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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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C.R. BARD, INC.  
Petitioner

v.

MEDLINE INDUSTRIES, INC.  
Patent Owner

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Case IPR No. *To be assigned*  
Patent 8,631,935  
Claims 7-8, 10, 21-23, 25, 27-28, and 30-34

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**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,631,935  
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *et seq.***

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## APPENDIX LISTING OF EXHIBITS

<b>Exhibit</b>	<b>Description</b>
1101	U.S. Patent No. 8,631,935 (“’935 Patent”)
1102	Declaration of Dr. Robert Kimmel
1103	Curriculum Vitae of Dr. Robert Kimmel
1104	Declaration of Susan Carrow MSN/Ed, CEN, RN
1105	Curriculum Vitae of Susan Carrow MSN/Ed, CEN, RN
1106	Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use, January 12, 2009 (“EC Guideline 2009”) ( <a href="http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm">http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm</a> )
1107	A Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use September 29, 1998 (“EC Guideline 1998”)
1108	U.S. Patent No. 3,329,261 (“Serany”)
1109	U.S. Patent No. 6,840,379 (“Franks-Farah”)
1110	U.S. Patent No. 3,978,983 (“Brezette”)
1111	U.S. Patent No. 4,160,505 (“Rauschenberger”)
1112	U.S. Patent No. 4,226,328 (“Beddow”)
1113	U.S. Patent No. 3,542,019 (“Gittins”)
1114	U.S. Pub. No. 2004/0004019 (“Busch”)
1115	U.S. Pub. No. 2010/0274205 (“Morelli”)
1116	“wrap”, Soroka, W. Illustrated Glossary of Packaging Terminology, Second Edition (2008)
1117	“bag”, Soroka, W. Illustrated Glossary of Packaging Terminology, Second Edition (2008)
1118	“bag”, Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition 2003
1119	“bag”, Dorland’s Medical Dictionary for Health Consumers 2007
1120	Reducing the risks associated with urinary catheters”, Nursing Standard (2009)(“Nursing Standard”)
1121	“Dispose”, Webster's Third New International Dictionary (1993)
1122	Bardex Catheter Directions for Use (2006) (“Bardex DFU 2006”)
1123	Medline Industries, Inc. v. CR Bard, Inc. Civil Action No.: 1:14-cv-03618 (ILND August 22, 2014) (Excerpts from Medline's Initial Infringement Contentions )

1124	U.S. Patent No. 3,485,352 (“Pilger”)
1125	U.S. Pub. No. 2006/0264822 (“Nagamatsu”)
1126	“Guidance for the Content of Premarket Notifications of Conventional and Antimicrobial Foley Catheters” (written prior to the February 27, 1997) ( <a href="http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080884.htm">http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080884.htm</a> )
1127	U.S. Patent No. 2,659,485 (“Duley”)
1128	U.S. Patent No. 5,024,326 (“Sandel”)
1129	Bardex Catheter Directions for Use (2010) (“Bardex DFU 2010”)
1130	Excerpts from Mosby’s Pocket Guide to Basic Skills and Procedures, Sixth Edition, 2007, pp. 524-542 (“Mosby’s”)
1131	’935 File History November 19, 2010 Response to Office Action
1132	’935 File History May 31, 2011 Response to Office Action
1133	’935 File History April 3, 2013 Response to Office Action
1134	“Medical Center Cuts Catheterizations by 21 Percent With Foley Catheter Management System”, submitted November 19, 2010 in ’935 File History
1135	“Floyd Medical Center Reduces Catheter Associated Urinary Tract Infections 83 Percent and Catheter Use by 23 Percent”, submitted May 31, 2011 in ’935 File History
1136	“Getting To Zero:” Medline's Erase Cauti Program Helps Hospitals Reduce Catheter Use By 20 Percent, submitted May 31, 2011 in ’935 File History
1137	“Catheter-associated urinary tract infections”, submitted April 3, 2013 in ’935 File History
1138	U.S. Patent No. 8,678,190 (“’190 Patent”)
1139	U.S. Patent No. 8,448,786 (“’786 Patent”)

Petitioner C.R. Bard, Inc. (“Bard”), pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 et seq., requests *inter partes* review of claims 7-8, 10, 21-23, 25, 27-28, and 30-34 of U.S. Patent No. 8,631,935 (“the ’935 patent”) (Ex. 1101).

## **I. INTRODUCTION**

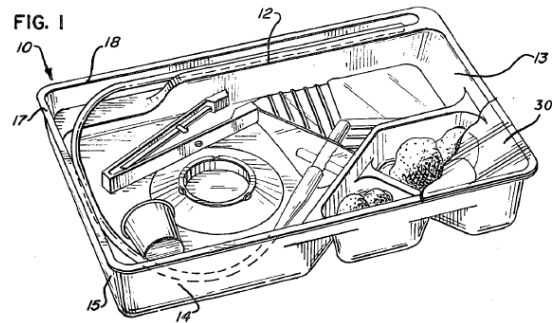
Challenged ’935 patent claims 7-8, 10, and 21 recite methods of manufacturing a packaged catheter assembly that include a tray while challenged claims 22-23, 25, 27-28, and 30-34 are product claims that recite a tray with many of the same components that are recited in the method claims. Each of the challenged claims recites providing (1) a tray with compartments and implements for a catheterization, and (2) one of the compartments having a base member with an “inclined, stair-step contour.” All of the method claims also recite (3) enclosing instructions on how to lubricate the catheter within the tray.

These elements and others recited in the claims were well known, alone and in combination, when the Patent Owner filed its application in June of 2009. The claims are precisely the unpatentable type contemplated in *KSR*: they merely recite known elements, used in their conventional way, to achieve predictable results. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

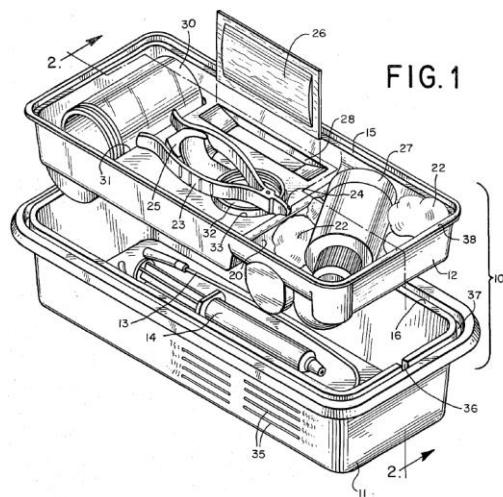
**(1) A syringe, catheter, and a tray with compartments.** The background of the ’935 patent asserts that “[t]raditional catheters are packaged, for example, in individual packaging.” ’935 patent at 1:40-41. However, the § 102(b) prior art

relied on in this Petition shows differently.

**Brezette** (Ex. 1110) discloses a catheterization package with a tray holding a catheter and “other implements useful in a catheterization procedure.”



Brezette at Abstract. **Rauschenberger** (Ex. 1111) discloses a similar tray to hold



everything for a catheterization, including not only the catheter, but also gloves, lubricant, various drapes or wraps, forceps, and cleaning solution. Rauschenberger at 2:23-28 and figure 1 (at right). **Beddow** (Ex. 1112) likewise teaches using a tray to contain “all of

the components required for accomplishing a catheterization procedure.” Beddow at Abstract and figure 1 (at above, left). *See also* Declaration of Susan Carrow, MSN/Ed, CEN, RN (Ex. 1104) (“Carrow Decl.”) at ¶¶ 16, 21.

**(2) Inclined, stair-step contour.** Although many of the challenged claims do not functionally limit the “inclined, stair-step contour,” Claim 22 recites that the plungers on the syringes placed on the contour “project upward and out of the tray.” Claim 22; *see also* ’935 patent at 5:32-35. Such a concept is not new. *See, e.g.,* U.S. Patent No. 5,024,326 (Ex. 1128) at 2:35-38 (describing a syringe held by

a tray with “tips down toward the underlying container surface with the free end of the syringe positioned in an upwardly and outwardly inclined manner to facilitate the manipulation thereof by a user.”) It is

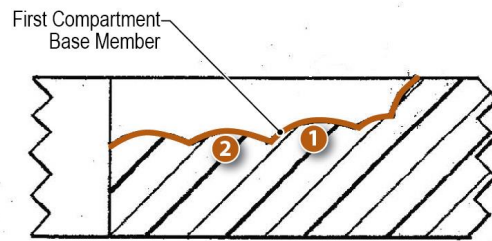
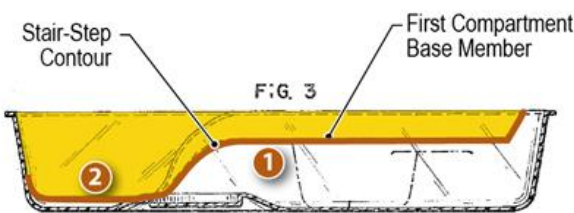


Fig. 4

common sense to place syringes such that the plunger is accessible. Brezette and Rauschenberger both show inclined, stair-step contours that can be used to dispose



a syringe such that its plunger protrudes upwardly. An annotated copy of Brezette’s figure 4 is above, and an annotated copy of Rauschenberger’s

figure 3 is a left, both showing forms of an inclined, stair step contour.

### ***(3) Enclosing instructions on how to lubricate the catheter within the tray.***

The recitation of “enclosing printed instructions” in the claims should be given no weight as the instructions do not have a functional relationship with the tray, and add nothing to the use of the tray that would make it or its manufacture patentable. *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004) (finding an applicant is not “entitled to patent a known product by simply attaching a set of instructions to that product”). The instructions merely instruct a user to use the tray in the

conventional manner for which it was designed by placing lubricant in a compartment and passing the catheter through it to lubricate the catheter.

Even if the “instructions” limitations are given weight, however, instructions have long been included with medical products such as catheterization kits. **Franks-Farah** (Ex. 1109) is just one example of such inclusion. The examples abound as the FDA required the inclusion of instructions prior to 2009. *See* Ex. 1126.

Also, each of **Brezette**, **Rauschenberger**, and **Beddow** show that trays have long been designed with compartments in which to dispense lubricant to lubricate a catheter. *See* also Carrow Decl. at ¶¶ 26-27. It would have required only common sense for a POSA to include instructions to direct a practitioner to use a tray as it was designed.

***Patent Owner’s alleged secondary considerations.*** During prosecution, Patent Owner presented articles purportedly establishing its commercial tray was an embodiment of the claims and was successful in helping hospitals reduce infection. The Patent Owner, however, did not show any nexus between the *claims* and the alleged success of the commercial tray. *In re GPAC*, 57 F.3d. 1573, 1580-81 (Fed. Cir. 1995) (finding that patent owner failed to show nexus to the claimed subject matter and finding claims obvious). The Patent Owner’s articles listed several reasons why doctors allegedly liked Medline’s kits and *none* of those

attributes are recited in the claims. One article relied upon by Patent Owner stated “*the single most important factor*” in reducing infection was “[e]ducation, education, education”—not the Patent Owner’s commercial tray. Ex. 1137.<sup>1</sup>

The applicants invented nothing new. They took features from the prior art and the general knowledge of a practitioner (*e.g.*, a nurse) and put them together to arrive at the “invention” recited in the challenged claims. The “inferences and creative steps” one of skill in the art would have needed to employ to arrive at the subject matter of the challenged claims were minimal at best. *KSR*, 550 U.S. at 418; Kimmel Decl. at ¶¶ 95-96. Bard respectfully requests the Board institute an *inter partes* review and find the challenged claims unpatentable as obvious.

## **II. MANDATORY NOTICES**

### **A. Real Party-in-Interest**

C.R. Bard, Inc. is the real party-in-interest and submits this *inter partes* review petition as to the claims of the ’935 patent.

### **B. Related Matters**

The following would affect or be affected by a decision in this proceeding:

(1) Petitioner is filing three other IPR petitions concurrently with this Petition. Collectively, these four petitions address claims 1-4, 7-8, 10-23, 25, 27-28, and 30-34 of the ’935 patent; claims 1 and 2 of U.S. Patent No. 8,448,786; and

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<sup>1</sup> Emphasis added throughout unless otherwise noted.



claims 1-7 and 9-18 of U.S. Patent No. 8,678,190. The '935, '786, and '190 patents share similar specifications, claim priority to related provisional applications, and were all asserted by the Patent Owner, Medline Industries, Inc., against Bard in a complaint served on Bard on May 21, 2014. For the sake of efficiency and a consistent outcome, Bard requests that the Board assign a single administrative panel to address the four *inter partes* review petitions.

(2) Related pending applications and/or issued patents claiming or which may claim the same effective filing date as the '935 patent include U.S. Patent Nos. 8,448,786; 8,678,190; and 8,746,452; and U.S. Application Nos. 12/647,515; 14/265,909; 14/265,920; 13/153,265; 13/153,300; 13/374,509; 14/165,044; 13/860,902; and PCT/US11/068193.

### C. Counsel and Service Information

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Powers of attorney are submitted with this petition. Counsel for Bard consents to service of all documents via electronic mail.

### **III. NOTICE OF FEES PAID**

Fees are submitted with this Petition. If additional fees are due during the proceeding, the Office is authorized to charge Deposit Account No. 23/2825.

### **IV. CERTIFICATION OF GROUNDS FOR STANDING**

Bard certifies under 37 C.F.R. § 42.104(a) that the '935 patent is available for *inter partes* review and that Bard is not barred or estopped from requesting *inter partes* review as to the '935 patent claims identified herein.

### **V. IDENTIFICATION OF CHALLENGE UNDER 37 C.F.R. § 42.104(B) AND RELIEF REQUESTED**

Bard seeks cancellation of claims 7-8, 10, 21-23, 25, 27-28, and 30-34 of the '935 patent.

#### **A. Level of ordinary skill in the art**

The person of ordinary skill in the art of the '935 patent in the June 2009 timeframe would be a person with at least a Bachelor of Science degree in packaging science or package engineering, chemical engineering, mechanical engineering, or industrial design. Alternatively, the POSA would have had a bachelor's degree in an alternative technical field and about two years of experience in the packaging of medical devices. This person would also have had an understanding of and experience with thermoforming and the design of thermoformed packages. A POSA would not need to be a practitioner that would perform catheterization procedures or use the claimed products (*i.e.*,

catheterization trays), but would have learned about the procedures from those skilled in catheterization procedures (*e.g.*, a nurse) to understand how these procedures were performed. Declaration of Dr. Robert Kimmel (Ex. 1102) (“Kimmel Decl.”) at ¶¶ 21-23, 47.

## **B. Statutory grounds for challenge**

Cancellation of claims 7-8, 10, 21-23, 25, 27-28, and 30-34 of the ’935 patent is requested on the following grounds:

	<b>Reference(s)</b>	<b>Claims</b>	<b>Basis</b>
1	Rauschenberger in view of Franks-Farah	21	§ 103
2	Brezette in view of Beddow and Franks-Farah	7-8	§ 103
3	Brezette	22-23, 25, 27-28, 30-34	§ 103
4	Rauschenberger	22-23, 25, 31-34	§ 103
5	Brezette in view of Beddow, Franks-Farah, and Serany	10	§ 103

## **C. Claim construction**

In this proceeding, claim terms should be given their broadest reasonable construction in view of the specification. 37 C.F.R. § 42.100(b). Specific terms are discussed below.

### **1. “a”**

The term “a,” when construed in accordance with the specification, means **one or more**. The Patent Owner acted as its own lexicographer and defined the term “a” to include plural references, *i.e.*, one or more. ’935 patent at 2:54-58 (“As used in the description herein and *throughout the claims*, the following terms take

the meanings explicitly associated herein, unless the context clearly dictates otherwise: *the meaning of “a,” “an,” and “the” includes plural reference.”*).

## 2. “tray”

The term “tray” is a limitation in all challenged claims of the ’935 patent. The term “tray” should be given its broadest reasonable construction in view of the claims and specification in which it appears and should be construed to mean **a container that is shorter than it is wide**.

A POSA reading the ’935 patent would have understood that the Patent Owner did not intend to impart a special or otherwise limited definition—the specification uses the term broadly. Kimmel Decl. at ¶¶ 67-71. The background section states that one type of tray can be a “flat plastic tray.” ’935 patent at 1:46. The specification further provides exemplary dimensions of a tray that is shorter than it is wide (*id.* at 3:64-4:3 (disclosing height of three inches and width of nine inches)), and provides figures that depict a tray as container that is shorter than it is wide (*see* Fig. 1).

Art of record also supports a broad construction of the term “tray.” United States Publication No. 2004/004019 (“Busch”) (Ex. 1114) discusses an “interior tray or subtray 32 [which] rests inside the

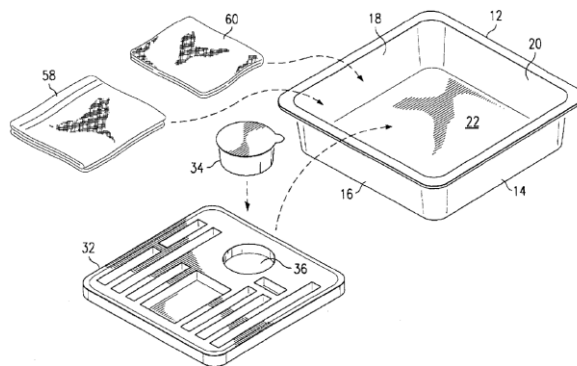


FIG. 3

outer tray 12 . . . when the kit 10 is in its packaged position.” Busch at [¶0028]. Figure 3 from Busch, at right above, shows the two level configuration where the upper container (32) and the lower container (12) are both shorter than they are wide and both are referred to as “trays.”

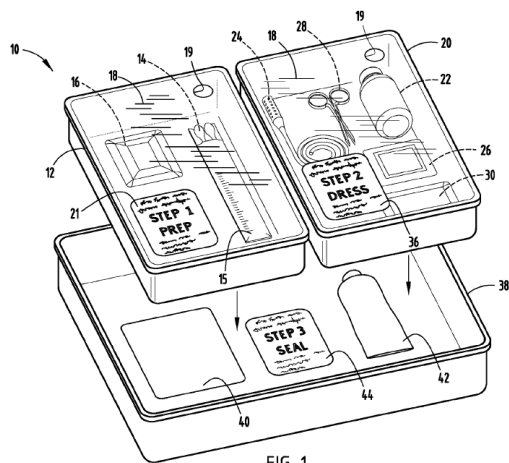
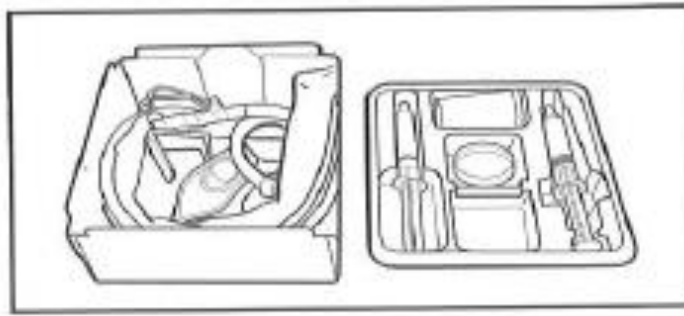


FIG. 1

Similarly, U.S. Publication No. 2010/0274205 (“Morelli”) (Ex. 1115) discloses three containers, each of which take the form of a “tray”: “the first container 12 can comprise a first tray 12 the second container 20 can comprise a second tray 20 and the third container 38 can comprise a third tray 38. Morelli at [¶0022] and Fig. 2 (at left).

Neither the ordinary meaning, nor the specification of the ’935 patent, limit a tray to a particular manner of manufacture. *See, e.g.*, ’935 patent at 3:53-63. For instance, one of skill in the art would have understood that a box made of paperboard would be a “tray,” if it was shorter than wide. Kimmel Decl. at ¶¶ 74-75. Bard used the term “tray” in such a manner in its instructions for use from around the time of the priority date, calling a paperboard container that is shorter than it is wide (at left below) a “bottom tray”:



9. Remove top tray and place next to bottom tray (keep on CSR wrap)

Bardex Catheter Directions for Use at 2 (2010) (Ex. 1129) (“Bardex DFU 2010”); Kimmel Decl. at ¶ 75.

The proper construction under the broadest reasonable construction standard for the term “tray” as it is used in the ’935 patent is **a container that is shorter than it is wide**. Also, along with the construction of “a” above, there is nothing in the context of the claims when “a tray” appears that would lead a POSA to believe the Patent Owner intended to deviate from the explicit definition of “a.” Kimmel Decl. at ¶ 65-76. Thus, “a tray” should be construed as **one or more containers where each is shorter than it is wide**.

### 3. “inclined, stair-step contour” and “inclined, stair-stepped contour”

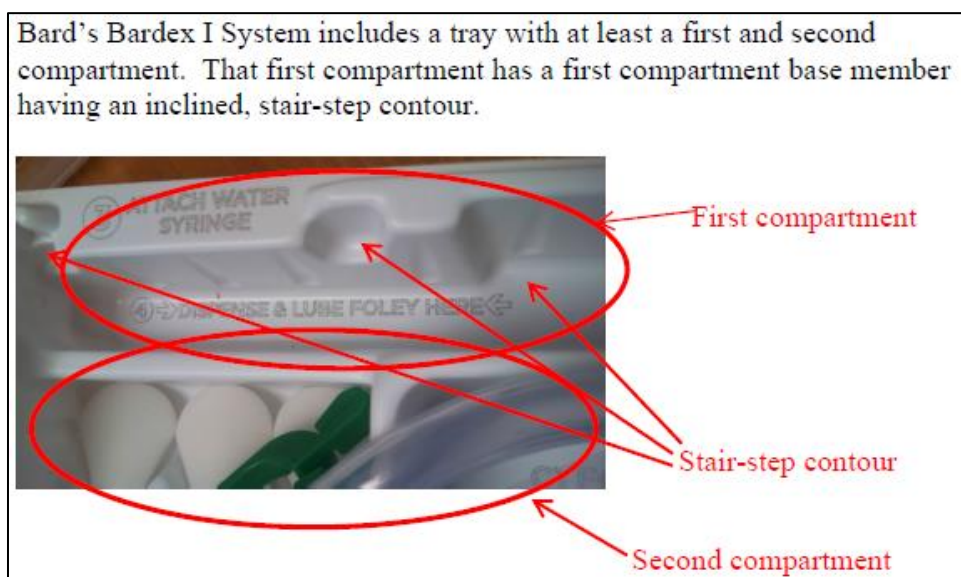
Either the term “inclined, stair-step contour” or “inclined, stair-stepped contour” is a limitation in all challenged claims of the ’935 patent, except claim 21. The two terms should be construed to mean that the base member (as opposed to the side walls or barrier) has a **shape that resembles platforms of a stair and**

**where at least a portion of the stair shape is sloped or inclined in at least one direction.**

Many of the challenged claims contain no functional limitation on the term “inclined, stair-step contour.” The specification states, however, that, “[f]or example, a compartment containing syringes, in one embodiment, includes an inclined, stair-stepped bottom member to present the plungers of each syringe at an easy to reach angle.” ’935 patent at 3:22-25. Other portions suggest that the contour be used as a mnemonic device so that the higher level instruments on the stair-step contour are grasped first during a procedure. *Id.* at 5:5-15. Without any of this functional language in the claims (besides independent claim 22), the broadest reasonable interpretation of the term “inclined, stair-step contour” should not be restricted to the specification’s embodiments. It is axiomatic that a patentee is entitled to the “full scope” of his claims and should not be limited to an embodiment or otherwise import a limitation from the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005); *see FedEx Corp. v. IPVenture, Inc.*, No. IPR2014-00833, 2014 WL 6847484, at \*4 (PTAB, Dec. 3, 2014) (applying broadest reasonable interpretation and finding specification did not “expressly disclaim the full scope of the term.”). The fact that patent drawings or statements discuss a particular embodiment does not operate to limit the claims. *Prima Tek II, LLC v. Polypap*, 318 F.3d 1143, 1148 (Fed. Cir. 2003).

It is also “rarely, if ever, correct” that a construction would read out a preferred embodiment. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). The patent uses the terms “inclined” and “stair-step” to describe different aspects of the base member. In one embodiment, the specification states that “the first compartment base member 107 is *inclined* relative to other compartment base members.” The figures show that only a *portion* of the base member 107 is inclined; part is flat. *See also id.* at 5:42-44 (recognizing base member may have other features as well). Thus, the specification reinforces that only a portion of the stair-step contour must be inclined.

In its infringement contentions in the co-pending litigation, Medline has adopted an expansive interpretation of “inclined, stair-step” contour, identifying a structure on Bard’s products that does not resemble any embodiment in the ’935 patent:





Medline's Initial Infringement Contentions (relevant portions at Ex. 1123), App. C at 20 (claim 1) and 91 (claim 22) (**red annotations are Medline's, in original**). Without conceding that Bard's products have a base member with an "inclined, stair-step contour" (they do not; Medline does not even identify an "incline"), Medline should not be permitted to take a more narrow view of the construction of "inclined, stair-step contour" in response to this Petition. *See Russell v. Rolfs*, 893 F.2d 1033, 1037 (9th Cir. 1990) (judicial estoppel applies to prevent a party from "playing 'fast and loose with the courts'").

The file history of the '935 patent further supports the broad interpretation Bard offers. In an Office Action response, the Patent Owner stated:

In the figures above, Applicant respectfully asks, where are the stair steps? Where is there anything in either picture that resembles a stair, *i.e., platforms upon which one can change elevation by traversing from one to the next*? Moreover, where is there anything resembling an inclined, stair-stepped member that resembles the term when considered in context with Applicant's specification and drawings?

FH 4/3/13 Resp. (Ex. 1133) at 34. By using the term "*i.e.*," the Patent Owner equated a "stair-step contour" with the broad concept of "platforms upon which one can change elevation by traversing from one to the next." In combination with the word "inclined," this response supports Bard's proposed construction—a

**shape that resembles platforms of a stair and where at least a portion of the stair shape is sloped or inclined in at least one direction.**

#### **4. “wrap”**

The term “wrap” appears in claim 1, from which challenged claims 7, 8, and 10 depend, and it recites “placing a sterile wrap about the tray.” The term “wrap” should be given its broadest reasonable construction in view of the claims and specification in which it appears and should be construed to mean **a flexible material capable of being placed about an object.**

The term “wrap” is not defined in the claims and the specification uses the term broadly in different ways. The background references “sterile plastic *wrap*” as being a type of packaging for kits which was prone to damage because other types of “wrap” provided little physical protection. ’935 patent at 1:40-44. The patent also states that the catheter tray “can be sealed with a CSR *wrap* 1000 to keep the internal components sterile,” *id.* at 8:52-54, and describes a sterile *wrap* “as a thermally sealed bag.” *Id.* at 9:12-15.

Given this broad use of the term “wrap” in the ’935 patent, the proper construction for the claim term “wrap” is **a flexible material capable of being placed about an object.**

## 5. “disposing” and “disposed”

The terms “disposing” or “disposed” are used in in the claims to refer to putting in place certain objects (*e.g.*, syringes or a catheter assembly) in the compartments of the tray. Neither the claims nor the specification provide special definitions for the terms that would suggest they should be given a meaning other than the broad, ordinary meaning—**to put in place**. Kimmel Decl. at ¶¶ 88-90.

A POSA would have understood the ordinary meaning of the term “dispose” to mean to “put in place.” Webster’s Dict. (Ex. 1021). A POSA also would have understood from the specification and the claims that when the terms “disposing” or “disposed” are used, they are not used in an exclusive sense. Kimmel Decl. at ¶¶ 89-90. When claim 1 says “disposing a catheter assembly in the second compartment,” it does not mean that the catheter must be *exclusively* in that compartment (*i.e.*, not spanning multiple compartments); as long as a portion of the catheter assembly is in the second compartment, it is “disposed” there. Kimmel Decl. at ¶¶ 89-90. The specification of the ’935 patent reinforces this broad usage when it states in one embodiment that “a towel 704 is disposed beneath the catheter assembly.” ’935 patent at 8:11-12. As shown in figure 8, the towel is only *partially* “disposed beneath the catheter assembly,” as part of the towel, near the perimeter wall, is not covered by the catheter assembly in the figure.

Accordingly, a POSA would have understood the terms “disposing” or “disposed” to mean **to put in place**, and to not more narrowly mean that an item must be entirely placed in a particular location.

## **VI. THRESHOLD REQUIREMENT FOR *INTER PARTES* REVIEW**

This petition meets the threshold requirement for *inter partes* review because the cited references, applied to the claims as detailed below, demonstrate “a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition.” 35 U.S.C. § 314(a). All elements of claims 7-8, 10, 21, 27-28, and 30-34 are taught in the prior art as demonstrated below in Section VII, which is supported by the declarations of Susan Carrow MSN/Ed, CEN, RN (Ex. 1104), a nurse practitioner with extensive experience in catheterization procedures, and Dr. Robert Kimmel (Ex. 1102), an Associate Professor of Packaging Science at Clemson University.

## **VII. EXPLANATION OF GROUNDS FOR UNPATENTABILITY OF CLAIMS 7-8, 10, 21-23, 25, 27-28, AND 30-34**

### **A. The '935 patent's “instructions” limitations should be entitled to no patentable weight**

Many of the challenged claims recite “enclosing printed instructions” or “enclosing with the tray printed instructions.” Although including instructions with a catheterization kit also would have been obvious to a POSA (see sections VII.B.5 and VII.C.1.h), absent some “functional relationship”—which is not

present here—the mere inclusion of instructions with an otherwise known device or method cannot render the claim patentable. *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1280 (Fed. Cir. 2010) (***applying the Federal Circuit’s printed matter cases to method claims*** and holding that an instructional limitation—which involved “informing” a patient regarding use of a drug—was not functional; “the relevant inquiry here is whether the additional instructional limitation of [the disputed] claim . . . has a ‘new and unobvious functional relationship’ with the known method of administering metaxalone with food”); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1065 (Fed. Cir. 2010) (regardless of FDA regulations requiring instructions, holding that instructions on one-a-day dosing for known drug “in no way function[s] with the drug to create a new, unobvious product. Removing the instructions from the claimed kit does not change the ability of the drug to treat respiratory diseases”); *In re Ngai*, 367 F.3d at 1339 (holding that an inventor could not “patent a known product by simply attaching a set of instructions to that product”).

The “enclosing ... instructions” limitation imparts no functional connection between the printed matter (the instructions) and the known method of manufacturing a catheterization kit—let alone a “new and unobvious functional relationship.” All the claimed instructions do is instruct a user to use the claimed trays in the manner for which they were designed—and in the manner in which

such trays had been used for years. Carrow Decl. at ¶¶ 16, 34-39, 43. The procedure for performing a catheterization, and manufacturing a catheterization kit, was well known prior to 2009. *E.g.*, Carrow Decl. at ¶¶ 15, 17-30 and sections VII.B and VII.C. The limitation of “enclosing ... instructions,” like the limitation of “informing a patient” regarding a drug as analyzed in *King Pharmaceuticals*, falls short of converting these known methods into an invention. The inclusion of instructions “does not change the ability of the” trays to be used for catheterization procedures as they are designed. *AstraZeneca*, 633 F.3d at 1065. The “enclosing printed instructions” and “enclosing with the tray printed instructions” elements confer no patentable weight to the claims.

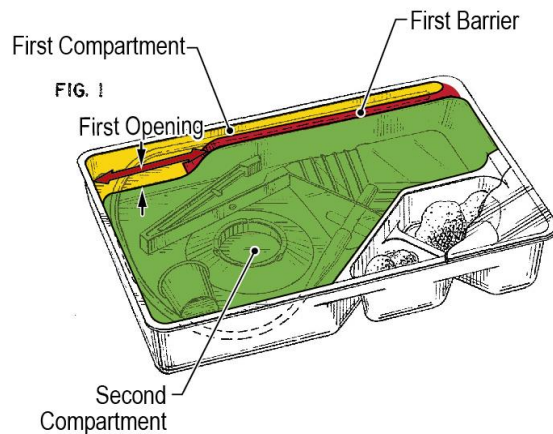
**B. Ground 1: Claim 21 is obvious under 35 U.S.C. § 103 over Rauschenberger in view of Franks-Farah**

Each of the elements of claim 21 is disclosed in Rauschenberger, except for the element of “enclosing with the tray printed instructions.” It would have been obvious to a POSA as of June 2009 to include with the catheterization kit instructions as to how to use the kit.

**1. *Claim 21, Element A: “A method of manufacturing a packaged catheter assembly, comprising:”***

Rauschenberger discloses a method of manufacturing a packaged catheter assembly. *See, e.g.*, Rauschenberger at 1:4-7; Kimmel Decl. at ¶ 185.

2. **Claim 21, Element B: “providing a tray having at least a first and a second compartment separated by a first barrier having an opening therein;”**



Rauschenberger discloses the elements of this claim. Rauschenberger Figure 1 at left, shows the first compartment highlighted in yellow, the second compartment highlighted in green, the barrier shown in red, and the

opening shown by a red, double-sided arrow. Kimmel Decl. at ¶ 186.

3. **Claim 21, Element C: “disposing at least one syringe in the tray;”**

Rauschenberger does not disclose disposing at least one syringe in the tray, but does disclose disposing implements for catheterization in the tray. Rauschenberger at 2:22-27. The implements taught by Rauschenberger include a “lubricant packet.” *Id.* at 2:30. It was common knowledge well before 2009 that liquid or jelly could be stored in a syringe instead of a packet. *See, e.g.*, “Reducing the risks associated with urinary catheters,” *Nursing Standard* at 52 & Box 1 (2009) (Ex. 1020) (“Nursing Standard”); Bardex Catheter Directions for Use (2006) (Ex. 1022) (“Bardex DFU 2006”); Carrow Decl. at ¶¶ 24-25, 82; Kimmel Decl. at ¶¶ 187-188. Substituting one container for another type of container (*e.g.*, substituting a lubricant in a “packet” with a lubricant in a syringe) would have

been an obvious substitution of components known to be suitable to yield predictable results. *KSR Int’l Co.*, 550 U.S. at 416 (recognizing obviousness inquiry easier when it involves “simple substitution of one known element for another”); *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1355 (Fed. Cir. 2001) (finding obvious substitution between claimed threaded studs with welds shown in prior art reference, especially in light of evidence that use of studs was “common”). Kimmel Decl. at ¶ 188; Carrow Decl. at ¶¶ 25, 82. Substitutability of the two is confirmed by the ’935 patent itself. ’935 patent at 4:40-44 (“The syringe holding sterile water, [and] syringe holding lubricating jelly, ... are used for illustration purposes only, as it will be clear that *other objects may be added to or substituted for these objects.*”). Also, a POSA would have had reason to make the switch because the use of syringes can be less messy than foil packets. Kimmel Decl. at ¶¶ 188-189.

#### **4. Claim 21, Element D: “sealing the tray; and”**

Rauschenberger discloses sealing the tray. Rauschenberger at 2:15-20 (“In 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.”); Kimmel Decl. at ¶ 190.



**5. Claim 21, Element E: “enclosing with the tray printed instructions directing a user to discharge contents of the at least one syringe into the first compartment and to pass at least a portion of the catheter assembly into the contents.”**

This “printed matter” limitation should be given no patentable weight. *See* Section VII.A. Even if this limitation is given patentable weight, it would have been obvious for a POSA to include the claimed instructions with Rauschenberger. Rauschenberger teaches discharging the contents of a container into the first compartment and to pass at least a portion of the catheter assembly through the opening and into the contents. *See* Rauschenberger at 2:30-33 (“[A] lubricant packet is utilized to put lubricant on the catheter in channel 21. The catheter is then rotated within channel 21 to spread lubricant about it[s] insertion end.”). Figure 1 of Rauschenberger shows a portion of the catheter assembly passing through the opening into the first compartment.

The inclusion of instructions with a urethral catheter assembly such as the one described in Rauschenberger in order to help a user understand how to use the assembly was well known—if not universally adopted across the industry—prior to 2009. Carrow Decl. at ¶¶ 16, 34-39, 43, 85; Kimmel Decl. at ¶¶ 191-192. *See Randall Mfg. v. Rea*, 733 F.3d 1355, 1363 (Fed. Cir. 2013) (overturning Board’s finding of nonobviousness because of failure to consider that it would have been common knowledge to use “prevalent, perhaps even predominant, method” as shown in the prior art). For example, Franks-Farah is directed to a catheterization

system that includes information devices (including instructions) within the catheter kit itself. Franks-Farah at 2:25-32 (“In a more preferred embodiment of the system, the system contains ... (VI) *step-by-step instructions*; (VII) *clinician step-by-step instructions* or self-care documentation.”); Kimmel Decl. at ¶ 193.

A POSA would have had reason to include instructions with Rauschenberger’s catheter assembly in order to avoid penalties under Federal regulations governing medical devices. *See* 21 U.S.C. § 352(f) and 21 C.F.R. § 801.5; “Guidance for the Content of Premarket Notifications of Conventional and Antimicrobial Foley Catheters” (written prior to the Feb. 27, 1997) (Ex. 1126). Accordingly, it would have been obvious for a POSA to follow the industry accepted practice and FDA guidelines and include instructions (as was taught by Franks-Farah) explaining how to properly lubricate the device during catheterization (as taught in Rauschenberger). Kimmel Decl. at ¶ 194.

Additionally, as discussed in section VII.B.3, although Rauschenberger does not explicitly disclose discharging the contents of a *syringe* into the first compartment, substituting one type of packaged lubricant (*e.g.*, a packet) for another type of packaged lubricant (*e.g.*, a syringe) would have been an obvious substitution of known components. Kimmel Decl. at ¶ 195. Thus, in a Rauschenberger tray containing a syringe of lubricant, it would have been standard and customary in light of Franks-Farah to enclose printed instructions directing a

user to discharge contents of a syringe into the first compartment of the Brezette tray and to pass at least a portion of the catheter assembly through the opening and into the contents to lubricate the catheter.

**C. Ground 2: Claims 7-8 obvious under 35 U.S.C. § 103 over Brezette in view of Beddow and Franks-Farah**

**1. CLAIM 7, Element A: “The method of Claim 1,”**

As shown below, claim 1, on which claim 7 depends, is obvious under 35 U.S.C. § 103 over Brezette in view of Beddow and Franks-Farah.

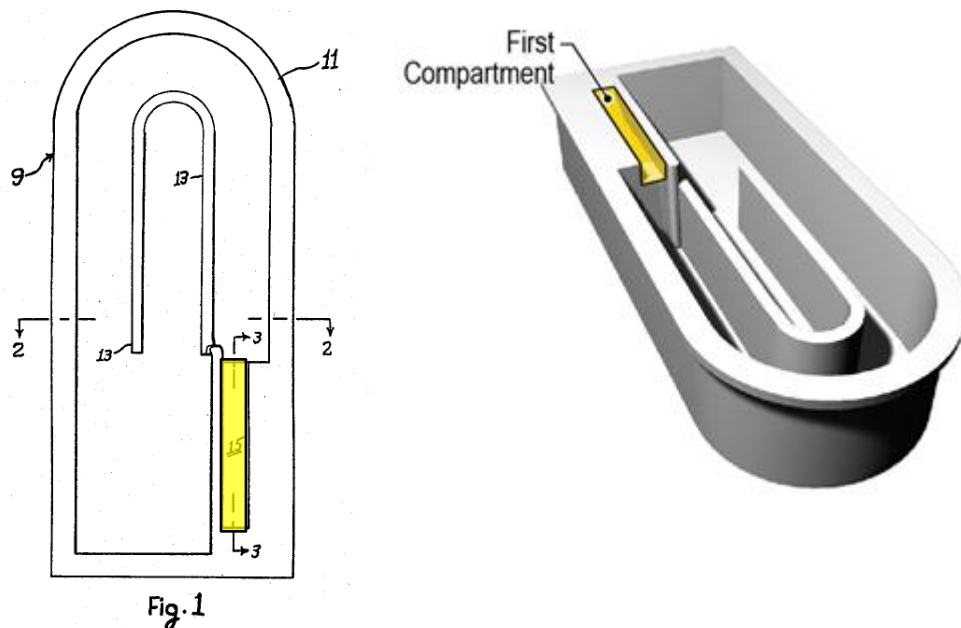
**a. *Claim 1, Element A: “A method of manufacturing a packaged catheter assembly, comprising:”***

Brezette discloses a method of manufacturing a packaged catheter assembly. Brezette at 1:6-8 (“The present invention relates to the field of surgical trays, and more particularly, to surgical trays for use in urethral catheterization.”); 1:66-2:3; 2:46-50 (disclosing “compartments for receiving a urethral catheter”). Kimmel Decl. at ¶ 100.

**b. *Claim 1, Element B: “providing a tray having at least a first compartment”***

Brezette discloses providing a tray having at least a first compartment. The image below on the left is figure 1 from Brezette, showing the first compartment (Brezette calls it a “lubrication channel”) highlighted in yellow. The image to the right is a perspective drawing of Brezette figure 1 showing the same. Kimmel Decl. at ¶ \_\_\_\_\_. The perspective drawing (and others like it below) are not part of the

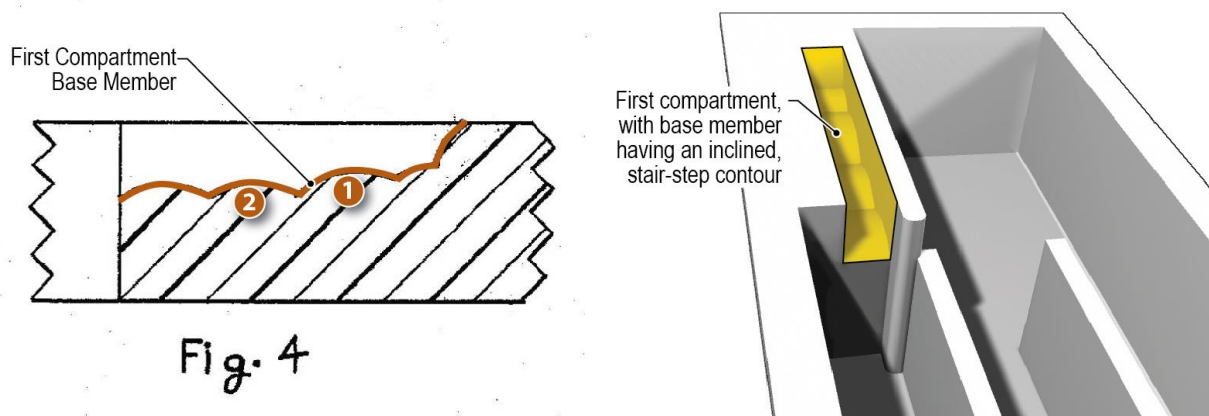
figures of Brezette, but instead were drawn as a POSA would have understood Brezette's figures in light of the specification. Kimmel Decl. at ¶ 101.



**c. Claim 1, Element C: “with a first compartment base member having an inclined, stair-step contour and”**

Brezette discloses a first compartment base member having at least one inclined, stair-step contour. Figure 4 is an embodiment of the Brezette first compartment (the “lubrication channel”). Figure 4 is annotated below at left with the inclined, stair-step contour—*i.e.*, a shape that resembles platforms of a stair and where at least a portion of the stair shape is sloped or inclined in at least one direction—outlined in orange. The same figure is illustrated in perspective view on the right. Kimmel Decl. at ¶ 102; Brezette at Fig. 4; 3:4-6 (“the lubrication channel 25 shown in FIG. 4 provides a lower surface of varying depth along its length”). The “stair-step” shape is formed by the curved platforms (*e.g.*, appearing

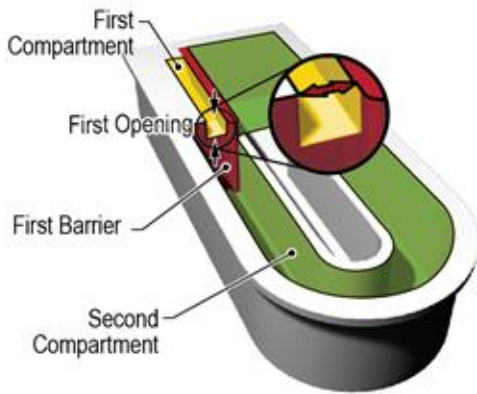
immediately above the 1 and 2 in the annotated figure) and the change in elevation between them. The “incline” of the contour is formed throughout the base of the compartment by the curves on the platforms that rise from left to right. An incline is most dramatically displayed at the far right of figure 4 as the compartment base platform inclines upwards to meet the top of the tray. Kimmel Decl. at ¶ 102.



Thus the embodiment of the Brezette first compartment shown in figure 4 has a base member with an inclined, stair-step contour. Kimmel Decl. at ¶ 103.

**d. Claim 1, Element D: “a second compartment, wherein the first compartment and the second compartment are separated by a first barrier having an opening therein”**

Brezette’s tray has a second compartment, wherein the first compartment and the second compartment are separated by a first barrier having an opening therein. Figure 4 shows the barrier at the left-hand side of the figure, below the channel; the opening is the entrance above the cross hatching. The opening in the barrier is also shown in a perspective drawing of Brezette Figure 1, at left below.



In that view, the first compartment is highlighted yellow, and the second compartment is highlighted green. The first barrier separating the first compartment and the second compartment is shown in red at the front of the first compartment. The red, double-sided arrow in the close-up view identifies the opening in the barrier. Kimmel Decl. at ¶ 104.

**e. *Claim 1, Element E: “disposing at least one syringe in the first compartment”***

Brezette teaches storage of lubricant in the first compartment. Brezette at 3:30-31 (“[I]f desired, lubrication channel 15 can also have a sterile lubricant packaged therein.”). Brezette also teaches that lubricant may be provided in a “packet.” *Id.* at 3:16-18. It was common knowledge well before 2009 that liquid or jelly could be stored in a syringe instead of a packet. *See, e.g.,* Nursing Standard at 52 & Box 1; Bardex DFU 2006; Carrow Decl. at ¶¶ 24-25, 82; Kimmel Decl. at ¶ 105. Substituting one container for another type of container (*e.g.,* substituting a lubricant in a “packet” with a lubricant in a syringe) would have been an obvious substitution of components known to be suitable to yield predictable results. *KSR Int’l Co.*, 550 U.S. at 416; *Sandt Tech., Ltd.*, 264 F.3d at 1355 (finding obvious substitution between claimed threaded studs with welds shown in prior art reference, especially in light of evidence that use of studs was

“common”). Kimmel Decl. at ¶ 105; Carrow Decl. at ¶¶ 25, 82. Substitutability of the two is confirmed by the ’935 patent itself. ’935 patent at 4:40-44 (the “syringe holding lubricating jelly, ... [is] used for illustration purposes only, as it will be clear that *other objects may be added to or substituted for these objects.*”). Also, a POSA would have had reason to make the switch because the use of syringes can be less messy than foil packets. Kimmel Decl. at ¶ 105.

Finally, when replacing the “sterile lubricant” packet from Brezette with a syringe of lubricant, a POSA would have known it may have been necessary to modify the first compartment to adequately hold the syringe (*e.g.*, make the compartment longer or wider, or otherwise modify the configuration of the stair-step within the compartment). Kimmel Decl. at ¶ 105; *see also* Brezette at 2:63-64 (“Lubrication channel 15 can be any length suitable for pushing or swirling the catheter through a lubricant.”). Thus, a POSA would have had reason to substitute Brezette’s packet of lubricant with a syringe of lubricant, and to modify the first compartment of Brezette as necessary to accommodate the syringe.

**f. Claim 1, Element F: “disposing a catheter assembly in the second compartment;”**

Brezette teaches disposing a catheter assembly in the second compartment. Brezette at 1:66-2:3 (“receiving a catheter”); 2:46-50; Kimmel Decl. at ¶ 106.

**g. Claim 1, Element G: “sealing the tray;”**

Brezette teaches the importance of maintaining sterility during a catheterization procedure. Brezette at 1:17-18 (providing recommendations for “the most efficacious sterile catheterization practice”). Brezette also discloses urethral catheterization trays containing sterile components. *Id.* at 1:45-47. It was common knowledge by June 2009 to seal catheterization trays in order to keep contents sterile. Carrow Decl. at ¶¶ 16-17, 84; Kimmel Decl. at ¶ 107. *See also* Rauschenberger at 2:15-20 (disclosing tray “sealed with a cover sheet 30 about flange 17.”); Pilger at 2:70-3:13 (disclosing a “cover sheet 21 sealed by an adhesive”). Accordingly, a POSA would have sealed the Brezette tray with a cover sheet or by some other means in order to maintain the sterility of the components within the catheterization package prior to use. Carrow Decl. at ¶¶ 16-17, 84; Kimmel Decl. at ¶ 107.

**h. Claim 1, Element H: “enclosing printed instructions directing a user to discharge contents of the at least one syringe into the first compartment and to pass at least a portion of the catheter assembly through the opening and into the contents; and”**

This “printed matter” limitation should be given no patentable weight. *See* Section VII.A. Even if this limitation were given patentable weight, it would have been obvious for a POSA to include the claimed instructions with Brezette.

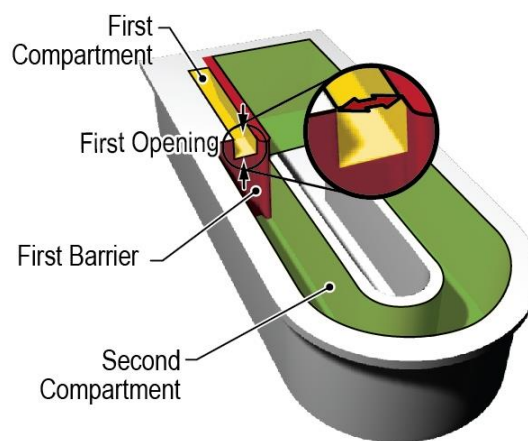


Brezette teaches discharging the contents of a container into the first compartment and to pass at least a portion of the catheter assembly into the contents:

In practice, where a packet of lubricating jelly has been provided, it is opened and squeezed into lubrication channel 15. The catheter to be inserted into a urethra is then pushed or swirled through the lubricating jelly until the portion of the catheter to be inserted has been adequately lubricated. Because lubrication channel 15 confines the lubricant and is relatively impermeable to the lubricant, the channel provides better utilization of a given volume of lubricant when compared to the utilization provided by the prior art towel. Further, the tray need not be held in one hand while the catheter is being swirled through the channel 15.

Brezette at 3:16-27.

Brezette also teaches a POSA to manufacture the tray such that a practitioner would pass a portion of the catheter through the opening in the barrier between the compartments. Kimmel Decl. at ¶¶ 108-109. The “opening” in the barrier is shown in the figure at right (which is a perspective view of Brezette figure 1). Kimmel Decl. at ¶ 109.



As explained above in Ground 1 (Section VII.B.5), the inclusion of instructions with a catheter assembly such as the one described in Brezette to guide

a user on the proper procedures for using the kit was well known—if not universally adopted across the industry—prior to 2009. For the reasons stated there, it would have been obvious for a POSA to follow the industry accepted practice and FDA guidelines and include instructions (as taught by Franks-Farah) explaining how to properly lubricate the device during catheterization (as taught in Brezette). Kimmel Decl. at ¶ 110.

Additionally, as discussed in section VII.C.1.e, although Brezette does not explicitly disclose discharging the contents of a *syringe* into the first compartment, substituting one type of packaged lubricant (*e.g.*, a packet) for another type of packaged lubricant (*e.g.*, a syringe) would have been an obvious substitution of known components. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007); *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1355 (Fed. Cir. 2001) (finding obvious substitution between claimed threaded studs with welds shown in prior art reference, especially in light of evidence that use of studs was “common”); Kimmel Decl. at ¶ 111. Thus, in a Brezette tray containing a syringe of lubricant, it would have been standard and customary in light of Franks-Farah to enclose printed instructions directing a user to discharge contents of a syringe into the first compartment of the Brezette tray and to pass at least a portion of the catheter assembly through the opening and into the contents to lubricate the catheter. Kimmel Decl. at ¶ 111.

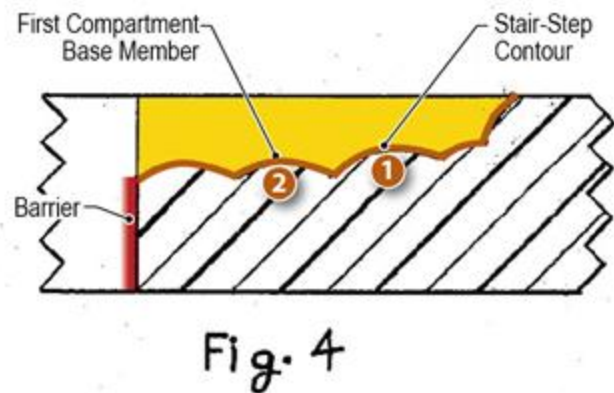
**i. Claim 1, Element I: “placing a sterile wrap about the tray.”**

Although Brezette does not disclose placing a sterile wrap about the tray, it would have been sensible and routine for a POSA to include such a wrap. As is evident from Beddow, U.S. Patent No. 4,226,328 (Ex. 1112), it was known as of at least June 2009 to place a sterile wrap about a catheterization tray to help keep the tray sterile as well as to establish a procedural sterile field. Beddow at 2:39-41 (“wrapping may be provided between the assembled trays and the pouch”); 2:47-50 (“the plastic pouch is opened and the wrap . . . [is] removed, unfolded and placed in position on the patient in a manner well known to the art.”); Rauschenberger at 1:8-14 (“Prior art devices have generally employed a tray . . . covered with a sterile folded central supply room (CSR) wrap.”); Serany at 2:1-5 (“The wrap 14, which may be a piece of sterile absorbent paper, is folded around the box 10.”); Carrow Decl. at ¶¶ 18-19, 42, 76, 86; Kimmel Decl. at ¶ 112.

Given Brezette’s teaching regarding the importance of maintaining sterility during a catheterization procedure (*id.* at 1:17-18), a POSA would have had reason to place a sterile wrap about the Brezette tray as taught by Beddow (and the prior art in general), to help maintain the sterility of the components within the catheterization package and establish a sterile work area. Carrow Decl. at ¶¶ 18-19, 42, 76, 86; Kimmel Decl. at ¶ 113.

**2. CLAIM 7, Element B: “wherein the first compartment base member comprises a first step portion and a second step portion, wherein the first step portion is disposed farther from the first barrier than the second step portion.”**

As described in section VII.C.1.b, Brezette discloses an inclined, stair-step contour in a first compartment. As shown in the annotated figure below, the disclosed contour has a first step portion and a second step portion, wherein the first step portion is disposed farther from the barrier than the second step portion. The first and second step portions are identified by number. Kimmel Decl. at ¶ 127.



**3. CLAIM 8: “The method of claim 7, wherein the second step portion is disposed at a greater depth within the tray than the first step portion.”**

As described in sections VII.C.1.b and VII.C.2, Brezette discloses an inclined, stair-step contour in a first compartment in which the contour has a first step portion and a second step portion, wherein the first step portion is disposed farther from the barrier than the second step portion. As shown in the image above in section VII.C.2, the second step portion (numbered 2) has a greater depth within the tray (from the top) than the first step portion (numbered 1). Kimmel Decl. at ¶ 128.

**D. Ground 3: Claims 22-23, 25, 27-28, and 31-34 are obvious under 35 U.S.C. § 103 over at least Brezette**

**1. CLAIM 22**

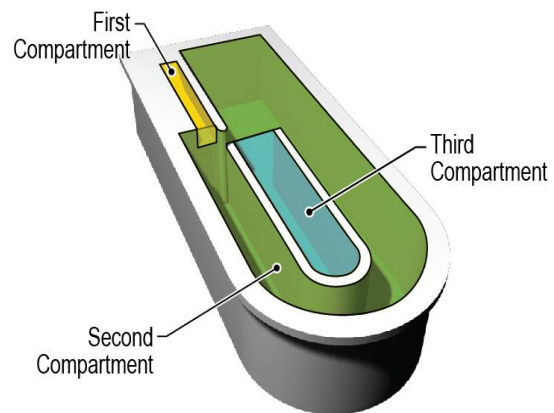
- a. *Claim 22, Element A*: “A tray configured to accommodate a catheter assembly and medical devices corresponding to catheter use, the tray comprising:”**

Brezette discloses a tray configured to accommodate a catheter assembly and medical devices corresponding to catheter use. *See* Section VII.B.1; Kimmel Decl. at ¶ 197.

- b. *Claim 22, Element B*: “a contoured surface defining at least three compartments separated by barriers and a perimeter wall, the at least three compartments comprising:”**

Brezette discloses a tray with a contoured surface having at least three compartments separated by barriers, and a perimeter wall.

A POSA would understand that claim 22 should be read to have a comma between “barriers” and “and”—*i.e.*, the “perimeter wall” need not separate the compartments; the tray need only have a perimeter wall (among the other elements). Kimmel Decl. at ¶ 198. Otherwise, the claim language would be nonsensical. The specification emphasizes that the barriers, not



perimeter walls, separate adjacent compartments. '935 patent at 4:4-9, 8:13-20. The figure at right above (a perspective view of Brezette figure 1) shows the first, second, and third compartments highlighted yellow, green, and blue; the barriers (white) are shown separating the compartments, and the perimeter wall encircles the tray. Kimmel Decl. at ¶ 126.

**c. Claim 22, Element C: “a first compartment comprising a first compartment base member”**

Brezette discloses a first compartment comprising a first compartment base member. See Sections VII.C.1.b and VII.C.1.c (discussing the first compartment and base member disclosed by Brezette); Kimmel Decl. at ¶ 199.

**d. Claim 22, Element D: “having at least one inclined stair-stepped contour defining a ramp upon which syringes may be placed so that a plunger of each syringe is predisposed to project upward and out of the tray;”**

As discussed in section VII.C.1.c, Brezette discloses at least one inclined stair-stepped contour. That contour defines a ramp upon which a syringe may be placed. Kimmel Decl. at ¶ 200.

A POSA would have had a reason to place an additional syringe on this ramp in the first compartment. Including two or more syringes with a catheterization assembly was well known in the art at the time that the '935 patent application was filed. Nursing Standard at 52 & Box 1; Bardex DFU 2006; Carrow Decl. at ¶¶ 24-25, 82. Also, a syringe of sterile liquid for filling the

catheter balloon was a well-known catheterization implement. *See, e.g.*, Nursing Standard at 52 & Box 1; Bardex DFU 2006; Beddow at Fig. 1, 2:50-52; Serany at 3:6-22; Pilger at 2:3-8; Carrow Decl. at ¶¶ 24, 82. A POSA would have had reason to include a second syringe in the Brezette tray—the first containing the lubricating jelly (*see* Section VII.C.1.e), and the second one containing a sterile liquid for inflating the retention balloon of a catheter. Kimmel Decl. at ¶¶ 168, 189.

A POSA further would have been motivated to group the two syringes together as they are both used directly with the catheter—one is used to lubricate the end of the catheter, and the other is used to inflate the catheter balloon. Kimmel Decl. at ¶ 171. As the syringes are usually of similar size and shape, it also would have been efficient to package them in close proximity to each other. Kimmel Decl. at ¶ 171. The products in the tray also would have been generally arranged in the order in which they would be used during a procedure. Kimmel Decl. at ¶ 171; Beddow at 1:9-13 (“all of the components necessary for accomplishing a catheterization procedure ... are arranged in their preferred order of use.”); Rauschenberger at 2:23-25 (“components [used in the procedure] generally are arranged sequentially from the top of the tray on down in the order [of use].”). These considerations would have motivated a POSA to dispose a second syringe in the first compartment. Such placement would have been reinforced by commonly applied design principles, which recommend simple and

intuitive placement of materials. Kimmel Decl. at ¶ 171. A POSA practicing Brezette would be led to place the two syringes alongside each other, with the first syringe to be used in the procedure disposed higher than the other, resting partially on the channel wall and partially on the other syringe, but with both syringes placed on the ramp defined by the inclined, stair-stepped contour. Kimmel Decl. at ¶¶ 200-203; *see also* Section VII.C.1.e regarding modifying the first compartment to accommodate syringes.

Also, it was common knowledge in the art at the time of the invention to dispose syringes with the plunger end elevated for ease of access. Kimmel Decl. at ¶ 200. *See also* U.S. Patent No. 2,659,485 (Ex. 1127) at Figs. 1-2 and 1:20-23 (teaching a tray with syringes supported plunger end up and “positioned as to be readily grasped”); U.S. Patent No. 5,024,326 (Ex. 1128) at Fig. 2 and 2:35-38 (showing a syringe held by a tray with “tips down toward the underlying container surface with the free end of the syringe positioned in an upwardly and outwardly inclined manner to facilitate the manipulation thereof by a user.”). Accordingly, a POSA would have further been led to place the syringes in the first compartment such that plunger end of the syringes project upward and out of the tray.

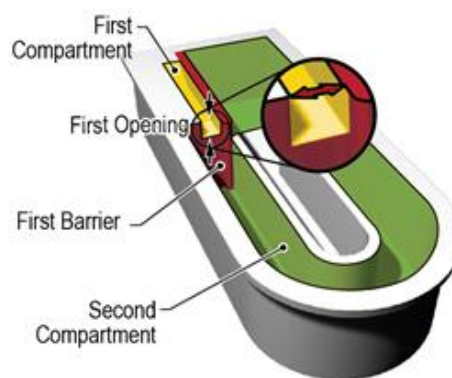


- e. ***Claim 22, Element E: “a second compartment comprising a second base member;”***

Brezette discloses a second compartment comprising a second base member. *See* Section VII.C.1.d (discussing a “second compartment”); Brezette at Figs. 1-2 (showing a second compartment with a floor—*i.e.*, a second base member).

- f. ***Claim 22, Element F: “a first barrier separating the first compartment from the second compartment, wherein the first barrier defines a first opening between the first compartment and the second compartment, the first opening having a first opening depth;”***

Brezette discloses a first barrier separating the first compartment from the second compartment, wherein the first barrier defines a first opening between the first compartment and the second compartment. *See* Section VII.C.1.d.



The first opening necessarily has an opening depth (*i.e.*, the distance from the top of the compartment to the lower bound of the opening; the area between the two black, vertical arrows). *See* Brezette at Fig. 2 and the illustrated, perspective view at right; Kimmel Decl. at ¶ 204.

- g. ***Claim 22, Element G: “a third compartment comprising a third base member; and”***

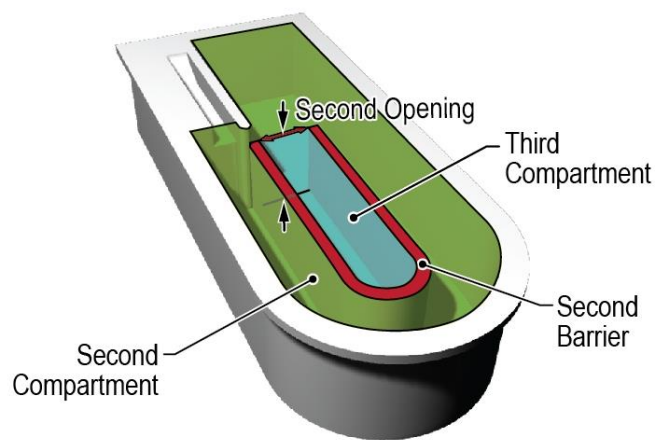
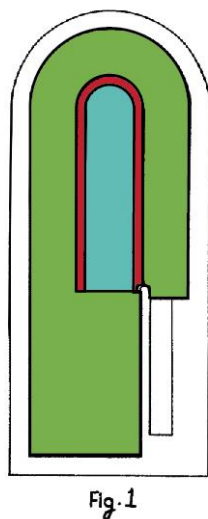
Brezette discloses a third compartment. *See* Brezette at Fig. 1. The third compartment comprises a third base member (*i.e.*, the third compartment has a

floor). See Brezette at Figs. 1 and 2 (third compartment shown below in blue).

Kimmel Decl. at ¶ 205.

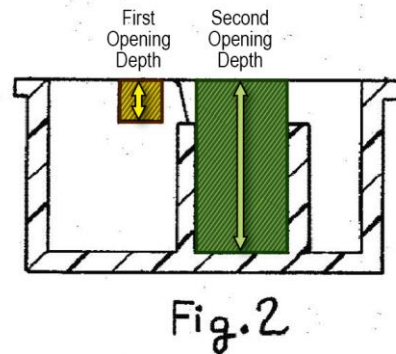
- h. Claim 22, Element H: “a second barrier separating the second compartment from the third compartment, wherein the second barrier defines a second opening between the second compartment and the third compartment, the second opening having a second opening depth.”**

Brezette discloses this limitation. Brezette figure 1 and a perspective illustration of figure 1 are below. Kimmel Decl. at ¶ 206. In each, the third compartment is highlighted blue, the second barrier separating the second compartment and the third compartment is shown in red. The two vertical arrows pointing at one another in the perspective illustration identify the second opening. Kimmel Decl. at ¶ 206. The second opening has a second opening depth, *i.e.*, the depth from the top of the barrier defining the opening and the base of the compartments.



**2. CLAIM 23: “The tray of claim 22, wherein the first opening depth and the second opening depth are different.”**

As shown in the annotated Figure 2 of Brezette at right, Brezette discloses a tray wherein the first opening depth and the second opening depth are different. Kimmel Decl. at ¶¶ 207-208.



**3. CLAIMS 25, 27-28, and 30-34**

Claims 25, 27-28, and 30-34 are product claims dependent on claim 22. Most the additional dependent claim elements mirror equivalent method of manufacture claims and are unpatentable for the same reasons.

**a. CLAIM 25**

- (1) *Claim 25, Element A: “The tray of claim 22, wherein the first compartment is configured to accommodate a plurality of syringes,”*

As shown above in Section VII.D.1.d, a POSA would have reason to configure the first compartment of Brezette to accommodate a plurality of syringes. Kimmel Decl. at ¶ 209.

- (2) *Claim 25, Element B: “the second compartment is configured to accommodate the catheter assembly, and”*

A POSA would have understood Brezette to teach disposing a catheter assembly in the second compartment, the largest of the three compartments in

Brezette. Brezette at 1:66-2:3 (“receiving a catheter”), 2:46-50; Kimmel Decl. at ¶ 209.

**(3) *Claim 25, Element C: “the third compartment is configured to accommodate at least one of a specimen container or a skin cleanser”***

Brezette discloses configuring the third compartment to accommodate at least one of a specimen container or a skin cleanser. Brezette teaches that additional implements necessary for catheterization may be included in any of the compartments of the tray. Brezette at 2:46-50 (“Recessed from upper surface 11 is ... a plurality of compartments for receiving a ... other implements necessary to the catheterization.”). Both a specimen container and a skin cleanser were known implements necessary for catheterization by June 2009. Beddow at 2:60-66 (“a bottle 21 of cleansing solution”); 3:23-26 (“specimen bottle”); *see also* Rauschenberger at 2:22-26 (“antiseptic solution” and “specimen container”); Carrow Decl. at ¶ 87. A POSA would have had reason to follow Beddow and include a specimen container or skin cleanser in the Brezette tray to enable the collection of a urine sample and the cleaning of the patient’s skin. Carrow Decl. at ¶ 87; Kimmel Decl. at ¶¶ 115-119.

- b. **Claim 27:** “The tray of claim 22, wherein the first compartment base member comprises a first step portion and a second step portion, wherein the first step portion is disposed farther from the first barrier than the second step portion”

*See* Sections VII.D.1. (addressing claim 22) and VII.C.2 (addressing this same limitation in method claim 7).

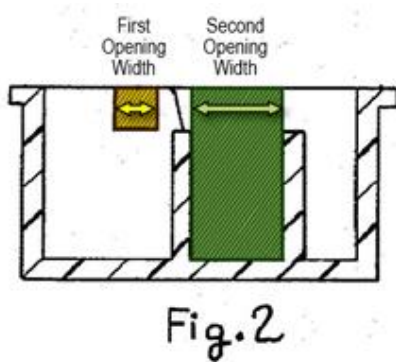
- c. **Claim 28:** “The tray of claim 27, wherein the second step portion is disposed at a greater depth within the tray than the first step portion.

*See* Section VII.D.1. (addressing claim 22) and VII.C.3 (addressing this same limitation in method claim 8).

- d. **Claim 30:** “The tray of claim 27, wherein each of the first step portion and the second step portion define a recess for accommodating a syringe flange.”

*See* Section VII.F (discussing claim 10 and a recess for accommodating a syringe flange).

- e. **Claim 31:** “The tray of claim 22, wherein the first opening has a first opening width associated therewith width that is less than a second opening width associated with the second opening.”

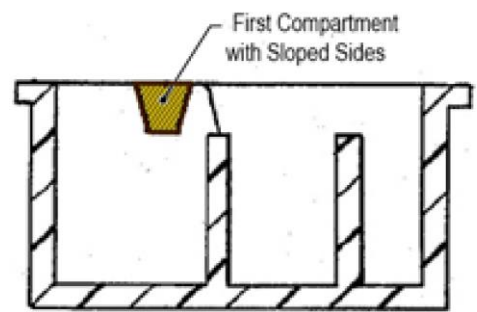


Brezette discloses a tray wherein the first opening width in the first barrier is less than a second opening width in the second barrier, as shown in the annotated copy of Brezette figure 2 at left. Kimmel Decl. at ¶¶ 132, 209. Also, the width of the two

compartments is a simple design choice; the patent does not attribute any patentable or inventive significance to having the first opening width be less than the second opening width.

**f. Claim 32: “The tray of claim 22, wherein the first opening is bounded by a first opening base member and two inclined first opening side members.”**

Brezette discloses a tray wherein the first opening is bounded by a first opening base member. Brezette at Figs. 2, 3, and 4 (showing embodiments of the lubrication channel with openings bounded by opening base members). The text of Brezette also discloses an embodiment with a first opening with two



**Modified Brezette Figure 2**

inclined first opening side members. *Id.* at 3:13-15 (noting that “if desired the width of the lubrication channel can be greater at its top than at its lower surface”). Although such a compartment is not shown in the Brezette figures, a modified version of Brezette figure 2 is shown at the right above as a POSA would have understood the specification of Brezette. Kimmel Decl. at ¶¶ 133-34, 209.

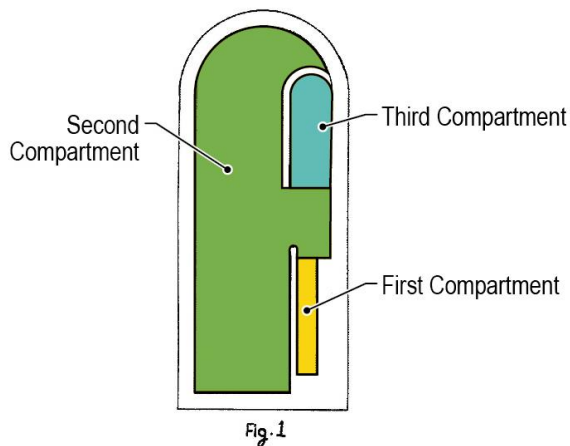
Also, it was common knowledge in the art by June 2009 that certain structures in molded plastic trays—such as opening side members and side walls—needed to be designed with a sloped angle to enable removal of the tray from a mold. Kimmel Decl. at ¶ 133. Accordingly, a POSA would have had reason to

design a tray with inclined opening side members to allow for the tray to be removed easily from a mold during manufacture. *Id.*

Thus, at least one embodiment of Figures 2, 3, and 4 would have had sloping side members (instead of the vertical opening side member shown in figure 2).

**g. Claim 33: “The tray of claim 32, wherein the second opening is bounded by a second opening base member, an inclined second opening side member, and the perimeter wall.”**

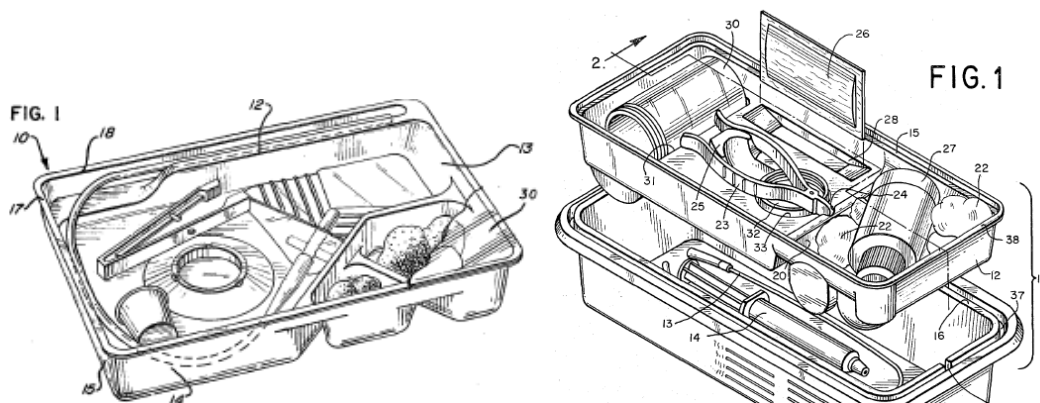
Brezette discloses a second opening bounded by an opening base member. Brezette at Fig. 2. A POSA would have easily been able to, and had reason to, modify the second compartment so that the opening in the barrier between the second and third compartments was also bounded by an inclined second opening side member. Kimmel Decl. at ¶¶ 135-139, 209. A POSA would have had reason to design a tray with inclined opening side members to, at least, allow for the tray to be removed easily from a mold during manufacture. Kimmel Decl. at ¶ 135.



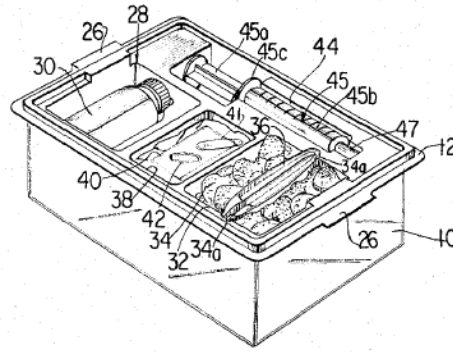
A POSA would have had a reason to modify the second compartment so that the opening in the barrier between the second and third compartment was also bounded by the perimeter wall, as shown in the modified drawing at right, above. Kimmel Decl. at ¶ 136. The placement of the third compartment is a simple design

choice—again, the patent does not attribute any inventive or patentable distinction as to the placement of the third compartment. A POSA would have been led to make such a change to enable the contents of the third compartment (*i.e.*, skin cleanser) to be placed along the wall so when the skin cleanser is dispensed in the compartment to apply to the patient (*see* Carrow Decl. at ¶ 28-29, 87; Mosby’s Pocket Guide to Basic Skills and Procedures (Ex. 1130) at 528 (“Pour sterile antiseptic solution into correct compartment containing sterile cotton balls”)), there is less potential of soaking the other contents in the kit. Kimmel Decl. at ¶ 137.

It was common practice by June 2009 to place the compartment that holds the skin cleanser and/or cleaning balls against a perimeter wall. *See* Beddow figure 1 (below right, showing skin cleansing balls at 22); Rauschenberger figure 1 (below left, showing skin cleansing balls in lower right corner); and Serany figure 5 (below center, showing both skin cleanser (30) and cleansing balls (34) against perimeter wall).







Because such changes would involve a minor modification of the shape/size to another suitable shape/size, and neither Brezette nor the '935 patent attribute any significance to the placement of the third compartment, a POSA would have been led as a design choice to configure the shape and size of the openings in the Brezette tray to position the third compartment against the perimeter wall. Kimmel Decl. at ¶ 138. *Honolulu Oil Corp. v. Halliburton*, 306 U.S. 550, 559 (1939) (ruling that location of valve in a sampling process was “mere mechanical contrivance and not invention,” and therefore claims were invalid).

**h. Claim 34: “The tray of claim 22, wherein each of the first compartment, the second compartment, and the third compartment are open along a side of the tray opposite the second base member.”**

Brezette discloses this element. Brezette figures 1 and 2 show a compartment with a floor—i.e., a second base member—and three compartments in which all of the compartments open on the side opposite the second base member—i.e., open at the top. Kimmel Decl. at ¶ 139, 209.

**E. Ground 4: Claims 22-23, 25, and 31-34 are obvious under 35 U.S.C. § 103 over at least Rauschenberger**

To the extent the Board finds any of the challenged claims would not have been obvious over Brezette in view of Beddow and Franks-Farah, at least claims 22-23, 25, and 31-34 would have been obvious over Rauschenberger in view of Beddow and Franks-Farah. Like Brezette, Rauschenberger discloses the majority of the limitations of the challenged claims.

**1. CLAIM 22**

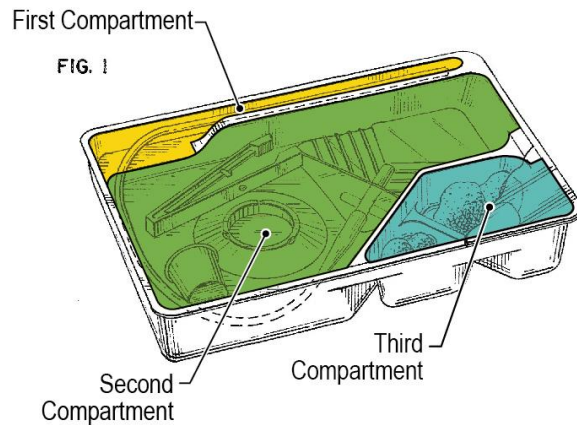
- a. *Claim 22, Element A: “A tray configured to accommodate a catheter assembly and medical devices corresponding to catheter use, the tray comprising:”***

Rauschenberger discloses this element. *See, e.g.*, Rauschenberger at 1:4-7 (“This invention . . . is concerned with a sterile, self-contained catheterization package . . . .”); Fig. 1 (showing various medical devices in tray).

- b. ***Claim 22, Element B: “a contoured surface defining at least three compartments separated by barriers and a perimeter wall, the at least three compartments comprising:”***

***and Element C: “a first compartment comprising a first compartment base member”***

Rauschenberger discloses a tray with a contoured surface having at least three compartments separated by barriers, and a perimeter wall. A POSA would understand that claim 22 should be read to have a comma between “barriers” and “and”—*i.e.*, the “perimeter wall” does not need to separate the compartments; the tray need only have a perimeter wall

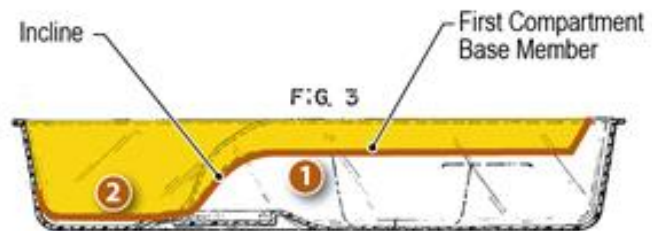


(among the other elements). Kimmel Decl. at ¶ 172, 198. Rauschenberger Figure 1, at right, shows the first, second, and third compartments highlighted yellow, green, and blue, respectively. Kimmel Decl. at ¶ 172. The first compartment has a base member (*i.e.*, a bottom). *Id.* at ¶ 199.

- c. ***Claim 22, Element D: “having at least one inclined stair-stepped contour defining a ramp upon which syringes may be placed so that a plunger of each syringe is predisposed to project upward and out of the tray;”***

Rauschenberger discloses an inclined, stair-step contour. Rauschenberger at Figs. 2 & 3; 1:56-58 (“Flange 17 and wall 12 are connected by a channel 21 which has a horizontal section 19

and an inclined section 20 forming a ramp.”); 1:64-66 (“The remainder of the catheter extends down the ramp



section 20.”); Kimmel Decl. at ¶ 200. As shown at left in an annotated version of figure 3, the platforms of the “stair step” of the first compartment base member are disposed at two different depths across the length of the first compartment, shown as horizontal lines above the 1 and below the 2. In between the 1 and 2, the orange line shows the location of the “incline” of the inclined, stair-step contour on the riser between the stair-step platforms.

This incline also defines the “ramp” (1:56-58) upon which a POSA would dispose syringes. Kimmel Decl. at ¶ 202. As discussed in Section VII.B.3, a POSA would be led to replace the lubrication packet in Rauschenberger with a syringe of lubricant and dispose that syringe in the first compartment.

Including two or more syringes with a catheterization assembly was well known in the art at the time that the '935 patent was filed. Nursing Standard at 52 & Box 1; Bardex DFU 2006; Carrow Decl. at ¶¶ 24-25, 82; Kimmel Decl. at ¶ 168. It was common that one of the syringes was used for a lubricant and another was a syringe of sterile liquid to fill a catheter retention balloon. *See, e.g.*, Nursing Standard at 52 & Box 1; Bardex DFU 2006; Beddow at Fig. 1; 2:50-52; Serany at 3:6-22; Pilger at 2:3-8; Carrow Decl. at ¶¶ 24, 82. Thus, a POSA would have had reason to include a second syringe in a Rauschenberger tray—a syringe of sterile liquid for inflating the retention balloon on a catheter.

As to the placement of the second syringe in the Rauschenberger tray, as discussed in section VII.B.3, a POSA practicing Rauschenberger would have had a reason to widen the first compartment of the Rauschenberger tray to accommodate the width of a syringe, if necessary. A POSA also would have had reason to dispose the second syringe adjacent to the first syringe (*i.e.*, in the first compartment), such that one syringe rests with its barrel on the incline of the inclined, stair-step contour, while the other syringe rests partially on the lower platform with its plunger on the incline. Kimmel Decl. at ¶ 202.

A POSA would have been motivated to place the two syringes in this configuration because they are both used with the catheter—one is used to lubricate the end of the catheter, and the other is used to inflate the balloon of the

catheter. Kimmel Decl. at ¶170-71. As the syringes are of similar size and shape, it also would have been efficient to package them in close proximity to each other. Kimmel Decl. at ¶171. It also would have been common sense to arrange the products in the tray also as they would be used during a procedure. Kimmel Decl. at ¶ 171; Beddow at 1:9-13 (“catheterization packages generally consist of a tray in which all of the components necessary for accomplishing a catheterization procedure, ... are arranged in their preferred order of use.”); Rauschenberger at 2:23-25 (“components [used in the procedure] generally are arranged sequentially from the top of the tray on down in the order [of use].”). These considerations would have motivated a POSA to dispose the second syringe in the first compartment as described above.

Further, it was common knowledge in the art at the time of the invention to dispose syringes with the plunger side up for ease of access and safety. *See, e.g.*, U.S. Patent No. 2,659,485 (Ex. 1127) at Figs. 1-2, 1:20-23 (teaching a tray with syringes supported plunger side up and “positioned as to be readily grasped”); U.S. Patent No. 5,024,326 (Ex. 1128) at Fig. 2, 2:35-38 (showing a syringe held by a tray with “tips down toward the underlying container surface with the free end of the syringe positioned in an upwardly and outwardly inclined manner to facilitate the manipulation thereof by a user.”); Kimmel Decl. at ¶ 200. Accordingly, it would have been obvious to a POSA to use their common sense and general

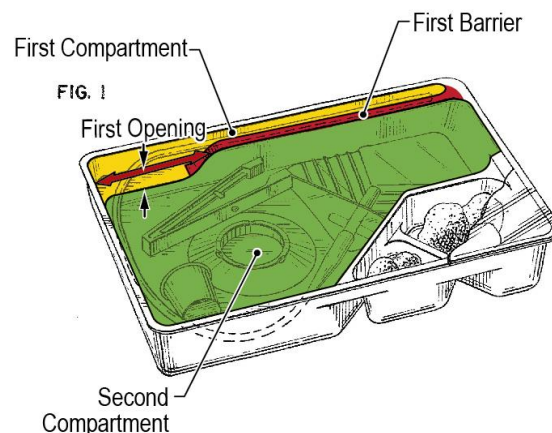
knowledge to dispose the syringes so that the plunger of each syringe is predisposed to project upward and out of the tray when placed on the ramp formed by the inclined, stair-step contour of Rauschenberger.

**d. Claim 22, Element E: “a second compartment comprising a second base member;”**

As shown in Section 0, Rauschenberger discloses a second compartment (highlighted in green) with a second base member (*i.e.*, a bottom).

**e. Claim 22, Element F: “a first barrier separating the first compartment from the second compartment, wherein the first barrier defines a first opening between the first compartment and the second compartment, the first opening having a first opening depth;”**

As discussed in Section VII.B.2, and as shown in the annotated Figure 1 at right, Rauschenberger discloses a first barrier (red) separating the first compartment (yellow) from the second compartment (green), and the first



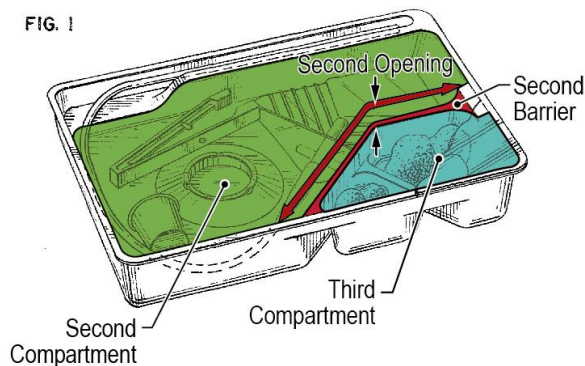
barrier defines a first opening (shown with a double-sided arrow) between the first compartment and the second compartment, the first opening having a first opening depth (the area below the double-sided arrow). Kimmel Decl. at ¶ 204.

**f. Claim 22, Element G: “a third compartment comprising a third base member; and”**

As shown in Section 0, Rauschenberger discloses a third compartment (highlighted in blue) with a third base member (*i.e.*, bottom). Kimmel Decl. at ¶ 205.

**g. Claim 22, Element H: “a second barrier separating the second compartment from the third compartment, wherein the second barrier defines a second opening between the second compartment and the third compartment, the second opening having a second opening depth.”**

As shown in the annotated figure 1 at left, Rauschenberger discloses a



second barrier (red) separating the second compartment (green) from the third compartment (blue), wherein the second barrier defines a second opening (shown with a double-sided red arrow) between the second compartment and the third

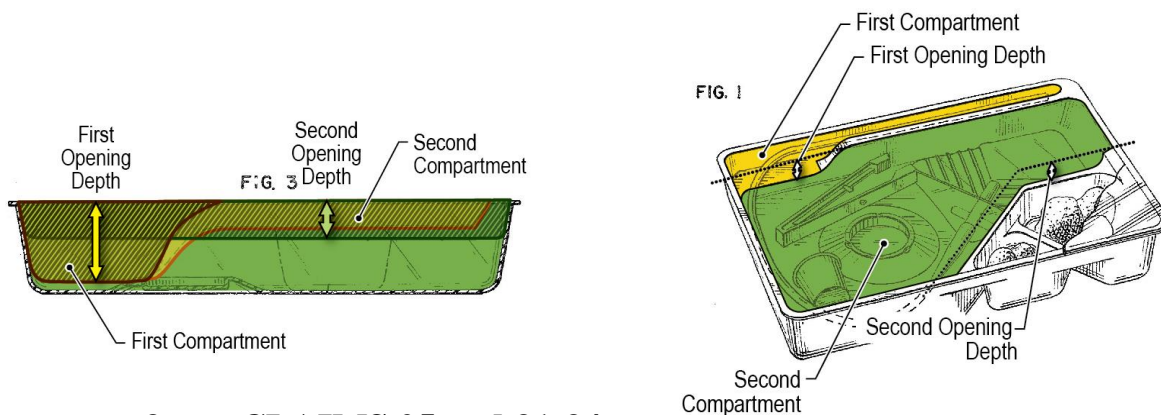
compartment, the second opening having a second opening depth (the area beneath the double-sided red arrow). Kimmel Decl. at ¶ 206.

**2. CLAIM 23: “The tray of claim 22, wherein the first opening depth and the second opening depth are different.”**

As shown in the annotated figures 1 and 3 of Rauschenberger below, Rauschenberger discloses a tray wherein the first opening depth and the second



opening depth are different. Kimmel Decl. at ¶ 208. The first opening depth appears from the bottom of first compartment to the top of the tray, and the second opening depth is less as it appears only from the top of the barrier defining the opening to the top of the tray.



### 3. CLAIMS 25 and 31-34

Claims 25 and 31-34 are dependent on claim 22, and are product claims directed to a tray that has the same characteristics described in the method claims.

- a. ***Claim 25, Element A: “The tray of claim 22, wherein the first compartment is configured to accommodate a plurality of syringes,”***

As explained in Section VII.E.1.c, a POSA would have reason to configure the first compartment of Rauschenberger to accommodate a plurality of syringes.

- b. ***Claim 25, Element B: “the second compartment is configured to accommodate the catheter assembly, and”***

Rauschenberger discloses disposing a catheter assembly in the second compartment. Rauschenberger figure 1 shows the catheter assembly (a tube attached to a bag) in the second compartment. Kimmel Decl. at ¶¶ 153, 209.

**c. *Claim 25, Element C: “the third compartment is configured to accommodate at least one of a specimen container or a skin cleanser.”***

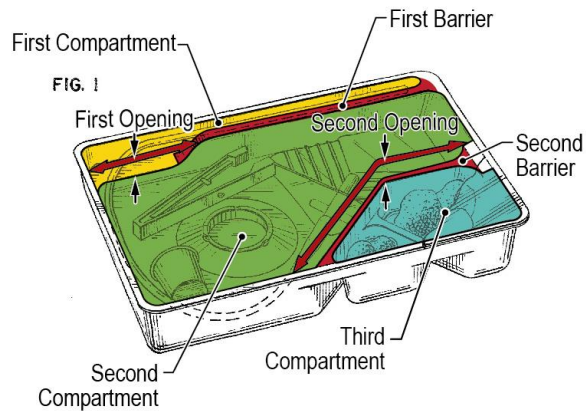
Rauschenberger discloses disposing absorbent pads used to cleanse a patient in the third compartment. Rauschenberger at 2:5-7 (“Compartments 23 and 24 are ... adapted to hold absorbent pads.”); 2:43-51 (“[A]ntiseptic solution is applied to the absorbent pads ... the patient is cleansed with the saturated absorbent pads.”). Rauschenberger also discloses putting skin cleanser (“antiseptic solution”) in the third compartment during the catheterization procedure. *Id.*

It was known in the art at the time of the invention that the skin cleanser could, during manufacture, be disposed in the same tray compartment as the “absorbent pads.” Carrow Decl. at ¶¶ 28-29, 87; Kimmel Decl. at ¶¶ 164, 209. *See also* Beddow at 2:60-3:8; Fig. 1. One purpose of the Rauschenberger invention was to provide a tray that “permit[ted] the catheterization procedure to take place within the sterile work area defined by the tray,” Rauschenberger at 1:5-7, and minimized “movement” or “contact” that might “contaminate the sterile work area.” *Id.* at 1:29-43. Given Rauschenberger’s teaching, in light of Beddow which shows the absorbent material and skin cleanser in the same compartment as manufactured (2:60-3:8; Fig. 1) and the general knowledge of a POSA, it would have been obvious to a POSA to dispose the skin cleanser in the third compartment of the Rauschenberger tray. Kimmel Decl. at ¶¶ 166, 209.

- d. **Claim 31: “The tray of claim 22, wherein the first opening has a first opening width associated therewith width that is less than a second opening width associated with the second opening.”**

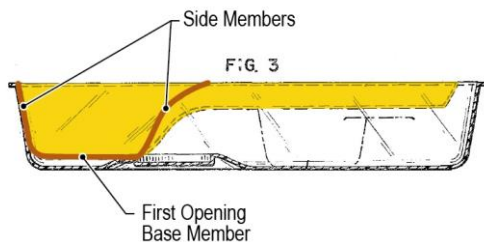
As annotated in Rauschenberger

Figure 1 at right, Rauschenberger discloses a first opening width of the first opening that is less than a second opening width of the second opening, the double sided arrows showing the



widths of the respective openings. Kimmel Decl. at ¶¶ 173, 209.

- e. **Claim 32: “The tray of claim 22, wherein the first opening is bounded by a first opening base member and two inclined first opening side members.”**



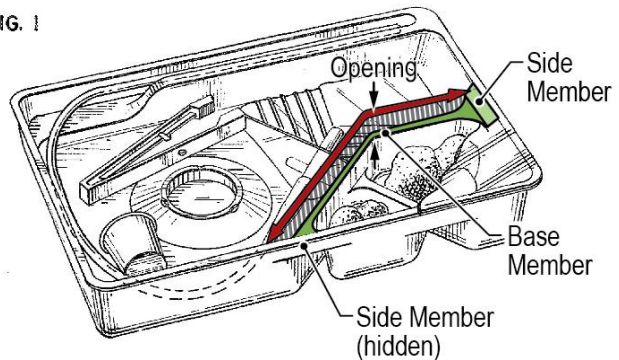
Rauschenberger discloses a first opening bounded by a first opening base member and two inclined first opening side members.

Rauschenberger Figure 1, annotated at left above, shows the first opening base member and the two inclined first opening side members. Kimmel Decl. at ¶¶ 174, 209.

- f. **Claim 33: “The tray of claim 32, wherein the second opening is bounded by a second opening base member, an inclined second opening side member, and the perimeter wall.”**

Rauschenberger discloses an opening (shown with double-sided arrow annotated on figure 1 at right) bounded by an opening base member (green), an inclined opening side member (the side walls would necessarily be inclined due to the thermoforming process), and the perimeter wall (either of the side members).

FIG. 1



Kimmel Decl. at ¶¶ 175, 209.

- g. **Claim 34: “The tray of claim 22, wherein each of the first compartment, the second compartment, and the third compartment are open along a side of the tray opposite the second base member.”**

Rauschenberger discloses a tray as claimed in claim 34. Rauschenberger Fig. 1 shows a multi-compartment tray with three compartments and all of the compartments open on the side opposite the second base member, *i.e.*, open at the top. Kimmel Decl. at ¶ 176, 209.

**F. Ground 5: Claim 10 is obvious under 35 U.S.C. § 103 over Brezette in view of Beddow, Franks-Farah, and Serany**

Claim 10 recites, “[t]he method of claim 8, wherein each of the first step portion and the second step portion define a recess for accommodating a syringe

flange.” As described in sections VII.C.1.c and VII.C.2, Brezette discloses an inclined, stair-step contour in the first compartment that has a first step portion and a second step portion. Further, as discussed in section VII.D.1.d, a POSA would have had reason to use this contour as a recess for accommodating a syringe flange.

It was well known in the art by 2009 to adapt portions of a tray to help hold a syringe flange in order to ensure stability and accessibility. U.S. Patent No. 3,329,261 (Serany) (Ex. 1108) at 3:6-22 (“*Indentations 44d along the sides of the depression 44 accommodate the flange* or finger grip 45c of the syringe.”); *see also* U.S. Patent No. 3,485,352 (Pilger) (Ex. 1124) at 3:61-68 (“A ledge section 17 abuts a plunger 18 of the hypodermic syringe and keeps it from working its way out of syringe barrel 19 during sterilization or shipping.”); U.S. Pub. No. 2006/0264822 (Nagamatsu) (Ex. 1125) at Figure 1 (showing a catheter tray with grooves that are adapted to fit the shape of syringe flanges). A POSA would have recognized, in light of Serany and the person’s general knowledge of package design for syringes, that each of the indented portions between the first and second step portions in the Brezette inclined, stair-step contour could be used as a recess for accommodating a syringe flange—depending on the size of the syringe and flange to be accommodated—allowing for better retention of the syringe during sterilization or shipping. Kimmel Decl. at ¶ 131. Further, to the extent the

indented portions between the steps was not adequate, a POSA would have had reason in light of Serany and the person's general knowledge of package design for syringes to further modify the stair-steps such that there was a larger recess between the steps to accommodate a syringe flange. *Id.*

#### **G. Patent Owner's alleged secondary considerations**

During prosecution, the Patent Owner offered four articles (Exs. 1134 - 1137) purportedly suggesting "unexpectedly improved properties or properties not present in the prior art" as "evidence of 'secondary considerations.'" '935 FH at 11/19/10 Resp. (Ex. 1131) at 12; '935 FH at 5/31/11 Resp. (Ex. 1132) at 15-16; '935 FH at 4/3/13 Resp. (Ex. 1133) at 17-18. The Patent Owner, however, failed to identify a **nexus** between the alleged evidence of secondary considerations and the *claimed* subject matter. *In re GPAC*, 57 F.3d. 1573, 1580 (Fed. Cir. 1995) (finding patent owner failed to show direct nexus from the subject matter claimed).

The articles identified at least the following features of Patent Owner's commercial product as helping reduce infections: (1) a one-layer tray design; (2) labels on the tray to help guide nurses to adhere to CDC recommendations, including aseptic technique; (3) a checklist to help make a decision on whether catheterization is appropriate; (4) a checklist that reviews the proper steps to catheter insertion; (5) a Foley InserTag, *i.e.*, a yellow sticker that wraps around the drain tubing with the date and time of the catheter insertion; (6) a checklist sticker

placed on the patient's chart informing caregivers when and why the catheters had been placed as well as whether it can be removed; (7) a patient education care card that looks like a get well card; (8) procedure components arranged in an intuitive manner from left to right; (9) a "larger" sterile barrier drape; (10) a catheter that is latex-free; and (11) a catheter that is silver-coated.

The challenged claims do not recite any of these features; the articles praising these features are inapposite. Also, one of the articles (Ex. 1137) **minimized the importance of the Medline product**, stating that "the single most important factor" in reducing infection was "[e]ducation, education, education, reinforcement and continual performance feedback to the nursing staff and physicians." Ex. 1137 at 4.

## VIII. CONCLUSION

For the reasons given above, *inter partes* review of U.S. Patent No. 8,448,786 under 35 U.S.C. § 311 and 37 C.F.R. § 42.101 is hereby requested.

Dated: December 30, 2014

Respectfully submitted,

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**CERTIFICATE OF SERVICE UNDER 37 C.F.R. § 42.6 (e)(4)**

It is hereby certified that on December 30, 2014, a copy of the foregoing document was served via USPS Priority Express Mail upon the following:

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Date: December 30, 2014

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