to Foley catheter kits as Foley catheters must be lubricated before inserting the catheter. (EX1002.¶¶260-61.)

(b) Limitation 13[b]

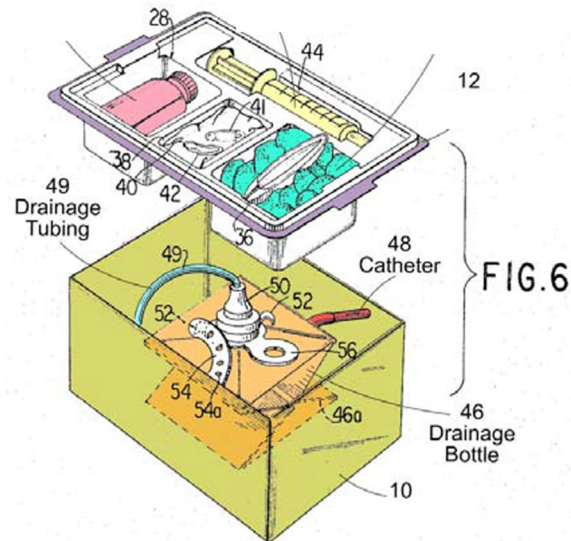
Rauschenberger and Serany render “*the medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter*” obvious. (EX1002.¶¶262-69.)

Rauschenberger discloses a “urethral catheter” attached to a “drainage bag.” (EX1021.Abstract,2:20-25;Fig.1)



Serany discloses “*a medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter.*” Serany discloses “a collapsible drainage bottle 46 and a Foley catheter 48 (partly shown) connected thereto by the

drainage tube 49 and ready for use.” (EX1009.3:23-26; EX1002.¶264.) The drainage tubing 49 that couples the fluid drainage bag and Foley catheter is “coiled in the box about the bottle.” (EX1009.3:32-34.)



For the reasons at 13[a], it would have been obvious to customize Rauschenberger’s tray to include Foley catheter equipment. This is a simple substitution of one type of well-known urethral catheter (a closed-system intermittent catheter) for another (a closed-system Foley catheter). Specifically, the catheter/bag of Rauschenberger could be replaced with the catheter/bag/coiled tubing of Serany.⁵ (EX1002.¶265-66.)

⁵ Serany’s tubing is coiled because drainage bags connected to indwelling catheters are typically hung from the side of a bed requiring a long run of tubing so it would

Serany’s drainage “bottle” is made of a “flexible plastic material” and is “collapsible” and would thus be considered a bag. (EX1002.¶267.) If Medline argues that Serany does not teach a bag, it is obvious to substitute the “bottle” of Serany with Rauschenberger’s “bag.” (EX1002.¶267.) Doing so involves a simple substitution of one container (a “bottle”) for another type of container (a “bag”) to produce predictable results. (EX1002.¶267.)

Rauschenberger could accommodate Serany’s closed-system Foley catheter because Rauschenberger’s tray is designed to hold a urinary catheter and bag. It could also accommodate tubing, which could be coiled around the bag as discussed by Serany, or could easily have been modified to do so. Indeed, Rauschenberger notes that “[c]hannel 21 is adapted to receive a conventional urethral catheter.” (EX1021.1:62-63), which a POSA would understand could refer to either a Foley or intermittent catheter. (EX1002.¶¶268-69.)

(c) Limitation 13[c]

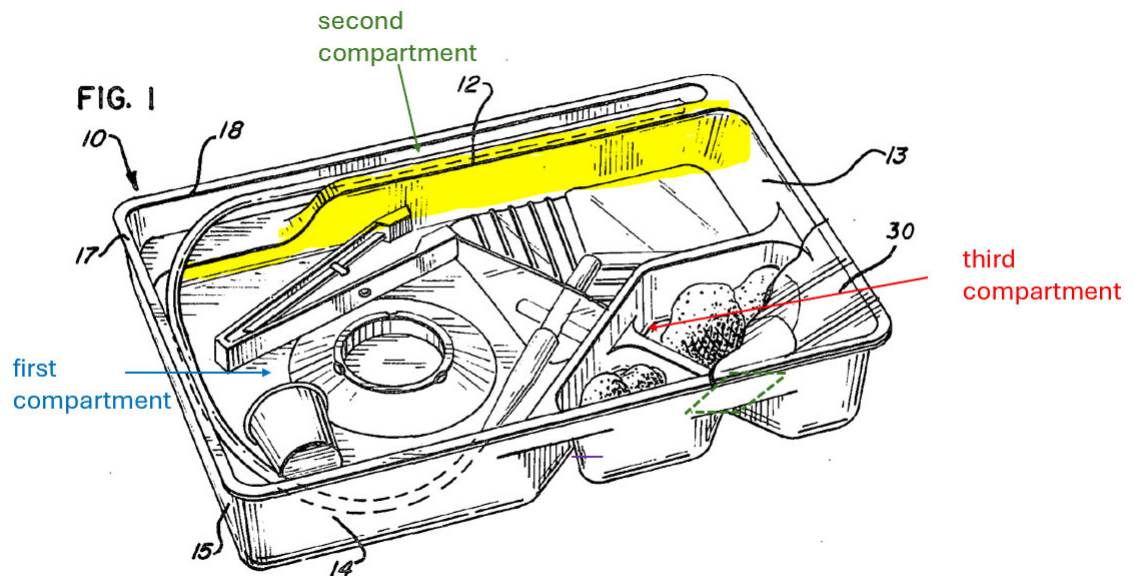
Rauschenberger and Serany render “*single layer tray comprising a first compartment for receiving the first syringe and the second syringe and a second*

be also necessary for Rauschenberger to include longer tubing that would be coiled to fit within the tray. (EX1009.3:36-44.)

compartment for receiving at least a portion of the medical assembly” obvious.

(EX1002.¶¶270-78.)

The equipment of Rauschenberger is stored in a single-layer tray 10:



(EX1007.Fig.1,1:50-61.)

Tray 10 has at least four compartments:

- Channel 21 (“adapted to receive a conventional urethral catheter,” which is positioned within channel 21)
- Main compartment of dish 11 (which stores the “remainder of the catheter,” the drainage bag, forceps, and a specimen container)
- Compartments 23 and 24 (which store absorbent pads)

(EX1021.1:62-2:27.)

Either channel 21 or the main compartment satisfies the requirement of “a second compartment for receiving at least a portion of the medical assembly”

because both receive a portion of the catheter assembly. (EX1002.¶272.) In this Petition,⁶ Bard identifies the main compartment as the “first compartment” and channel 21 as the “second compartment for receiving at least a portion of the medical assembly” as it “receive[s] a conventional urethral catheter.” (EX1021.1:62-64.)

Claim 13 further requires “*a first compartment for receiving the first syringe and the second syringe.*” For the reasons at 13[a], it would have been obvious to include a lubricant and an inflation syringe in the kit of Rauschenberger. (EX1002.¶273.) Besides a portion of the catheter and the absorbent pads, the

⁶ Whether a compartment is deemed a “first” or “second” compartment is an arbitrary designation. In IPR2019-00503, Bard mapped the claimed first compartment as “channel 21” because claim 22 of related U.S. Patent No. 8,631,935 (“’935 patent”) required that its first compartment was “inclined” and formed a “ramp,” channel 21 has an “inclined section 20 forming a ramp.” (EX1021.1:56-58.) But the Board was not persuaded that Bard had articulated why the syringe would be moved from the main compartment to channel 21. (EX1022.28.) Here, Bard has mapped the first compartment as the main compartment (as opposed to channel 21). Thus, the reason the Board denied institution of claim 22. Rather, claim 13 is similar to claim 21 of the ’935 patent where the Board instituted IPR. (EX1022.11-14.)

remainder of the components, including the lubricant, are stored in the main compartment dish 11 (a first compartment). (EX1021.2:20-27;Fig.1) Indeed, the Board previously recognized that the lubricant when replaced with a lubricant syringe could be stored in the main compartment of Rauschenberger. (EX1022.0027.)

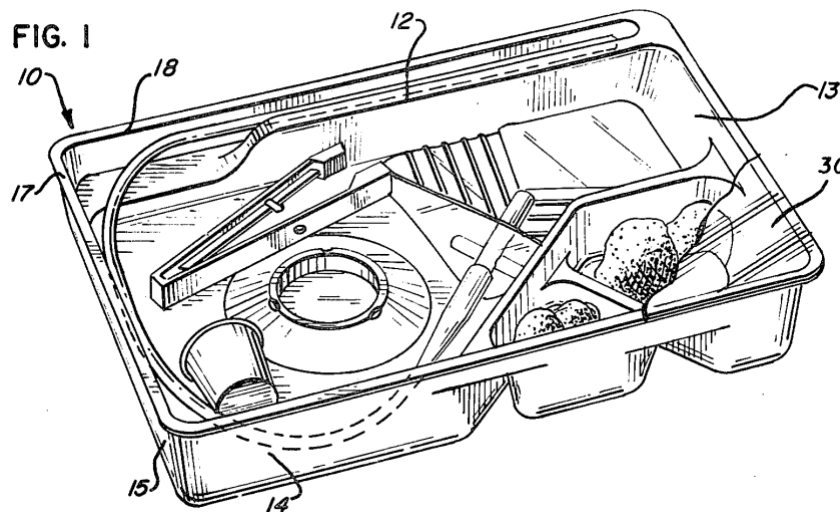
When adding an inflation syringe to the kit of Rauschenberger, it would have been obvious to store it with the lubricant in dish 11. (EX1002.¶274.)

First, Rauschenberger stores most of the equipment in the main compartment and designates compartment 21 for the catheter and compartments 23 and 24 are for absorbent pads. Second, it was known in the art to store like items in the same compartment. For example, Rauschenberger groups multiple absorbent pads in compartments 23 and 24. The lubricant of Rauschenberger (replaceable with a syringe) and added inflation syringe are like items. Third, it would have been obvious to try grouping the lubricant and water syringe 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.

Finally, for the reasons at 13[i], the syringe could be held in place within dish 11 using recesses (a well-known technique) to avoid damaging other equipment within dish 11. (EX1002.¶¶275-78.)

(d) Limitation 13[d]

Rauschenberger discloses “*the medical procedure kit allowing passage of at least some of the Foley catheter into a lubricating jelly application chamber.*” (EX1002.¶¶279-82.) Rauschenberger discloses using channel 21 (a lubricating jelly application chamber) to lubricate the catheter: “[g]loves are donned and a lubricant packet is utilized to put lubricant on the catheter in channel 21. The catheter then is rotated within channel 21 to spread lubricant about it insertion end.” (EX1021.2:31-36, Fig. 1.)



Rauschenberger allows passage of the catheter into the lubricating jelly application chamber formed by channel 11. As shown in Figure 1, there is an opening between the dish 11 and channel 21 that allows the passage of at least some of the Foley catheter into channel 21, which is a lubrication jelly application chamber. (EX.1021.Fig.1.)

(e) Limitation 13[e]

Rauschenberger discloses an “*outer packaging disposed about the single layer tray.*” (EX1002.¶¶283-88.) Rauschenberger discloses that “[i]n its packaged configuration the catheterization implements are placed in tray 10 as shown in FIG. 1 and sealed with a cover sheet 30 about flange 17.” (EX1021.2:15-20, Fig. 1) Because cover sheet 30 is disposed “about 17” it is an outer packaging disposed about single layer tray 10. If Medline argues this claim is not met by Rauschenberger, it would have been obvious to substitute cover sheet 30 with Serany’s bag 16, which is a simple substitution of one known element (a cover sheet) for another (a bag) to yield predictable results. (EX.1009.1:60-72; Fig. 1; EX1002.¶¶287-88.)

(f) Limitation 13[f]

For the reasons at 13[a], Rauschenberger and Serany discloses “*one of the first syringe or the second syringe contains lubricating jelly; another of the first syringe or the second syringe contains water.*” (EX1002.¶¶289-91.)

(g) Limitation 13[g]

Rauschenberger and Serany discloses “*the first syringe and the second syringe are ordered within the single layer tray in accordance an order with which they are drawn out of the single layer tray during a Foley catheterization procedure.*” (EX1002.¶¶292-96.) Rauschenberger discloses catheterization equipment arranged in the order in which they are drawn out of the tray and used: “The remaining components [sic.] generally are arranged sequentially from the top of the tray on

down in the order: gloves, lubricant, antiseptic solution, fenestrated drape, forceps, drainage bag and specimen container.” (EX1021.1:22-27.) Rauschenberger then describes using the “gloves, lubricant, antiseptic solution, fenestrated drape, forceps, drainage bag and specimen container” in the same sequence in which they are arranged.” (EX1021.2:60-60.)

Thus, it would have been obvious to arrange the added water syringe sequentially in the order in which it used and drawn out of the catheter kit during the procedure. For example, it could be arranged below the lubricant syringe (e.g., via stacking) consistent with Rauschenberger’s top down ordering as the catheter is lubricated before it is inserted and the retention balloon inflated with the water syringe.

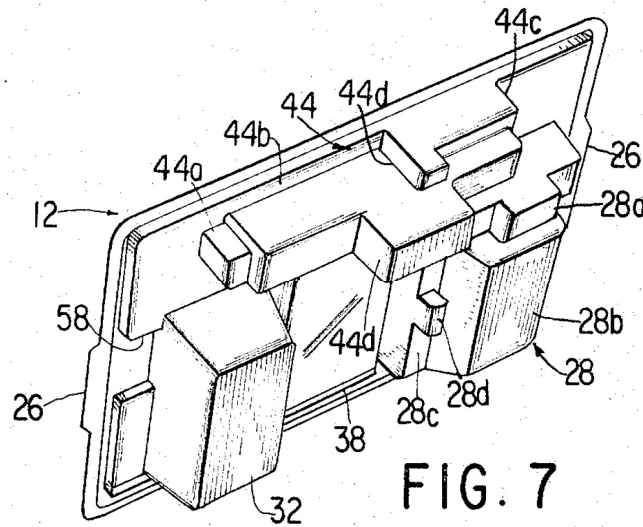
It was also well-known in the art to arrange components in a catheterization kit in their order of use. (EX1002.¶295.) Serany teaches a Foley catheter kit where “[e]verything is available in the proper order of use.” (EX1009.1:9-12,1:23-25,1:30-35 (emphasis added).) Thus, Serany provides further motivation to arrange the syringes in the order in which they are used and drawn out of the tray of Rauschenberger. 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”).

(h) Limitation 13[h]

Rauschenberger and Serany render “*the first compartment defines one or more contours for accommodating one or more of the first syringe or the second syringe*” obvious. (EX1002.¶¶297-302.)

Rauschenberger discloses “a circular recess for receiving and holding a upright specimen container” where the specimen container may be placed after a sample is collected. (EX1021.claim.1, Fig. 1, 2:55-63.) Rauschenberger does not provide any specific mechanism to hold other equipment (such as the added syringes) in place within the first compartment. If the syringes moved during shipment of the tray it could risk damaging the syringes or other equipment disposed within the first compartment. (EX1002.¶299.)

A known technique to prevent syringes from moving during shipping is to define one or more contours of a compartment to accommodate a syringe and its flange—thus holding the syringe in place as well as making it easier to grasp the syringe. (EX1002.¶300.) Serany teaches that depression 44 holds a syringe and includes an upper portion 44c that is wider than the diameter of the syringe plunger handle 45a “so that it may be easily grasped,” and indentations 44d to accommodate the “flange or finger grip 45c of the syringe.” (EX1009.3:6-22.) Storing the syringe in this manner “hold[s] the syringe against lateral movement in its stored condition.” (EX1009.3:15-16.) Depression 44 is shown in Figure 7:



It would have been obvious in view of Serany to add a contoured depression to the bottom surface of the first compartment of Rauschenberger to hold the syringe flange of one or more of the first and second syringes such that they do not move during shipping and can more easily be grasped. (EX1002.¶¶301-02.) This applies a known technique (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.¶¶301-02.)

2. Claim 14

For the reasons at 13[a], Rauschenberger and Serany render “*wherein the second syringe is attachable to the Foley catheter*” obvious. An inflation syringe only functions by being attached to the inflation port of a Foley catheter. (Ex.1008.Fig.1;EX1002.¶¶303-05.)

E. Ground 5: Obviousness over Rauschenberger, Serany and Salvadori

Rauschenberger, Serany, and Salvadori render claims 15 and 16 obvious.
(EX1002.¶¶306-17.)

1. Claim 15

Rauschenberger and Salvadori render “*wherein the single layer tray comprises a third compartment containing one or more swabsticks*” obvious.
(EX1002.¶¶306-15.) Rauschenberger discloses a third compartment—either compartment 23 or 24, which “are adapted to hold absorbent pads separately from each other.” (EX1021.2:5-7, Fig. 1.)

One of the steps of a Foley catheterization procedure is cleaning the patient with antiseptic solution such as iodine. (EX1003.¶142.) Rauschenberger discloses applying “antiseptic solution” to the “absorbent pads” and using forceps to hold the pads. (EX1021.2:43-56.) Similarly, Serany discloses “rayon balls,” “forceps,” and “cleansing solution” to clean the patient. (EX1009.2:57-72.)

Salvadori discloses “one or more swabsticks disposed within the single layer tray.” Salvadori teaches a “urethral catheter kit or tray” that includes “swab sticks 60.” (EX1013.1:12-16, 3:4.)

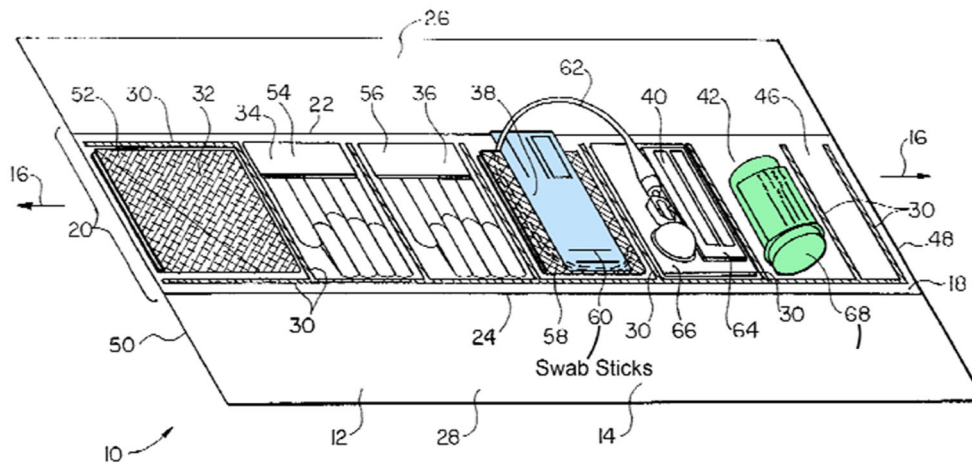


FIG. 1

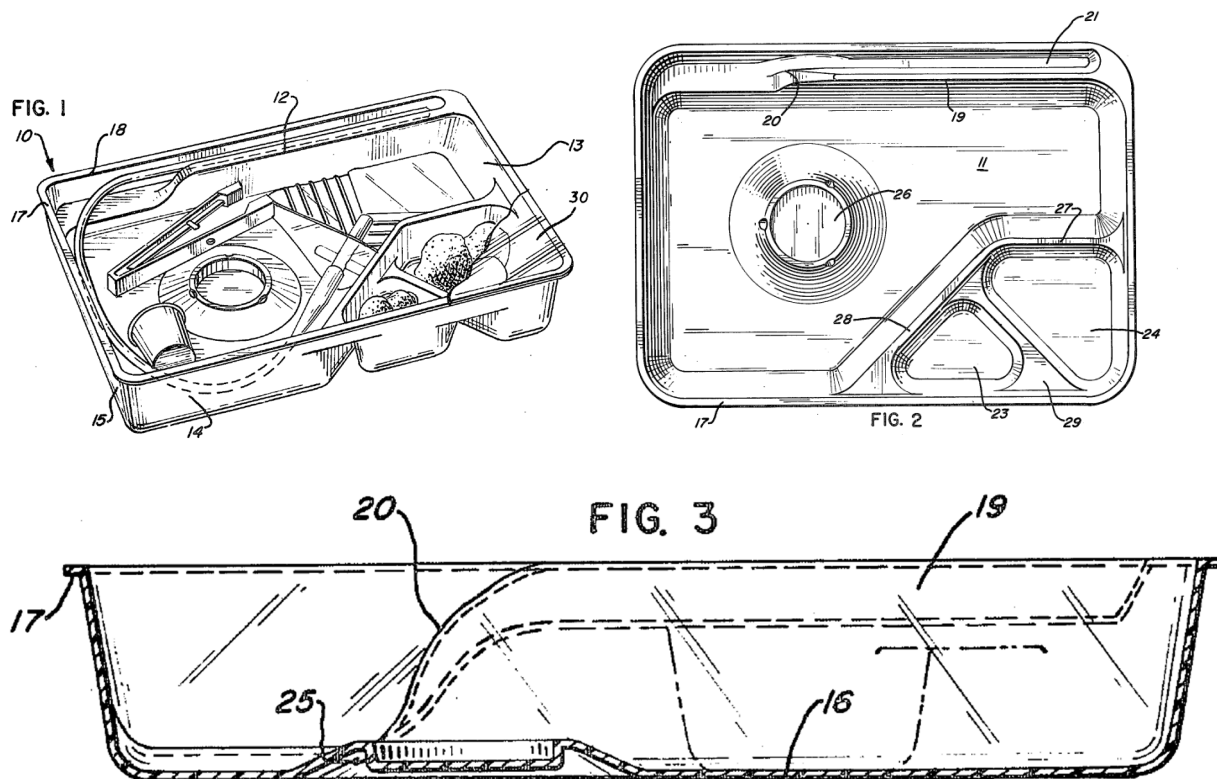
These swabsticks, which a POSA would understand to be presaturated with cleansing material, provide the same function as Rauschenberger's absorbent pads, antiseptic solutions, and forceps: they are used to clean the patient's genitalia. This is a simple substitution of one known device (forceps, antiseptic solutions, and absorbent pads) for another (swabsticks) to yield predictable results. The inclusion of a swabsticks in the catheterization kit of Rauschenberger also involves the use of a known technique (provision of swab sticks) to a known device (a urethral catheter kit) to yield predictable results (providing swab sticks to allow the practitioner to clean the patient). (EX1002.¶¶307-13.)

When replacing Rauschenberger's cleansing materials with swabsticks, it would have been obvious to store the swabsticks (which are packaged together in a packet as shown in Figure 1 of Salvadori) in compartment 23 or 24 (either of which

is a third compartment) as these compartments store absorbent pads, which would be replaced with swabsticks. (EX1002.¶¶314-15.)

2. Claim 16

Rauschenberger discloses “wherein a boundary surface defines the lubricating jelly application chamber.” (EX1002.¶¶316-17.) “Tray 10 is formed with a dished portion 11 defined generally by outside walls 12, 13, 14, 15 and 18 and bottom wall 16.” (EX1021.1:50-52.) Thus, as shown in Figures 1-3, the lubricating jelly application chamber (channel 21) is formed by the boundary surfaces of the tray, including at least walls 12 and 18: “Wall 12 ... cooperates with wall 18 to form the channel 21 in that portion of dish 11.” (EX1021.1:59-61.)



F. Ground 6: Obviousness Over Solazzo, Serany, Disston, and Imai

Solazzo, Serany, Disston, and Imai render claims 13-14 obvious.
(EX1002.¶¶318-92.)

1. Independent Claim 13

(a) Limitations 13[p] and 13[a]

Solazzo discloses “*A medical procedure kit, comprising: a first syringe and a second syringe.*” (EX1002.¶¶318-26.) Solazzo discloses a “medical procedure kit:” “an ergonomic urological catheterization/irrigation tray” with equipment for performing both Foley catheterization and irrigation procedures. (EX1005.2:34-35,3:12-24,Figs.1,8.)

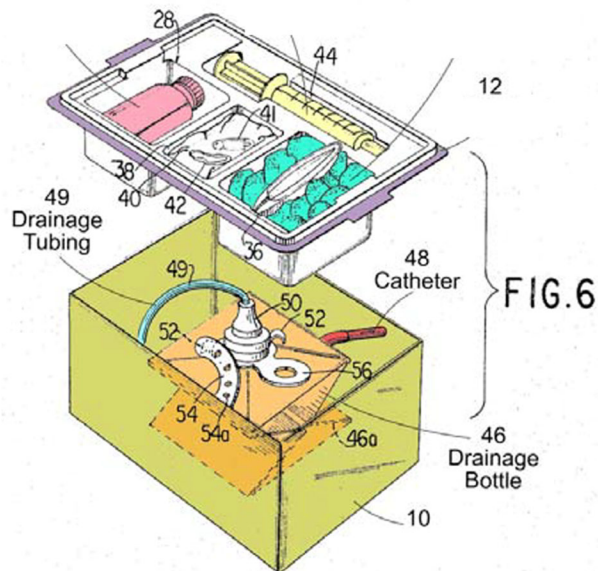
Solazzo discloses “[t]he kit includes: ...(c.) a urinary tract lubricant ... (e.) an inflation syringe ...; (f.) irrigation syringe.” (EX1005.3:15-24.) Solazzo thus discloses a “first syringe and second syringe.” Additionally, while Solazzo discloses a “tube of lubricant 140,” this tube is replaceable with a syringe. It would have been obvious to provide a lubricant syringe place of the tube. This is a simple substitution of one container (a tube) for another (syringe) to yield predictable results. (EX1002.¶¶324-25.) Providing lubricant in a syringe as part of a Foley catheter kit was well-known in the art. 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. (EX1020.2:43-49,4:48-55) 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.¶325; EX1003¶.49.)

The PTAB previously found an identical claim limitation obvious in view of the prior art presented in this petition. (EX1020.0017-18).

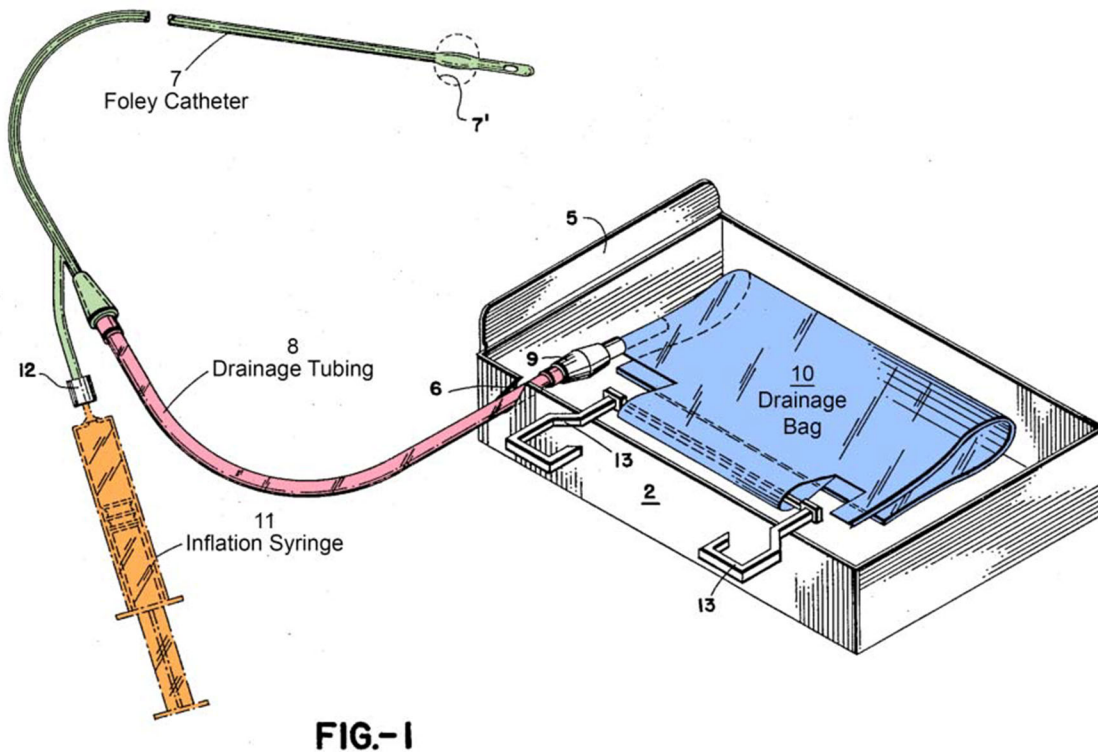
(b) Limitation 13[b]

Solazzo, Serany and Disston render “*a medical assembly that comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter*” obvious. Serany discloses coiled tubing 49 coupled between a Foley catheter 48 and a drainage bottle 46. (EX1009.3:23-36; EX1002.¶¶327-42.)



Serany’s drainage “bottle” is made of a “flexible plastic material” and is “collapsible” and would thus be considered a bag. (EX1002.¶333.)

Disston discloses a “medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter.” 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.¶334.)



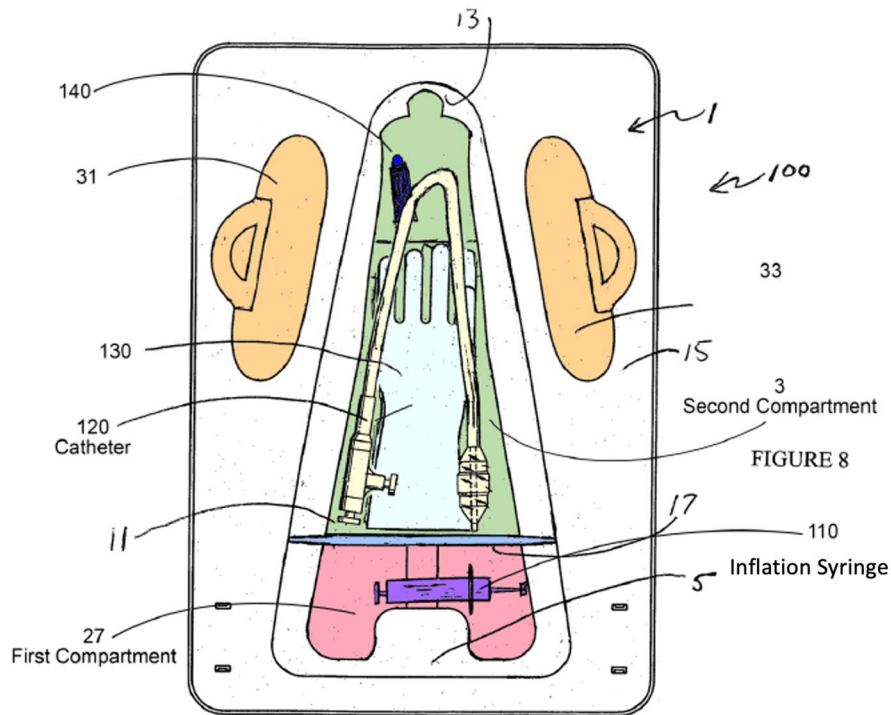
If Medline argues that Serany does not teach a bag, it would have been obvious to substitute the “bottle” of Serany with the “bag” of Disston. (EX1002.¶335.) Doing so would merely involve a simple substitution of one container for another known type of container to produce predictable results.

In view of Serany and Disston, a POSA would have been motivated to include a closed-system Foley catheter in the tray of Solazzo. (EX1002.¶¶336-37; 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.¶¶338; 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. The tray can be best utilized for both purposes when a closed-system Foley catheter is provided in the tray of Solazzo. (EX1002.¶¶339-342; EX1003.¶¶61-92.)

The PTAB previously found an identical claim limitation obvious in view of the same prior art. (EX1015.0015-18; EX1023.0018-23.)

(c) Limitation 13[c]

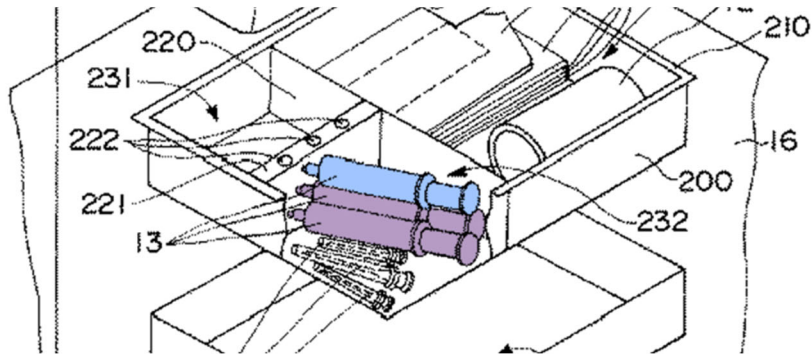
Solazzo, Serany and Disston render “*a single layer tray comprising a first compartment for receiving the first syringe and the second syringe and a second compartment for receiving at least a portion of the medical assembly*” obvious. (EX1002.¶¶343-53.) Solazzo discloses a single layer tray having multiple 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. (EX1005.3:15-24, Fig. 8.) The location of the “irrigation syringe” within the tray is not expressly provided. (*Id.*) 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.¶¶346-49.)

Solazzo also discloses a “tube of lubricant 140.” The tube is replaceable with a syringe for the reasons at 13[a]. It would also have been obvious to group the lubricant syringe with the inflation and irrigation syringes in first compartment 27. (EX1002.¶¶347-50.) It was well-known in the art to group like items in the same compartment of a tray. For example, Serany discloses grouping multiple balls of cleansing material in the same compartment. (EX1009.2:57-61.) Additionally, Imai

(EXS1011,1012) discloses grouping three syringes in the same compartment of a catheter tray:



(EX.1012.¶¶0014,0031, Fig. 1.)

In view of Serany and Imai, 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. (EX.1009.1:31-35.)

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.¶¶351-53.)

Second compartment 3 stores a medical assembly: Foley catheter 120, which can be substituted with a closed-system Foley catheter, as discussed at 13[b]. (EX1002.¶¶343-53.)

The Federal Circuit and PTAB previously found an identical claim limitation obvious in view of the same prior art. (EX1015.0015-17.)

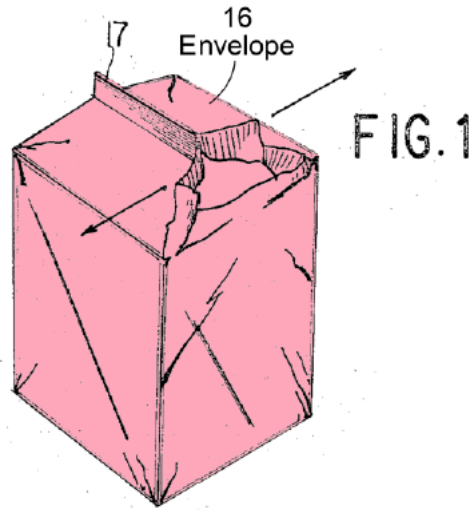
(d) Limitation 13[d]

Solazzo discloses “*the medical procedure kit allowing passage of at least some of the Foley catheter into a lubricating jelly application chamber.*” (EX1002.¶¶354-56.) Solazzo discloses “[o]ptional Foley catheter lubricating wells 31 and 33 [which] are available for right handed and left handed users so that lubricating material could be applied to the catheter or other insertion device by filling the well with lubricant and then sliding the device through the lubricant in the well.” (EX1005.4:21-25.) These wells must allow passage of at least some of the Foley catheter into them in order to lubricate, and that is also disclosed by Solazzo: “sliding the device through the lubricant in the well.” (*Id.*)

(e) Limitation 13[e]

Solazzo and Serany render “*an outer packaging disposed about the single layer tray*” obvious. (EX1002.¶¶357-66.)

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



This is an “outer” packaging. (EX1009.1:42-45,1:60-66).

It would have been obvious to a POSA to combine the outer packaging taught by Serany with the tray of Solazzo. (EX1002.¶¶358-62.) 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.¶362.) 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.¶¶363-66.)

The PTAB previously found a substantively identical claim limitation obvious in view of the same prior art. (EX1015.0020-21.)

(f) Limitations 13[f] and 13[g]

Solazzo and Serany render “one of the first syringe or the second syringe contains lubricating jelly; another of the first syringe or the second syringe contains water” obvious. (EX1002.¶¶367-71.)

For the reasons at 13[a], Solazzo includes “a tube of lubricant,” which is substitute with a lubricant syringe. (EX1002.¶369.)

For the reasons at 13[a], Solazzo’s kit includes “an inflation syringe,” which a POSA would understood to include water. (EX1002.¶368.) In the background, Solazzo mentions “a syringe prefilled with bacteriostatic water.” (EX1005.1:38-42.) Serany also discloses an inflation syringe with “sterile water.” (EX1009.3:50-51.)

(g) Limitation 13[h]

Solazzo in view of Serany and Disston discloses “*the first syringe and the second syringe are ordered within the single layer tray in accordance an order with which they are drawn out of the single layer tray during a Foley catheterization procedure.*” (EX1002.¶¶372-81.)

The original configuration of Solazzo presents the lubricant at a higher height than inflation syringe because of the “terraced arrangement” of bottom 11. (EX.1005.3:63-66,Figs.2,8.;EX.1002.¶372). This arrangement (lubricant above the inflation syringe) is consistent with the order of use of these components as described by Solazzo: “The gloves being worn by the surgeon, the catheter being

lubricated, inserted **and then inflated** with fluid using the syringe.” (EX.1005,4:46-48(emphases added); EX.1002.¶373.)

A POSA would have understood that items are drawn out (i.e., removed) from the tray as they are used. (EX1002.¶374.) Disston notes that “contents of the tray portion,” including “lubricant, syringe and water packet are removed and put to their respective intended uses.” (EX1008.2:41-45.) Serany also describes items arranged in their order of removal and subsequent use. (EX1009. 2:57-72;Fig.6.)

Also, it was well-known in the art to arrange components in a catheterization kit in the order in which they are removed and subsequently used. (EX1002.¶¶372-74.) Serany discloses providing all “components in their preferred order of use” and “proper order of use.” (EX1009.1:9-12,1:23-35.) Disston has a similar teaching. (EX1008.2:15-19.)

When grouping the lubricant and inflation syringes in compartment 3 for the reasons at 13[c], it would have been obvious to position the lubricant syringe higher than inflation syringe (e.g., by stacking them) to maintain the same relative positioning of Solazzo’s original configuration. (EX1002¶375.) Doing so would arrange them in their order of drawing out and subsequent use.

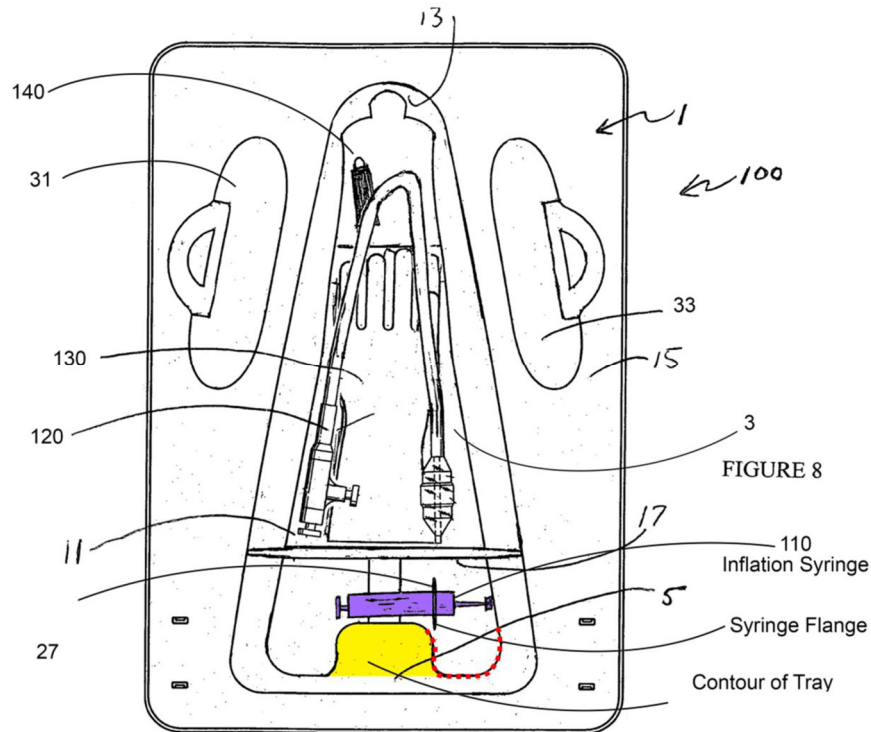
Serany provides motivation by teaching components that are “arranged in logical step-by-step order to facilitate the nurse’s or physician’s task.” (EX1009.1:9-35.) This makes it more likely that the user will perform operations in the correct

order as well as quicker to retrieve the correct device. (EX1002.¶379.) This also provides an affordance for the user. (EX1002.¶376-77.) 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”). (EX1002.¶379.)

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

(h) Limitation 13[i]

Solazzo discloses “*the first compartment defines one or more contours for accommodating one or more of the first syringe or the second syringe.*” (EX1002.¶382-90.) As shown in annotated Figure 8, Solazzo discloses the syringe barrel rests on a portion of the tray that is contoured to accommodate the flange of the syringe. (EX.1005.382.)



This contouring prevents movement of the syringe, as the Board previously concluded. (EX.1014.28-29;EX.1005.383-84.)

Additionally, it would have been obvious to contour the first compartment of Solazzo to hold the syringes in place within the first compartment of the tray.

A known technique to prevent syringes from moving during shipping is to contour a tray to accommodate a syringe and its flange—thus holding the syringe in place as well as making it easier to grasp the syringe. (EX1002.¶386.) Serany teaches that depression 44 holds a syringe and includes an upper portion 44c that is wider than the diameter of the syringe plunger handle 45a “so that it may be easily grasped,” and indentations 44d to accommodate the “flange or finger grip 45c of the syringe.” (EX1009.3:6-22, Fig.7) Storing the syringe in this manner “hold[s] the

syringe against lateral movement in its stored condition.” (EX1009.3:15-16.) It therefore would have been obvious to contour the first compartment of Solazzo to hold the syringes in place and so they can be more easily be grasped. (EX1002.¶¶387-90.) This applies a known technique (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.¶¶387-90.)

The PTAB previously found a substantively identical claim limitation obvious in view of the same prior art. (EX1014.0026-29)

2. Claim 14

Solazzo discloses “*the second syringe is attachable to the Foley catheter*” because its inflation syringe is attachable to its “Foley catheter,” which includes an inflation port for such attachment. (EX1005.1:15-21, Fig. 8; EX1002.¶¶391-92.)

G. Ground 7: Obviousness over Solazzo, Serany, Disston, Imai, and Salvadori

Solazzo, Serany, Disston, Imai, and Salvadori render claims 15-16 obvious. (EX1002.¶¶393-408.)

1. Claim 15

Solazzo in view of Salvadori discloses “*wherein the single layer tray comprises a third compartment containing one or more swabsticks.*”

Swabsticks. Salvadori discloses “one or more swabsticks.” Salvadori teaches a “urethral catheter kit or tray” that includes “swab sticks 60.” (EX1013.1:12-16,3:4.)

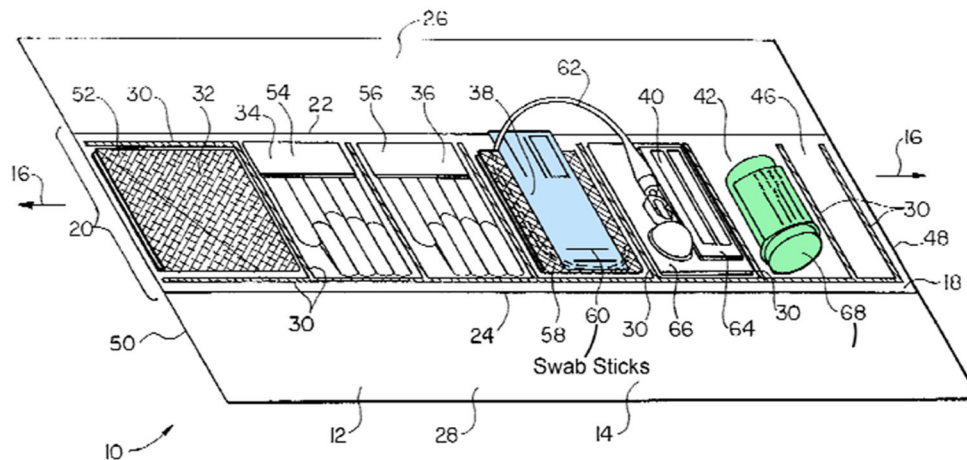


FIG. 1

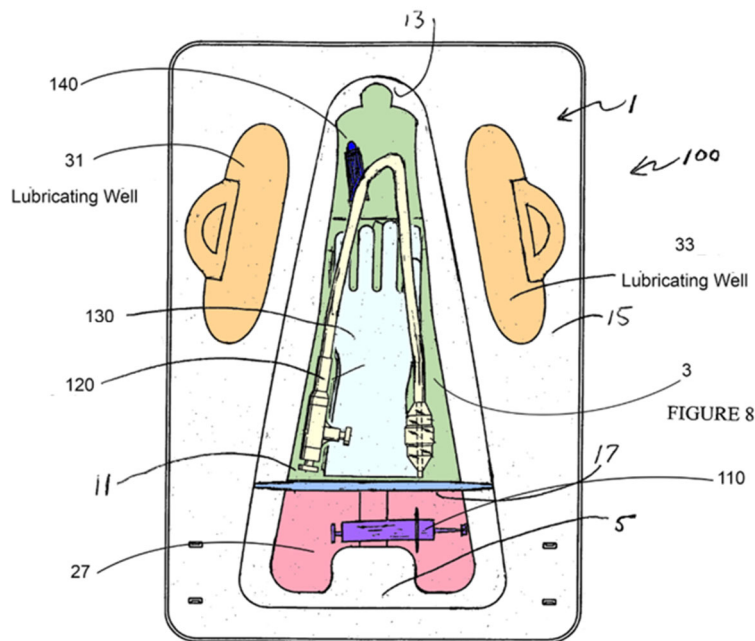
As discussed at Ground 5, claim 15, it would known to include items to clean the patient’s genitals in a Foley catheter kit. (EX1002.¶396.) In view of Salvadori, a POSA would have been motivated to include swabsticks—a common device used with a catheterized patient—in the catheterization kit of Solazzo to allow a practitioner to cleanse the patient’s genitals. (EX1002.¶¶397-405; EX1003.¶¶142-48.)

Furthermore, the inclusion of one or more swabsticks in the catheterization kit of Solazzo involves the use of a known technique (providing swabsticks) to a

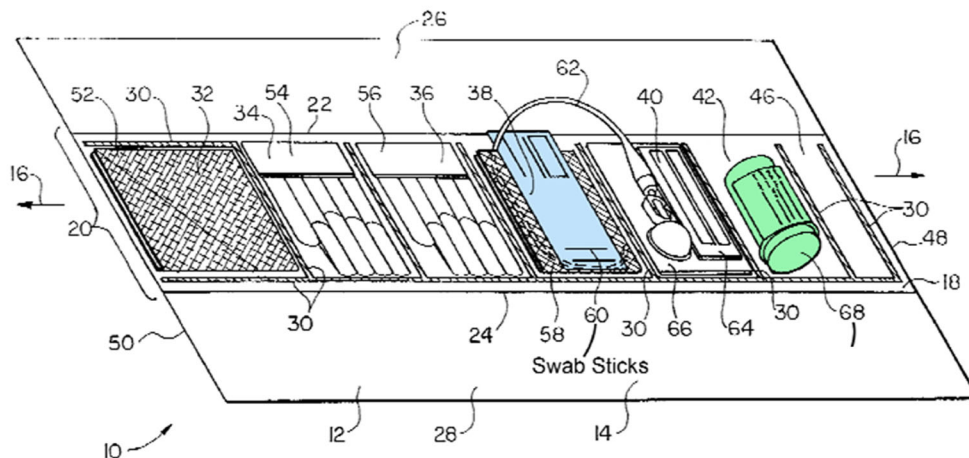
known device (a Foley catheter kit) to yield predictable results (providing swab sticks to allow the practitioner to clean the patient). (EX1002.¶¶397.)

The Board previously found it would have been obvious to include swabsticks in the kit of Solazzo. (EX1015.0026-27.)

Third Compartment. Solazzo’s tray discloses four compartments: 3, 27, 31, and 33. (EX.1005.Figs.1,8.2:52:3:25.) Either of lubricating wells 31 and 33 is a “third compartment” as Solazzo uses the term “well” and “compartment” interchangeably. (EX1002.¶¶399.) It would have been obvious to select compartment 31 or 33 to contain swabsticks given the finite number of identified, predictable solutions to storing the swabsticks (i.e., storage in compartment 3, 27, 31, or 33) with a reasonable expectation of success. (EX1002.¶¶398-412.)



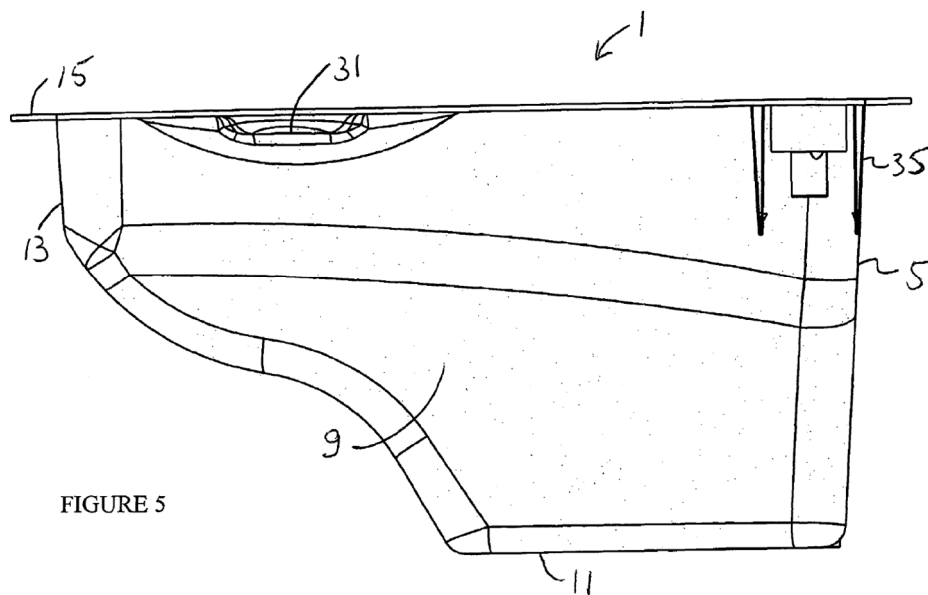
A POSA had ample motivation to select storing the swabsticks in a separate compartment away from other equipment (including the Foley catheter in compartment 3), both to avoid damaging the catheter and because storing equipment by itself in a designated compartment arrange them “in logical step-by-step order to facilitate the nurse’s or physician’s task.” (EX1009.1:16-30; EX1002.¶¶401-04.) Indeed, in Salvadori, the swabsticks are stored in a separate location (in pocket 38) away from the “lubricating gel 64” (in pocket 40) and “gloves 54, 56” (in pockets 34 and 36). (EX1013.3:2-8, Fig. 1.)



Serany also stores forceps 36 and balls 34 in a separate (which perform the same function as swabsticks) in a separate compartment of the tray away from other equipment, such as the inflation syringe. (EX1009.2:57-72, Fig. 6.) Thus, it would have been obvious in view of Salvadori to store the swabsticks separate from

compartment 3 (housing lubricant and gloves) and separate from compartment 27 (housing an inflation syringe). (EX1002.¶404.)

This placement further “facilitate[s] the nurse’s or physician’s task” because compartments 31 and 33 are positioned near the front of the tray which is “tapered” to be placed between the legs such the compartments such that they are close to the patient’s genitals and the swabsticks they are used to clean the patient’s genitals. (EX1005.1:7-132:34-47,Figs.1-5,8; EX1009.1:23-35; EX1002.¶¶406-07)



And storing them at the top of the tray also positions them in their order of use. Storing the swabsticks in one of the wells does not interfere with the lubrication function of the wells because the swabsticks will be removed to clean the patient before the catheter is lubricated and there are multiple wells regardless. (EX1002.¶404; EX1003.¶¶46-47.)

Finally, a POSA would have understood that Salvadori’s swabsticks would fit (or easily could have been made to fit) within Solazzo’s compartment 31 or 33. (EX1002.¶¶408-11.)

2. Claim 16

Solazzo discloses “a boundary surface defines the lubricating jelly application chamber.” (EX1002.¶¶413-15.) Lubricating wells 33 and 34 are defined by a boundary surface of the tray (flange 15) as shown in Figures 1 and 2:

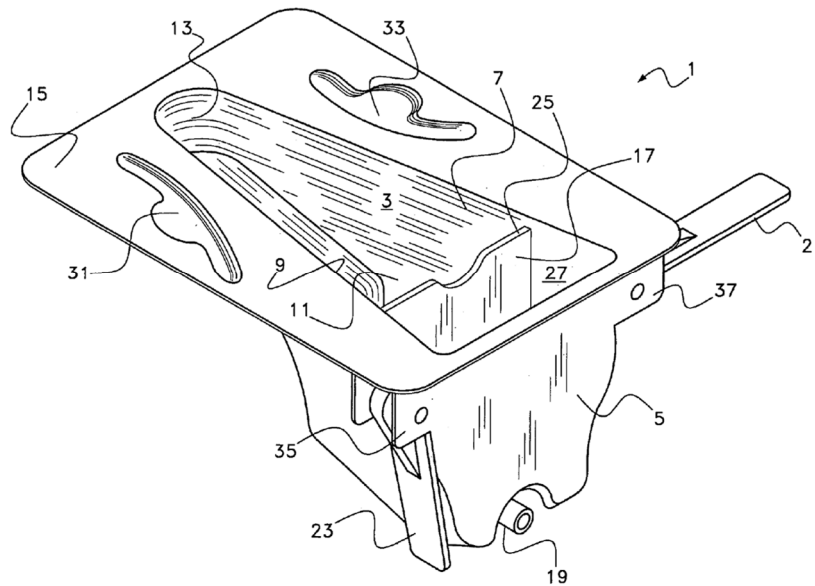
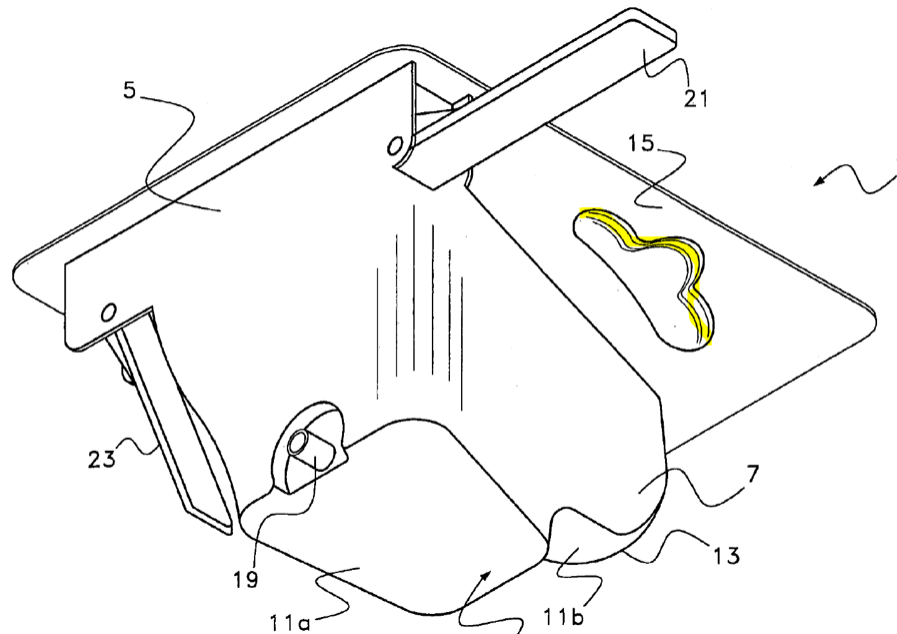


Fig. 1



(EX1005.Figs.1-2,3:52-4:3;4:21-25.)

X. NO SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS

In the Prior IPRs, Medline raised numerous 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.¶¶409-13.) 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 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 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 ’219 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 1-3. And while Petitioner’s other primary references, Solazzo and Rauschenberger, were previously before the Office, the remand FWDs in the Prior IPRs were not nor was Medline’s subsequent abandonment of its appeals of those FWDs. The remand FWDs combine Solazzo with several secondary references to find similar limitations in the ’088 patent unpatentable. 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, 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.

As mentioned above in Section V.D, the applicant disclosed the 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 similar to the issued claims of the '219 patent. *Compare* '088 patent claims 1, 25, 37 with '219 patent claims 1, 13.

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 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 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 (July 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).

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).

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 '219 patent. Every aspect of the claimed invention was already known in the art, and the Examiner failed to consider the Numata and the remand FWDs, which found that claims similar to those in the '219

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 '219 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, 2024

Respectfully submitted,

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Attorney for Petitioner

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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