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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C.R. BARD, INC.
Petitioner

v.

MEDLINE INDUSTRIES, INC.
Patent Owner

Case IPR No. *To be assigned*
Patent 8,631,935
Claims 1-4 and 11-20

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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1039	U.S. Patent No. 8,448,786 (“’786 Patent”)

Petitioner C.R. Bard, Inc. ("Bard") requests *inter partes* review of claims 1-4 and 11-20 of U.S. Patent No. 8,631,935 ("'935 patent") (Ex. 1001).

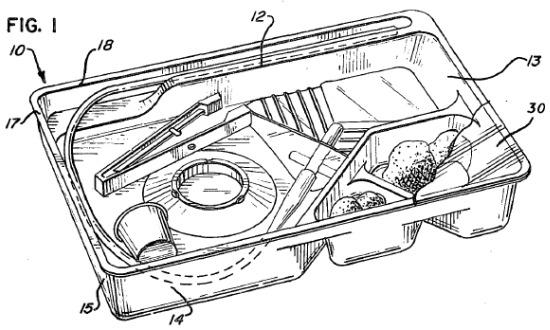
I. INTRODUCTION AND BACKGROUND

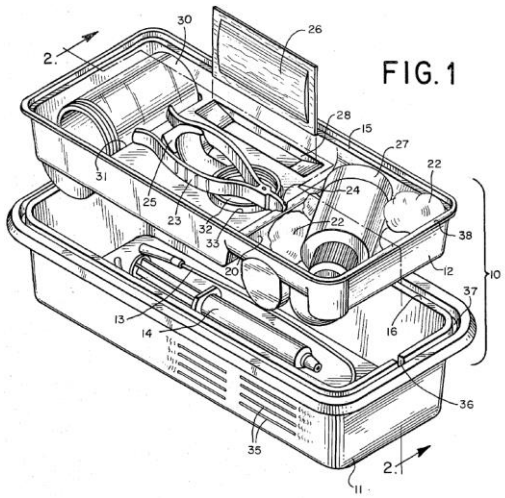
Challenged '935 patent claims 1-4 and 11-20 recite a method of manufacturing a packaged catheter assembly that includes a sealed tray containing the components necessary to perform a catheterization procedure. Each of the challenged claims recites providing (1) a tray with compartments, one of the compartments having a base member with an "inclined, stair-step contour," (2) putting a syringe and catheter in the tray, (3) enclosing instructions on how to lubricate the catheter within the tray, and (4) providing a wrap about the tray.

These elements 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).

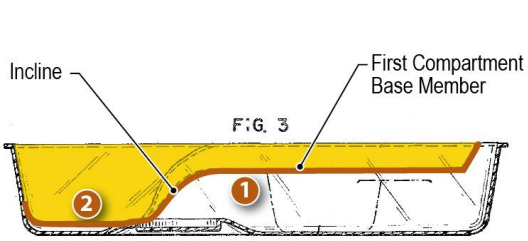
(1) A syringe, catheter, and a tray with compartments. The background of the '935 patent asserts that "[t]raditional catheters are packaged, for example, in individual packaging." '935 patent at 1:40-41. The § 102(b) pieces of prior art relied on in this Petition show differently. **Brezette** (Ex. 1010) discloses a catheterization package with a tray holding a catheter and "other implements useful

in a catheterization procedure." Brezette at Abstract. **Rauschenberger** (Ex. 1011) discloses a similar tray to hold everything necessary 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 above, right). **Beddow** (Ex. 1012) likewise teaches using a tray to contain "all of the components required for accomplishing a catheterization procedure." Beddow at Abstract and figure 1 (at left). *See also* Declaration of Susan Carrow, MSN/Ed, CEN, RN (Ex. 1004) ("Carrow Decl.") at ¶¶ 16, 21.





(2) Inclined, stair-step contour. The claims challenged in this Petition do not functionally limit the "inclined, stair-step contour." Brezette and Rauschenberger both show inclined, stair-step contours. An annotated copy of Brezette's figure 4 is below at right, and an annotated copy of Rauschenberger's figure 3 is below, at left, both showing forms of an inclined, stair-step contour.



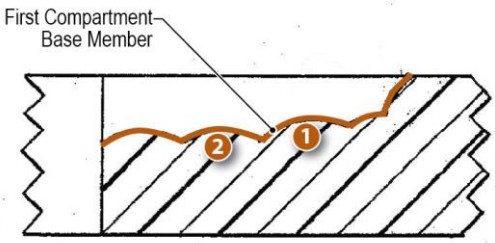


Fig. 4

(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 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, instructions have long been included with medical products such as catheterization kits. **Franks-Farah** (Ex. 1009) is just one example of such inclusion. The examples abound as the FDA required the inclusion of such instructions prior to 2009. *See* "Guidance for the Content of Premarket Notifications of Conventional and Antimicrobial Foley Catheters" (written prior to the February 27, 1997) (Ex. 1026).

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.

(4) Providing a wrap around the tray. Using a wrap to maintain sterility and protect a catheterization tray was also a known practice. **Beddow,** as far back as 1980, taught that a catheterization tray should be wrapped. *Id.* at 2:39-41. Petitioner Bard described such a wrap as far back as 1967. U.S. Pat. No. 3,329,261 ("**Serany**") (Ex. 1008) at 2:1-5 ("The wrap 14, which may be a piece of sterile absorbent paper, is folded around the box 10.").

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. 1037.[1]

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 claims 1-4 and 11-20 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 claims 1-7 and 9-18 of U.S. Patent No. 8,678,190. The '935, '786, and '190

[1] Emphasis added throughout unless otherwise noted.

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 AND RELIEF REQUESTED

Bard seeks cancellation of claims 1-4 and 11-20 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. 1002) ("Kimmel Decl.") at ¶¶ 21-23, 47.

B. Statutory grounds for challenge

Cancellation of claims 1-4 and 11-20 of the '935 patent is requested on the following grounds:

	Reference(s)	Claims	Basis
1	Brezette in view of Beddow and Franks-Farah	1-4 and 11-20	§ 103
2	Rauschenberger in view of Beddow and Franks-Farah	1-4 and 11-20	§ 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 1:45-46. The specification further provides exemplary dimensions of a tray that is shorter than it is wide (*id*. at 3:64-4:3 (disclosing an illustrative height 1.750 inches and an illustrative width of 9.250 inches)), and provides figures that depict a tray as container that is shorter than it is wide (*see* Fig. 1).

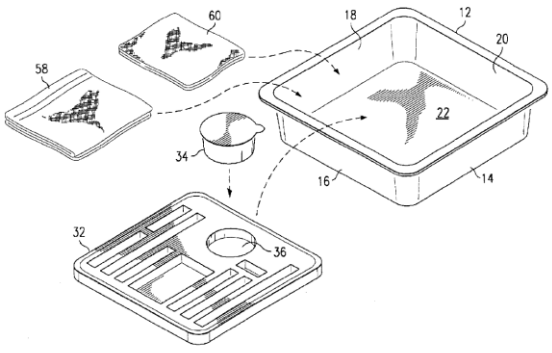


FIG. 3

Art of record also supports a broad construction of the term "tray." United States Publication No. 2004/004019 ("Busch") (Ex. 1014) discusses an "interior tray or subtray 32 [which] rests inside the 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."

Similarly, U.S. Publication No. 2010/0274205 ("Morelli") (Ex. 1015) 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. 1 (above, at left).

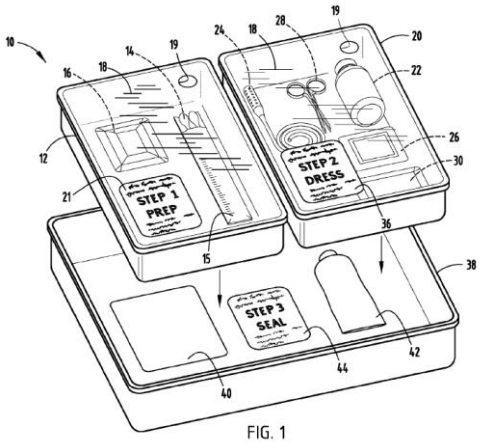
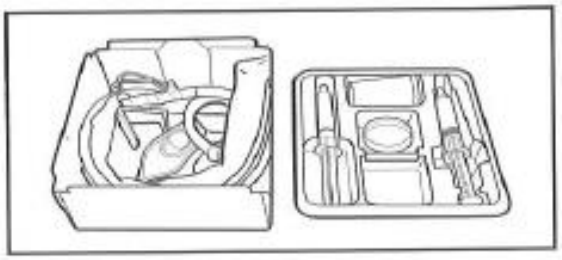


FIG. 1

Neither the ordinary meaning, nor the specification of the '935 patent, limits 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 right) a "bottom tray." *See* Bardex Catheter Directions for Use at 2 (2010) ("Bardex DFU 2010") (Ex. 1029); Kimmel Decl. at ¶ 75.


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

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 where "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"

The term "inclined, stair-step contour," a limitation in challenged independent claims 1, 17, and 19, 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**.

The term "inclined, stair-step contour" is not further defined in the claims of the '935 patent. The independent claims challenged in this Petition also do not include any functional limitation on this 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

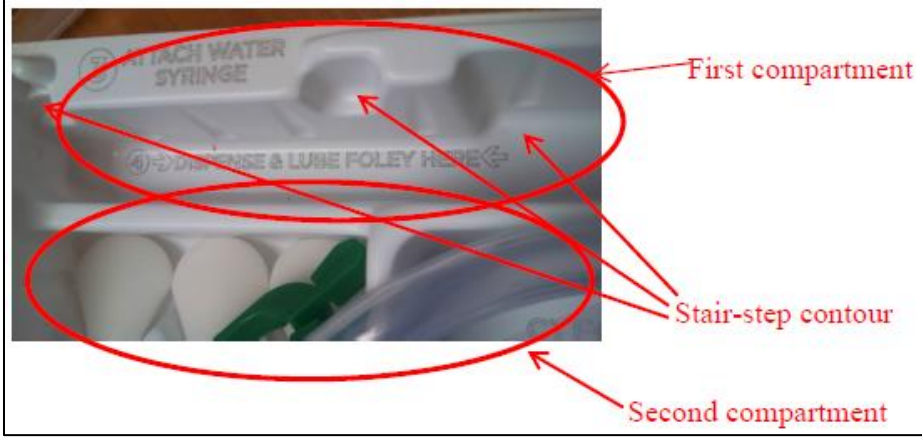
level instruments on the stair-step contour are grasped first during a procedure. *Id.* at 5:5-15. Without this functional language in the independent claims challenged here, however, the broadest reasonable interpretation of the term "inclined, stair-step contour" should not be restricted to the embodiments. 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." '935 patent at 5:19-20. The figures show that only a portion of the base member 107 is inclined. *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 described in the '935 patent:

Bard's Bardex I System includes a tray with at least a first and second compartment. That first compartment has a first compartment base member having an inclined, stair-step contour.



Medline's Initial Infringement Contentions (relevant portions at Ex. 1023), 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 cannot take a more narrow view of the construction of "inclined, stair-step contour" in response to this Petition than it is in the litigation. *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. 1033) 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 challenged method claims 1, 17, and 19, which all recite “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 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 1-4 and 11-20 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. 1004), a nurse practitioner with extensive experience in catheterization

procedures, and Dr. Robert Kimmel (Ex. 1002), an Associate Professor of Packaging Science at Clemson University.

VII. CLAIM-BY-CLAIM EXPLANATION OF GROUNDS FOR UNPATENTABILITY OF CLAIMS 1-4 AND 11-20

A. The "instructions" limitations have 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.1.h 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, 1279-80 (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: Claims 1-4 and 11-20 are obvious under 35 U.S.C. § 103 over Brezette in view of Beddow and Franks-Farah

Brezette discloses the majority of the limitations of the challenged claims. The remaining limitations either add no patentable weight (the "instructions" limitations), or it would have been obvious to a POSA to modify Brezette based on the POSA's background knowledge alone, or in light of Beddow (showing "placing a sterile wrap") and/or Franks-Farah (showing "enclosing printed instructions").

1. CLAIM 1

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").

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, below, is a perspective drawing of Brezette figure 1 showing the same. Kimmel Decl. at ¶ 101. The perspective drawing (and others like it below) are not part of the figures of Brezette, but instead were drawn as one of ordinary skill in

the art would have understood Brezette's figures in light of the specification. Kimmel Decl. at ¶¶ 97-98.

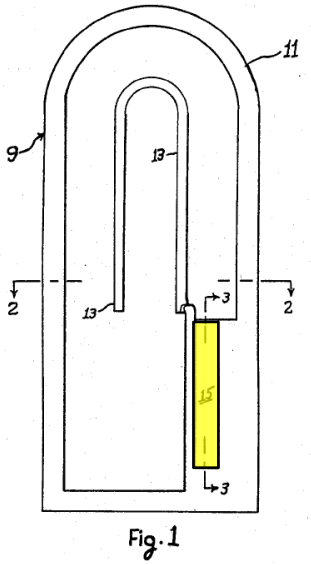
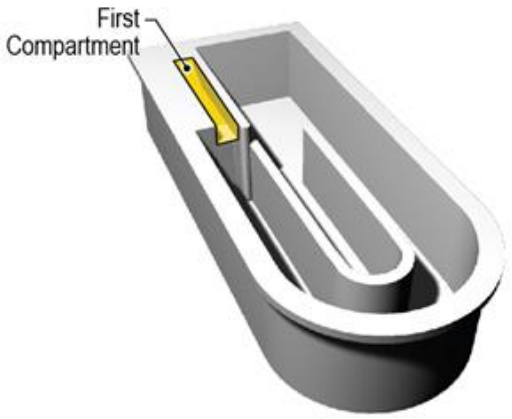


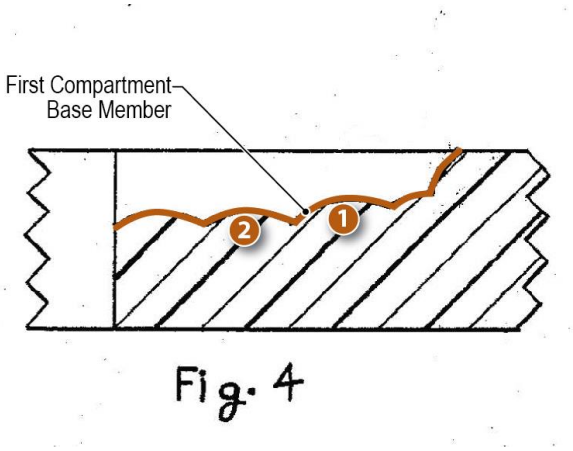
Fig. 1

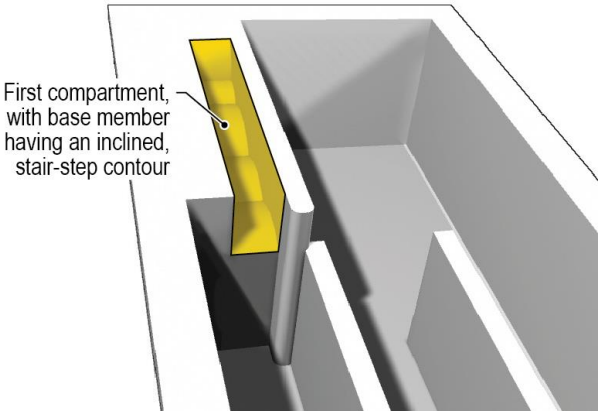


c. *Claim 1, Element C*: "with a first compartment base member having an inclined, stair-step contour and"

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

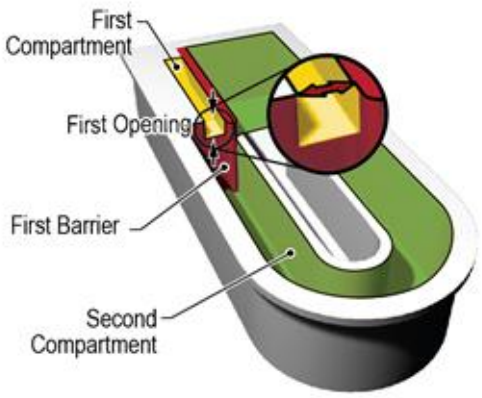
between them. The "incline" of the contour is formed throughout the base of the compartment by the curves on the platforms that rise from left to right. An incline is most dramatically displayed at the far right of figure 4 as the compartment base platform inclines upwards to meet the top of the tray. 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.

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. Kimmel Decl. at ¶ 104. 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. *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. 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 ¶ 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 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 ¶ 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, it would have been obvious to a POSA 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.

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."); U.S. Patent No. 3,485,352 to Pilger at 2:70-3:13 (Ex. 1024) ("Pilger") (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"

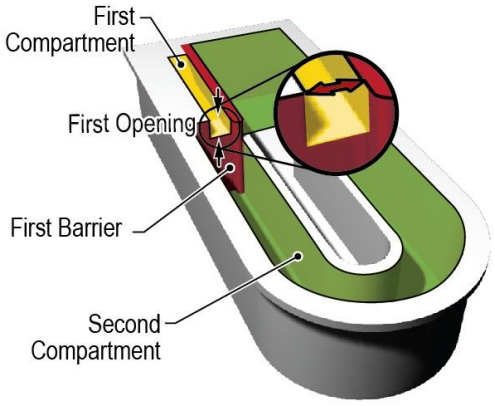
This "printed matter" limitation should be given no patentable weight. *See* Section VII.A. Even if this limitation were given patentable weight, it would have been obvious for a POSA to include the claimed instructions with Brezette. Brezette teaches discharging the contents of a container into the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



The inclusion of instructions with a urethral catheter assembly such as the one described in Brezette 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 ¶ 110; *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 ¶ 110.

A POSA would have had reason to include instructions with Brezette'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 February 27, 1997) (Ex. 1026). 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 Brezette).

Additionally, as discussed in section VII.B.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.*, 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 ¶ 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, 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 2

a. *Claim 2, Element A*: "The method of claim 1, wherein the tray further comprises a third compartment separated from the second compartment by a second barrier having a second opening therein, further comprising:"

Brezette discloses this limitation. Brezette figure 1 and perspective illustration of figure 1 are below. Kimmel Decl. at ¶ 114. 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 arrows pointing at one another in the perspective illustration identify the second opening. Kimmel Decl. at ¶ 114.

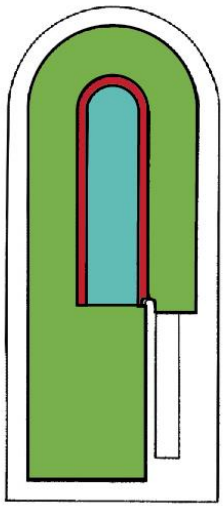
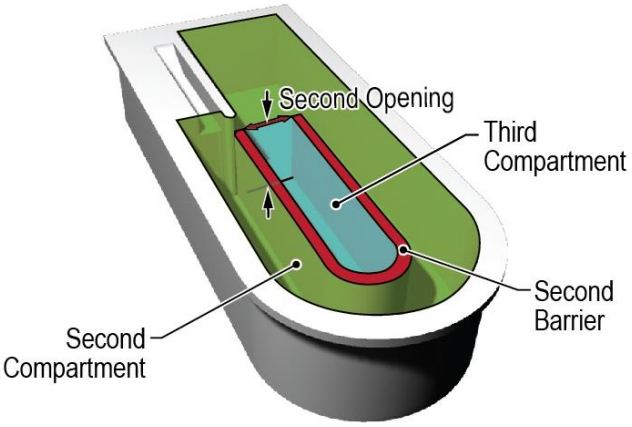


Fig. 1



b. *Claim 2, Element B*: "disposing at least one of a specimen container or a skin cleanser in the third compartment."

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 ¶¶ 115-116.

It also would have only required common sense for a POSA to place those items in the third compartment of Brezette. Carrow Decl. at ¶ 87; Kimmel Decl. at ¶ 116. A POSA would have understood that the other two compartments of Brezette already contained the lubricant and catheter assembly. It would have been a simple design choice to place the remainder of the "implements necessary to the catheterization," *e.g.*, at least a specimen container or skin cleanser, in the third compartment. Kimmel Decl. at ¶ 116-119.

3. CLAIM 3: "The method of claim 2, further comprising disposing at least another syringe in one of the first compartment or within both the opening and the second opening."

Although Brezette does not disclose disposing at least another syringe in one of the first compartment or within both the opening and the second opening, there are predictable reasons for a POSA to modify Brezette to do so such that this modification is not inventive. 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 lubricating jelly (Section VII.B.1.e, h), and the second one containing a sterile liquid for inflating the retention balloon of a catheter. Kimmel Decl. at ¶¶ 120-121.

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 ¶ 122. 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.

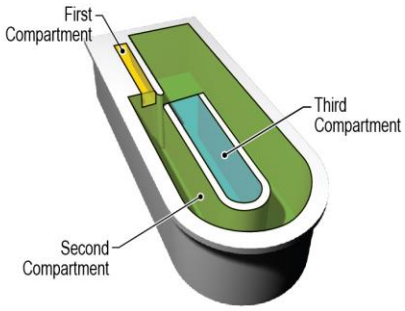
Kimmel Decl. at ¶ 122. The products in the tray also would have been generally arranged in the order in which they would be used during a procedure. Kimmel Decl. at ¶ 123; Beddow at 1:9-13 ("all of the components necessary for accomplishing a catheterization procedure … are arranged in their preferred 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 the 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 and would have provided reason for a POSA to group the syringes together. Kimmel Decl. at ¶¶ 123-124.

Given the motivation to group syringes used directly with a catheter in a catheterization procedure—and given the ease with which the first compartment in the Brezette tray could have been modified as needed—it would have been obvious for a POSA practicing Brezette to dispose at least another syringe in the first compartment. Kiimmel Decl. at ¶ 125

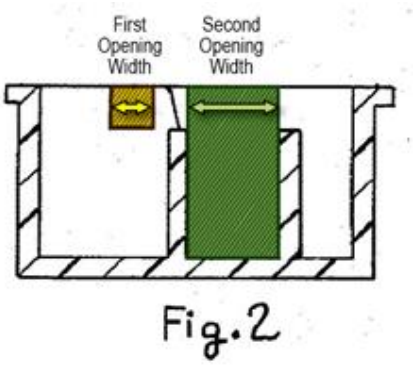
4. CLAIM 4: "The method of claim 1, wherein the tray comprises a contoured surface having at least three compartments separated by barriers and a perimeter wall."

Brezette discloses the elements of claim 4. A POSA would understand that claim 4 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 ¶ 126. The figure at right (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.

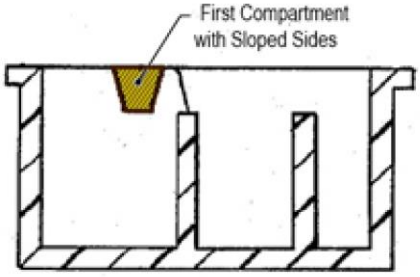


5. CLAIM 11: "The method of claim 2, wherein a first opening width of the first opening is less than a second opening width of the second opening."



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. 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.

6. CLAIM 12: "The method of claim 1, wherein the first opening is bounded by a first opening base member and two inclined first opening side members."



Modified Brezette Figure 2

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 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 ¶¶ 132-134.

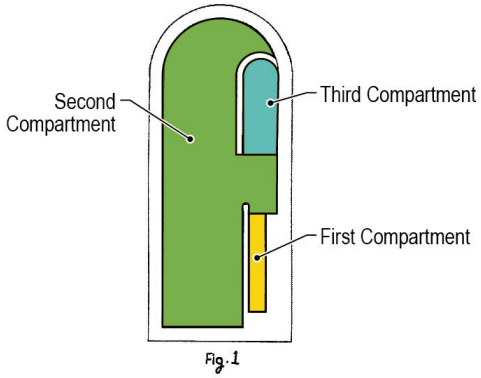
Also, it was common knowledge in the art by June 2009 that certain structures in molded plastic trays—such as opening side members and side walls—needed to be designed with a sloped angle to enable removal of the tray from a mold. Kimmel Decl. at ¶¶ 133-134. Accordingly, a POSA would have had reason to design a tray with inclined opening side members to allow for the tray to be removed easily from a mold during manufacture. Kimmel Decl. at ¶¶ 133-134.

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).

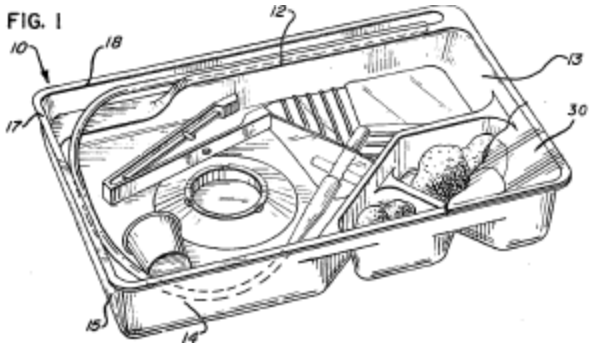
7. CLAIM 13: "The method of claim 2, wherein the second opening is bounded by a[n] opening base member, an inclined opening side member, and the perimeter wall."

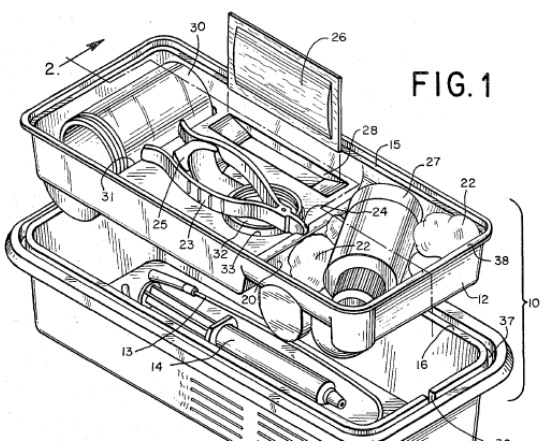
Brezette discloses a second opening bounded by an opening base member. Brezette at Fig. 2. For the reasons discussed in section VII.B.6 concerning claim 12, a POSA would have easily been able to, and had reason to, modify the second compartment so that the opening in the barrier between the second and third compartments was also bounded by an inclined second opening side member. Kimmel Decl. at ¶ 135. 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.

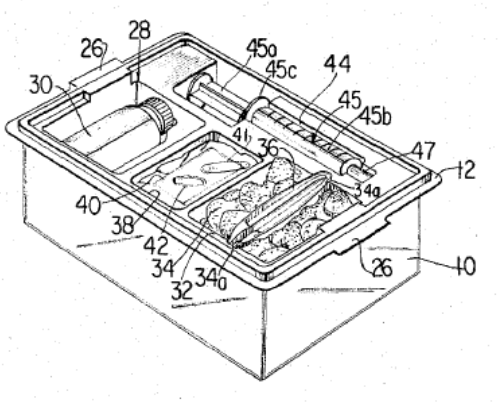
A POSA would have had a reason to modify the second compartment so that the opening in the barrier between the second and third compartment was also bounded by the perimeter wall, as shown in the modified drawing at right. Kimmel Decl. at ¶ 136. The placement of the third compartment is a simple design 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. 1030) 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).

8. CLAIM 14: "The method of claim 2, wherein the second compartment comprises a second compartment base member, 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.

9. CLAIM 15: "The method of claim 1, wherein the second compartment comprises a second compartment base member, wherein first compartment base member is configured to support the at least one syringe at a shallower depth within the tray than a depth of the second compartment base member, and in a non-parallel configuration with the second compartment base member."

Brezette discloses a tray in which the first compartment base member has a shallower depth within the tray than the depth of the second compartment base member. Brezette at Fig. 1; Kimmel Decl. at ¶ 140. Because the first compartment base member is at a shallower depth (*i.e.*, higher) than the second compartment base member, see Section VII.B.1.b above, any syringes supported in the first compartment or lubrication channel would be supported at a shallower depth within the tray than the depth of the second compartment base member. Kimmel Decl. at ¶ 140.

As discussed in section VII.B.1.c, Brezette teaches a first compartment with a inclined, stair-step contour. Any syringe disposed in the first compartment of Brezette would follow that same incline as it rested on the base member. As the second compartment base member is flat (not inclined), and the syringe in the first compartment would follow the incline and stair-step contour of the first compartment base member, the syringe would be disposed in a non-parallel configuration with the second compartment base member. Kimmel Decl. at ¶ 141. A POSA would have further been motivated to place the syringes in this

configuration, likely stacked on one another, so that the syringes are more easily accessible. *See* U.S. Patent No. 5,024,326 (Ex. 1028) 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.")

10. CLAIM 16: "The method of claim 14, wherein the at least one syringe comprises a plurality of syringes, wherein the first compartment base member is configured to support each of the plurality of syringes at different depths within the tray relative to the depth of the second compartment base member."

As discussed in section VII.B.1.c, Brezette discloses a first compartment that includes an inclined, stair-step contour. Further, as discussed in sections VII.B.1.e and VII.B.3, it would have been obvious for a POSA to dispose two or more syringes (*e.g.*, one for the lubricant and one for inflation of the balloon on the catheter) on this stair-step contour in the first compartment, such that the plurality of syringes were supported at different depths within the tray (as one possibility, stacked on one another). As discussed in section VII.B.9, the depths of the plurality of syringes would have been different relative to the second compartment base member as the syringes rested on each other. Kimmel Decl. at ¶ 142.

11. CLAIMS 17-19

Claims 17-19 are directed to a method of manufacturing a packaged catheter assembly comprising providing a tray with the same characteristics described in

claims 1-4 and 11-16, and are obvious over the same references for the same reasons described in sections VII.B.1 through VII.B.10. The tables below summarize which sections apply to which claim elements. *See also* Kimmel Decl. at ¶ 143.

'935 Claim 17	**Prior Art Reference Sections**
[A] 17. A method of manufacturing a packaged catheter assembly, comprising:	*See* Section VII.B.1.a (discussing Claim 1, element [A]).
[B] providing a tray having at least a first compartment	*See* Section VII.B.1.b (discussing Claim 1, element [B]).
[C] with a first compartment base member having an inclined, stair-step contour and	*See* Section VII.B.1.c (discussing Claim 1, element [C]).
[D] a second compartment, wherein the first compartment and the second compartment are separated by a first barrier having an opening therein, and	*See* Section VII.B.1.d (discussing Claim 1, element [D]).
[E] a third compartment;	*See* Section VII.B.2.a (discussing a "third compartment" in Claim 2, element [A]).
[F] disposing at least one syringe in the first compartment;	*See* Section VII.B.1.e (discussing Claim 1, element [E]).
[G] disposing a catheter assembly in the second compartment;	*See* Section VII.B.1.f (discussing Claim 1, element [F]).
[H] disposing a skin cleanser in the third compartment;	*See* Section VII.B.2.b (discussing "disposing a skin cleanser in the third compartment," in Claim 2, element [B]).
[I] sealing the tray;	*See* Section VII.B.1.g (discussing Claim 1, element [G]).
[J] 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	*See* Section VII.B.1.h (discussing Claim 1, element [H]).

’935 Claim 17	Prior Art Reference Sections
[K] placing a sterile wrap about the tray.	*See* Section VII.B.1.i (discussing Claim 1, element [I]).

’935 Claim 18	Prior Art Reference Sections
18. The method of claim 17, further comprising disposing at least another syringe in the tray.	*See* Section VII.B.3, discussing “disposing at least another syringe in the tray” in Claim 3).

’935 Claim 19	Prior Art Reference Sections
[A] 19. A method of manufacturing a packaged catheter assembly, comprising:	*See* Section VII.B.1.a (discussing Claim 1, element [A]).
[B] providing a tray having at least a first compartment	*See* Section VII.B.1.b (discussing Claim 1, element [B]).
[C] with a first compartment base member having an inclined, stair-step contour and	*See* Section VII.B.1.c (discussing Claim 1, element [C]).
[D] a second compartment, wherein the first compartment and the second compartment are separated by a first barrier having an opening therein, and	*See* Section VII.B.1.d (discussing Claim 1, element [D]).
[E] a third compartment;	*See* Section VII.B.2.a (discussing a “third compartment” in Claim 2, element [A]).
[F] disposing at least one syringe in the first compartment;	*See* Section VII.B.1.e (discussing Claim 1, element [E]).
[G] disposing a catheter assembly in the second compartment;	*See* Section VII.B.1.f (discussing Claim 1, element [F]).
[H] disposing another syringe in the tray;	*See* Section VII.B.3 (discussing “disposing another syringe in the tray” in Claim 3).
[I] sealing the tray;	*See* Section VII.B.1.g (discussing Claim 1, element [G]).
[J] 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 into the contents; and	*See* Section VII.B.1.h (discussing Claim 1, element [H]).

’935 Claim 19	Prior Art Reference Sections
[K] placing a sterile wrap about the tray.	*See* Section VII.B.1.i (discussing Claim 1, element [I]).

12. CLAIM 20

a. *Claim 20, Element A*: “The method of claim 19, wherein the second compartment comprises a second compartment base member,”

Brezette discloses a second compartment comprising a second base member. *See* Sections VII.B.1.d (discussing a “second compartment”) and VII.B.8 (discussing “a second base member”); Kimmel Decl. at ¶ 181.

b. *Claim 20, Element B*: “wherein the disposing another syringe comprises disposing the another syringe within both the opening and a second opening.”

As discussed in section VII.B.3, it would have been obvious to a POSA to dispose another syringe in the Brezette tray. Section VII.B.3 describes one obvious configuration for storing this second syringe, in which it was disposed in the first compartment. Section VII.B.3 further describes obvious modifications to the first compartment that a POSA would have used to accommodate two syringes in the first compartment, if needed. Kimmel Decl. at ¶¶ 182-183.

As discussed in section VII.B.7, it would also have been obvious for a POSA to modify the second compartment in Brezette so that the opening in the barrier between the second and third compartment was bounded both by the second opening side member and the perimeter wall. In using the configuration discussed in section VII.B.7, it would have been obvious to dispose the second syringe

within both the opening and a second opening. As noted before, a POSA would have been motivated to group the two syringes together because 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 balloon of the catheter. Kimmel Decl. at ¶ 184. In the configuration shown in section VII.B.7, it would be possible to accomplish this by disposing the second syringe within the opening and a second opening.

C. Ground 2: Claims 1-4 and 11-20 are obvious under 35 U.S.C. § 103 over Rauschenberger in view of Beddow and Franks-Farah

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, those claims 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. The remaining limitations either add no patentable weight (the "instructions" limitations), or it would have been obvious to a POSA to modify Rauschenberger based on his background knowledge alone or in light of, for example, Franks-Farah (showing "enclosing printed instructions").

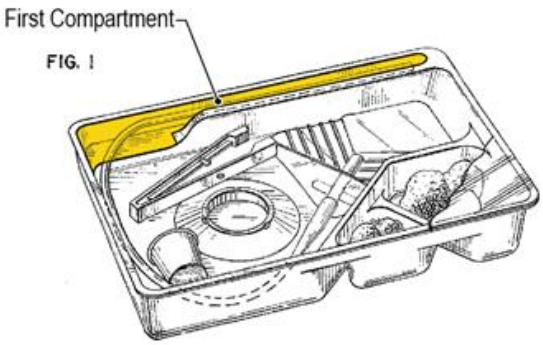
1. CLAIM 1

a. *Claim 1, 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 1:3-5 ("This invention . . . is concerned with a sterile, self-contained catheterization package . . . .").

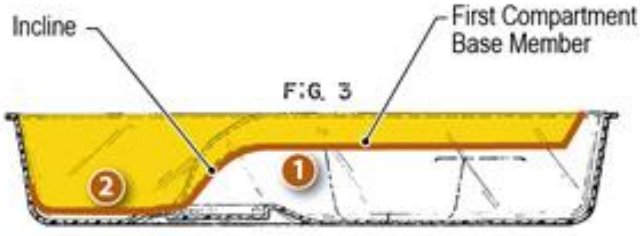
b. *Claim 1, Element B*: "providing a tray having at least a first compartment"

Rauschenberger discloses a tray having at least a first compartment, shown in the upper portion of Rauschenberger Figure 1, yellow at right. Kimmel Decl. at ¶ 145.



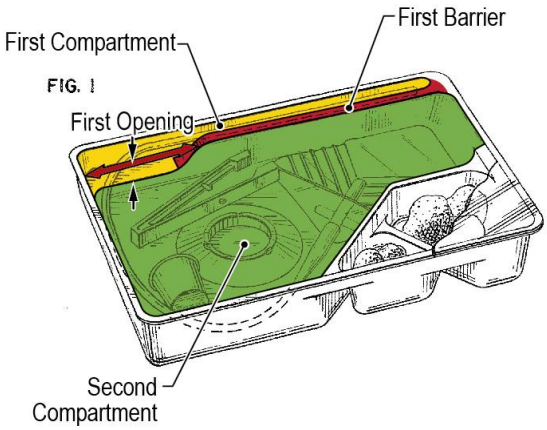
c. *Claim 1, Element C*: "with a first compartment base member having an inclined, stair-step contour and"

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 ¶ 146. 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 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.



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;"

Rauschenberger discloses this element. Rauschenberger figure 1, below, is annotated with the first compartment highlighted in yellow, the second compartment highlighted in green, the barrier shown in red, and the opening identified with a red, double-sided arrow. Kimmel Decl. at ¶ 147.



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

Rauschenberger does not disclose disposing at least one syringe in the first compartment, but does disclose disposing components for catheterization in the tray. Rauschenberger at 2:22-27. The components taught by Rauschenberger include a "lubricant packet." *Id.* at 2:30; Kimmel Decl. at ¶ 148. For the same reasons explained in section VII.B.1.e, a POSA would have been motivated by Beddow and the prior art and common sense in general, to modify the Rauschenberger tray to substitute the "lubricant packet" with a syringe and place that syringe in the first compartment. Kimmel Decl. at ¶ 149-151. The same analysis as to why a POSA would have reason to modify the first compartment in

Brezette to accommodate at least one syringe (Section VII.B.1.e) also applies here. *See also* Rauschenberger at 2:1-14 (teaching that using "variations" to the "outside" or "bottom" wall of a tray "present no problem"); Kimmel Decl. at ¶ 152. This element would have been obvious to a POSA.

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

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.

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

Rauschenberger discloses sealing the tray. Rauschenberger at 2:15-20 ("the catheterization implements are placed in tray 10 as shown in FIG. 1 and ***sealed with a cover sheet*** 30…. Cover sheet 30 is formed of conventional peelable lid stock such as coated paper or plastic which is permeable to sterilizing gases."); Kimmel Decl. at 154.

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"

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.

Rauschenberger does not disclose enclosing printed instructions. For the same reasons set forth in section VII.B.1.h, a POSA would have been motivated to include instructions with the Rauschenberger tray. Kimmel Decl. at ¶ 155-156. Also, Rauschenberger strove 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. Rauschenberger warned that procedures using prior art urethral catheterization devices created "less than ideal circumstances" for maintaining sterility. *Id.* at 1:8-43. Rauschenberger was designed to avoid such circumstances, so a POSA practicing Rauschenberger would have had reason to include instructions to inform a user how to properly use the tray and maintain sterility. Kimmel Decl. at ¶ 158.

As discussed in section VII.C.1.e, although Rauschenberger does not disclose discharging the contents of a "syringe" into the first compartment, substituting one type of container for another type of container (*e.g.*, a syringe) is an obvious substitution of components with predictable results. *See 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 ¶ 159.

Accordingly, in light of Franks-Farah (*see* Kimmel Decl. at ¶ 157), it would have been obvious to a POSA to enclose printed instructions with the Rauschenberger tray, directing a user to discharge contents of the at least one syringe into the first compartment of the Rauschenberger tray and to pass at least a portion of the catheter assembly through the opening and into the contents.

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

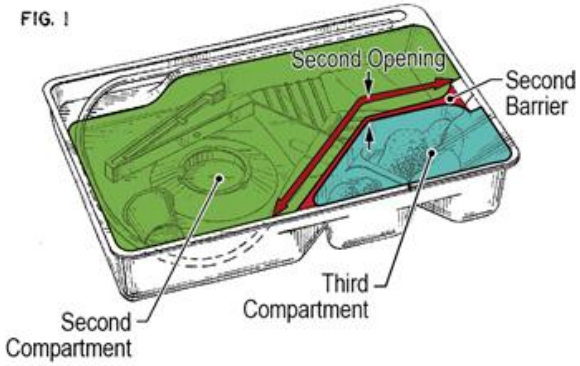
Rauschenberger acknowledges in its background that it was well known to place a sterile wrap about a catheterization tray. Rauschenberger at 1:8-14 ("Prior art devices have generally employed a tray containing the catheterization implements … ***covered with a sterile folded central supply room (CSR) wrap***."). A POSA would have been motivated to place a wrap about the tray in addition to using the cover sheet to add further protection to the package and help maintain sterility. Kimmel Decl. at ¶ 160. *See In re Gurley*, 27 F.3d 551, 553 (Fed. Cir.

1994) (finding that merely discouraging use of something is not a "teaching away"); *see also, In re Fulton*, 391 F.3d 1195 (Fed. Cir. 2004).

2. CLAIM 2

a. *Claim 2, Element A*: "The method of claim 1, wherein the tray further comprises a third compartment separated from the second compartment by a second barrier having a second opening therein, further comprising:"

Rauschenberger discloses a third compartment separated from the second compartment by a second barrier. Rauschenberger Figure 1, annotated at right, shows the second compartment highlighted green, the third compartment highlighted blue, the barrier shown in red, and the opening identified by a red, double-sided arrow. As shown, the opening in the second barrier is the space extending from the barrier to the top of the tray. Kimmel Decl. at ¶¶ 161-162



b. *Claim 2, Element B*: "disposing at least one of a specimen container or a skin cleanser in the third compartment."

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 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 ¶¶ 163-164; 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), it would have been obvious to a POSA to dispose the skin cleanser in the third compartment of the Rauschenberger tray. Kimmel Decl. at ¶¶ 165-166.

3. CLAIM 3: "The method of claim 2, further comprising disposing at least another syringe in one of the first compartment or within both the opening and the second opening."

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 ¶¶ 167-168. 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.,*

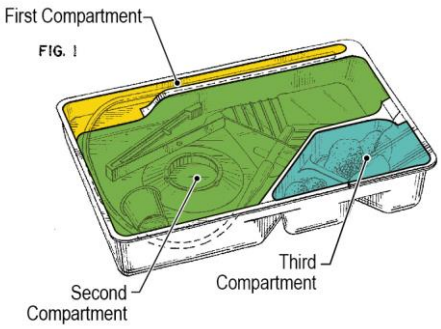
Nursing Standard at 52 & Box 1; Bardex DFU 2006; Beddow at Fig. 1; 2:50-52; Serany at 3:6-22; Pilger at 2:3-8; Carrow Decl. at ¶¶ 24, 82. Thus, a POSA would have had reason to include a second syringe in a Rauschenberger tray—a syringe of sterile liquid for inflating the balloon on a catheter. Kimmel Decl. at ¶ 169.

With respect to the placement of the second syringe in the Rauschenberger tray, as discussed in section VII.C.1.e, a POSA practicing Rauschenberger would have had a reason, in light of Beddow, to widen the first compartment of the Rauschenberger tray to accommodate the width of a syringe, if necessary. It also would have been obvious to a POSA to dispose the syringe adjacent to the first syringe (*i.e.*, in the first compartment), such that one syringe rests partially on the upper platform of the Rauschenberger stair-step contour and partially on the incline of the same contour, while the other syringe rests partially on the lower platform and partially on the incline. Kimmel Decl. at ¶¶ 170-171.

A POSA would have been motivated to place the two syringes in this configuration for the same reasons set forth in section VII.B.3 above.

4. CLAIM 4: "The method of claim 1, wherein the tray comprises a contoured surface having at least three compartments separated by barriers and a perimeter wall."

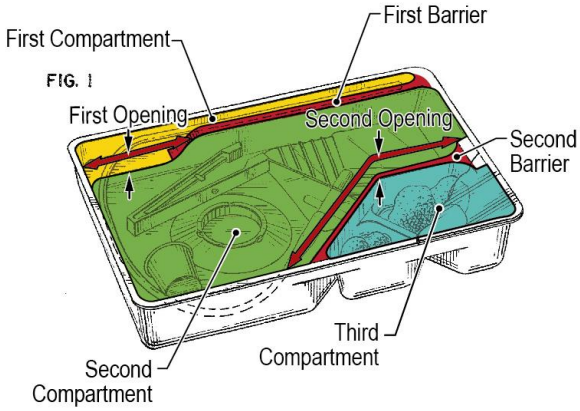
Rauschenberger discloses the elements of this claim. A POSA would understand that claim 4 should be read to have a comma between "barriers" and "and"—*i.e.,* the "perimeter wall" does not need to separate the compartments; the



tray need only have a perimeter wall (among the other elements). Kimmel Decl. at ¶ 172; *see also* Medline Initial Infringement Cont.s at App. C at 34-35 (Medline's contention as to perimeter wall). Rauschenberger Fig. 1, illustrates this configuration, as annotated at left, with the first, second, and third compartments highlighted yellow, green, and blue, and the barriers and perimeter wall in white. Kimmel Decl. at ¶ 172.

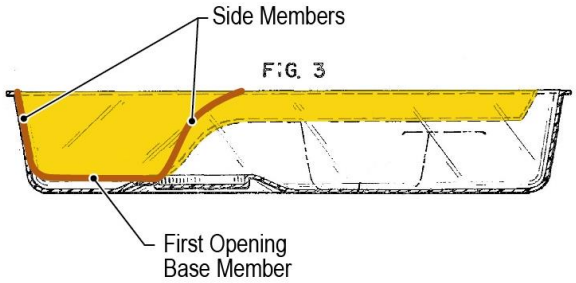
5. CLAIM 11: "The method of claim 2, wherein a first opening width of the first opening is less than a second opening width of the second opening."

As annotated in Rauschenberger Figure 1 at right, Rauschenberger discloses a width of the first opening that is less than the opening width of the second opening. Kimmel Decl. at ¶ 173. The arrows identifying the openings, each of which is the length of their respective openings, show that the first opening has a narrow width than the second opening.

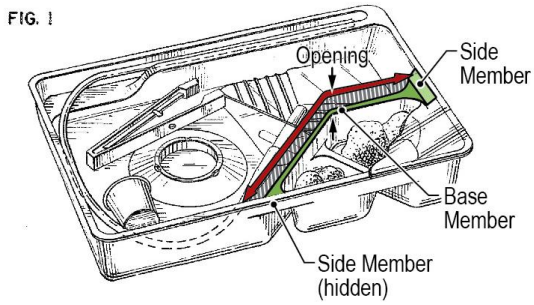


6. CLAIM 12: "The method of claim 1, wherein the first opening is bounded by a first opening base member and two inclined first opening side members."

Rauschenberger discloses a first opening bounded by a first opening base member and two inclined first opening side members. Rauschenberger Figure 1, annotated at right, shows the first opening base member and the two inclined first opening side members. Kimmel Decl. at ¶ 174.



7. CLAIM 13: "The method of claim 2, wherein the second opening is bounded by a[n] opening base member, an inclined opening side member, and the perimeter wall."



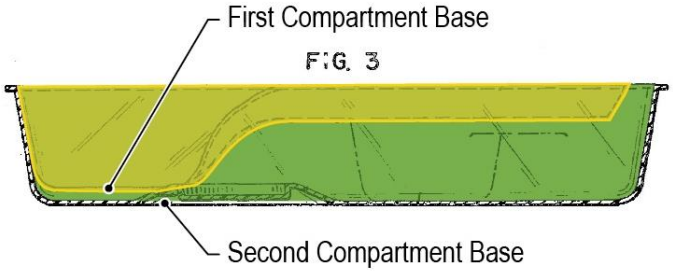
Rauschenberger discloses an opening bounded by an opening base member (as discussed in section VII.C.2.a, running along the barrier), an inclined opening side member, and the perimeter wall. Rauschenberger at Figure 1, left, shows the opening base member, the inclined opening side member, and the perimeter wall. As shown in figure 3, both side members of the second opening are inclined and constitute the perimeter wall. Kimmel Decl. at ¶ 175.

8. CLAIM 14: "The method of claim 2, wherein the second compartment comprises a second compartment base member, 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 14. Rauschenberger figure 1 shows a tray with three compartments and all of the compartments open on the side opposite the second base member, *i.e.*, the tray is open at the top. Kimmel Decl. at ¶ 176.

9. CLAIM 15: "The method of claim 1, wherein the second compartment comprises a second compartment base member, wherein first compartment base member is configured to support the at least one syringe at a shallower depth within the tray than a depth of the second compartment base member, and in a non-parallel configuration with the second compartment base member."

Rauschenberger discloses a tray in which the first compartment base member has a shallower depth within the tray than the depth of the second compartment base member, as annotated in Figure 1 below.



The first compartment base member is at a shallower depth (*i.e.*, higher) than the second compartment base member.

Any syringes supported in the first compartment (as described in section VII.C.1.c and VII.C.1.e) would accordingly be supported at a shallower depth within the tray than the depth of the second compartment base member. Kimmel Decl. at ¶ 177.

And, as discussed in section VII.C.1.c, Rauschenberger teaches that the first compartment has a base member with an inclined, stair-step contour. Accordingly, a syringe disposed in the first compartment—resting on the deeper step and the incline, as described in section VII.C.3—would be disposed in a non-parallel configuration with the second compartment base member. Kimmel Decl. at ¶ 178.

10. CLAIM 16: "The method of claim 14, wherein the at least one syringe comprises a plurality of syringes, wherein the first compartment base member is configured to support each of the plurality of syringes at different depths within the tray relative to the depth of the second compartment base member."

As discussed in section VII.C.1.c, Rauschenberger discloses an inclined, stair-step contour. Further, as discussed in sections VII.C.1.e and VII.C.3, it would have been obvious for a POSA to dispose two or more syringes on this stair-step contour, such that each of the plurality of syringes were supported at different depths within the tray. As discussed in section VII.C.9, these depths are different relative to the second compartment base member. Kimmel Decl. at ¶ 179.

11. CLAIMS 17-19

Claims 17-19 are directed to a method of manufacturing a packaged catheter assembly comprising providing a tray with the characteristics described in claims

1-4 and 11-16, and are obvious over the same references for the same reasons described in sections VII.C.1 through VII.C.10. The tables below summarize which sections apply to which claim elements. *See also* Kimmel Decl. at ¶180.

'935 Claim 17	**Prior Art Reference Sections**
[A] 17. A method of manufacturing a packaged catheter assembly, comprising:	*See* Section VII.C.1.a (discussing Claim 1, element [A]).
[B] providing a tray having at least a first compartment	*See* Section VII.C.1.b (discussing Claim 1, element [B]).
[C] with a first compartment base member having an inclined, stair-step contour and	*See* Section VII.C.1.c (discussing Claim 1, element [C]).
[D] a second compartment, wherein the first compartment and the second compartment are separated by a first barrier having an opening therein, and	*See* Section VII.C.1.d (discussing Claim 1, element [D]).
[E] a third compartment;	*See* Section VII.C.2.a (discussing a "third compartment" in Claim 2, element [A]).
[F] disposing at least one syringe in the first compartment;	*See* Section VII.C.1.e (discussing Claim 1, element [E]).
[G] disposing a catheter assembly in the second compartment;	*See* Section VII.C.1.f (discussing Claim 1, element [F]).
[H] disposing a skin cleanser in the third compartment;	*See* Section VII.C.2.b (discussing "disposing a skin cleanser in the third compartment," in Claim 2, part [B]).
[I] sealing the tray;	*See* Section VII.C.1.g (discussing Claim 1, element [G]).
[J] 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	*See* Section VII.C.1.h (discussing Claim 1, element [H]).
[K] placing a sterile wrap about the tray.	*See* Section VII.C.1.i (discussing Claim 1, element [I]).

’935 Claim 18	Prior Art Reference Sections
18. The method of claim 17, further comprising disposing at least another syringe in the tray.	*See* Section VII.C.3, discussing “disposing at least another syringe in the tray” in Claim 3).

’935 Claim 19	Prior Art Reference Sections
[A] 19. A method of manufacturing a packaged catheter assembly, comprising:	*See* Section VII.C.1.a (discussing Claim 1, element [A]).
[B] providing a tray having at least a first compartment	*See* Section VII.C.1.b (discussing Claim 1, element [B]).
[C] with a first compartment base member having an inclined, stair-step contour and	*See* Section VII.C.1.c (discussing Claim 1, element [C]).
[D] a second compartment, wherein the first compartment and the second compartment are separated by a first barrier having an opening therein, and	*See* Section VII.C.1.d (discussing Claim 1, element [D]).
[E] a third compartment;	*See* Section VII.C.2.a (discussing a “third compartment” in Claim 2, element [A]).
[F] disposing at least one syringe in the first compartment;	*See* Section VII.C.1.e (discussing Claim 1, element [E]).
[G] disposing a catheter assembly in the second compartment;	*See* Section VII.C.1.f (discussing Claim 1, element [F]).
[H] disposing another syringe in the tray;	*See* Section VII.C.3 (discussing “disposing another syringe in the tray” in Claim 3).
[I] sealing the tray;	*See* Section VII.C.1.g (discussing Claim 1, element [G]).
[J] 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 into the contents; and	*See* Section VII.C.1.h (discussing Claim 1, element [H]).
[K] placing a sterile wrap about the tray.	*See* Section VII.C.1.i (discussing Claim 1, element [I]).

12. CLAIM 20

a. *Claim 20, Element A*: "The method of claim 19, wherein the second compartment comprises a second compartment base member,"

Rauschenberger discloses this element. *See* Sections VII.C.1.d (discussing a "second compartment") and VII.C.8 (discussing "a second base member").

b. *Claim 20, Element B*: "wherein the disposing another syringe comprises disposing the another syringe within both the opening and a second opening."

As discussed in section VII.C.3, it would have been obvious to a POSA to dispose another syringe in the Rauschenberger tray. Section VII.C.3 discussed one obvious arrangement of syringes. It would also have been obvious for a POSA practicing Rauschenberger in light of Beddow to dispose the second syringe within both the opening in the first barrier and the opening in the second barrier (and necessarily, atop the catheter), as this would allow a user to grasp the second syringe early in the catheterization procedure. Kimmel Decl. at ¶ 184. As noted previously, a POSA would have taken into account the practice of arranging products in the tray in the order in which they would be used. Kimmel Decl. at ¶ 184; *see* Section VII.B.3. It was common knowledge that a practitioner using the catheter would want to attach a syringe of sterile fluid to the catheter. Carrow Decl. at ¶¶ 24, 82. Accordingly, a POSA would have had reason to group the sterile liquid syringe with the catheter as well as store the syringe in the manner described above.

D. Patent Owner's alleged secondary considerations

During prosecution, the Patent Owner offered four articles (Exs. 1034-1037) 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. 1031) at 12; '935 FH at 5/31/11 Resp. (Ex. 1032) at 15-16; '935 FH at 4/3/13 Resp. (Ex. 1033) 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, 1580-81 (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. 1037) **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. 1037 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,

/Jason M. Honeyman/

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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 /Jason M. Honeyman/