Filed on behalf of C.R. BARD, INC.
By: Richard F. Giunta
Jason M. Honeyman
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, MA 02210
Tel: (617) 646-8000
Fax: (617) 646-8646
RGiunta-PTAB@wolfgreenfield.com
JHoneymand-PTAB@wolfgreenfield.com

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 8,448,786

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,448,786 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *et seq*.

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1038	U.S. Patent No. 8,678,190 (“’190 Patent”)
1039	U.S. Patent No. 8,631,935 (“’935 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 1 and 2 of U.S. Patent No. 8,448,786 ("the '786 patent") (Ex. 1001).

I. INTRODUCTION

The challenged '786 patent claims recite old, existing techniques for using catheterization packages. The one independent claim of the '786 patent is directed to: (1) opening a bag that has a tray with a catheter assembly, (2) accessing an instruction manual, and (3) unfolding one or more layers of wrap from the package to expose an additional layer of wrap for placing beneath a patient. The only additional element dependent claim 2 adds is (4) that the claimed instructions contain a health care services portion and patient portion which are detachably coupled to each other.

All of these elements and steps were well known by the earliest possible critical date for the '786 patent, June 2009. This patent is precisely the type contemplated in *KSR*: the challenged claims merely recite prior art elements, used in their conventional way, to achieve predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

(1) Opening a bag with a catheter assembly. Using a bag to contain medical kits such as catheterization kits is old art. **Serany**, U.S. Patent No. 3,329,261 (Ex. 1008), issued in ***1967***, is directed to a "ready to-use-package

containing components for a catheterization procedure." Serany at 1:8-9. Serany describes the package as being contained in a bag, identified as 16 in figures 1 and 2 below:

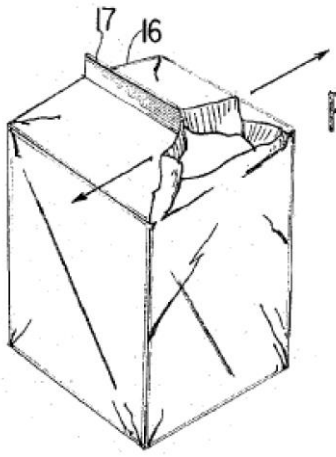


FIG. 1

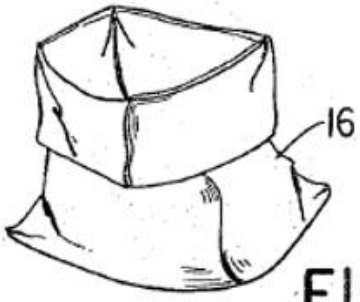


FIG.2

During a catheterization procedure, a practitioner would open this bag to access the catheter assembly and other components. *Id.* at 1:60-72. Declaration of Susan Carrow, MSN/Ed, CEN, RN at ¶¶ 17-18 ("Carrow Decl.") (Ex. 1004); Declaration of Dr. Robert Kimmel at ¶¶ 64, 215-216 ("Kimmel Decl.") (Ex. 1002).

(2) Accessing an instruction manual. This element should be given no weight as the instruction manual does not have a functional relationship with the package, and at the least, adds nothing to the use of the package that would make it 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").

Even if the "instruction manual" limitation is given weight, one of skill in the art would have been motivated by her own common sense to include such an instruction manual with the Serany kit. 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 instructions with catheterization kits prior to June, 2009. *See* "Guidance for the Content of Premarket Notifications of Conventional and Antimicrobial Foley Catheters" (written prior to Feb. 27, 1997) (Ex. 1026).

(3) Unfolding layers of wrap from the package to place beneath the patient. Serany discloses that after opening the outer bag, and unwrapping one layer of wrap, an additional wrap such as an underpad is exposed so that it can "be placed under the patient." Serany at 2:21-26. **Gittins** (Ex. 1013) affirms that it was routine procedure before 2009—in ***1970***—to place a sterilized drape or wrap "under the hips and between the legs of the patient." *Id.* at 1:22-34.

Those are the only elements of the one independent claim of the '786 patent. The ***fourth element, that the instructions contain a health care services portion and patient portion which are detachably coupled to each other***, is recited in dependent claim 2. Providing such detachably coupled instructions would have been obvious to one of skill in the art as of the earliest priority date. Medical companies, including as pharmaceutical companies, have been utilizing such

detachable instructions for years. The European Commission started issuing a series of guidelines in the late-1990s (**1998 EC Guidelines** (Ex. 1007) instructing medicinal manufacturers that, "[f]or a product administered by a health professional . . . instructions for use . . . could be included at the end of the patient leaflet ***in a tear-off portion***, to be removed prior to giving the leaflet to the patient." 1998 EC Guidelines at 12.[1] Such instructions for use could also be "provided in the product package." *Id.* Practitioners, by June 2009, understood that there would be instances where it would be important to educate a patient about their catheter. Carrow Decl. at ¶¶ 34-39, 43. A POSA would have been motivated to use the "tear-off" or detachably couple instructions described in the EC Guidelines to provide such education.

At most, the '786 patent claims are directed to a method that is "likely the product not of innovation but of ordinary skill and common sense," *KSR* 550 U.S. at 421. Bard respectfully requests the Board institute an *inter partes* review of claims 1 and 2 of the '786 patent and find those claims unpatentable.

[1] Emphasis is added throughout this Petition unless otherwise noted.

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 ("Petition") as to claims 1 & 2 of the '786 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 and 2 of U.S. Patent No. 8,448,786; claims 1-4, 7-8, 10-23, 25, 27-28, 30, and 31-34 of U.S. Patent No. 8,631,935; and claims 1-7 and 9-18 of U.S. Patent No. 8,678,190. The '786, '935, 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 to facilitate consistent outcomes, Bard requests that the Patent Trial and Appeal 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 '786 patent include U.S. Patent Nos. 8,631,935; 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

Lead Counsel	Richard F. Giunta (Registration No. 36,149)
Backup Counsel	Jason M. Honeyman (Registration No. 31,624)
Service Information	Email: RGiunta-PTAB@wolfgreenfield.com JHoneyman-PTAB@wolfgreenfield.com Post and hand delivery: Wolf Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210-2206 Telephone: 617-646-8000 Facsimile: 617-646-8646

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 pursuant to 37 C.F.R. § 42.104(a) that the ’786 patent is available for *inter partes* review and that Bard is not barred or estopped from requesting *inter partes* review as to the ’786 patent claims identified herein.

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

Bard seeks cancellation of claims 1 and 2 of the '786 patent.

A. Patents and printed publications upon which Bard relies

In seeking cancellation of the claims listed above, Bard relies on the following patents and printed publications:

1. U.S. Patent No. 3,329,261 ("Serany") (Ex. 1008)

"Serany," titled "Catheterization Package," issued on July 4, 1967 and is assigned to Petitioner, Bard. Serany is prior art to the '786 patent under 35 U.S.C. § 102(b). Though of record, Serany was not applied by the Examiner during the prosecution of the application that led to the '786 patent.

Serany discloses a "ready-to-use package containing components for a catheterization procedure." Serany at 1:8-9. Serany also discloses a method of using the catheter package nearly identical to the independent and dependent claims of the '786 patent. Specifically, Serany describes the use of a molded plastic tray stacked upon a second tray, the two stacked trays, together, containing the various components utilized in a catheterization procedure, including the catheter tubing/assembly itself. Serany at 1:26-30; 1:59-72; 2:40-41; 3:23-24.

Serany also explicitly discloses one or more layers of wrap folded about and enclosing the catheter tray. *See* Serany at 1:60-63 ("[A] box 10 having an open top with a tray 12 mounted thereon is enclosed within a wrap 14."); *see also id*. at Figs.

2, 2a, 3. Thus, this assembly is wrapped in sterile wrap which is adapted to be unfolded to provide a sterile field as the components are removed from the package and used. Serany at 2:1-20.

Serany also describes that, in addition to this outermost wrap, several pieces of folded wrap material designated as an underbuttocks pad and a fenestrated drape are contained within the catheter kit, each of which are made of wrap material and can be spread out to create a sterile field. Serany at 2:21-32.

Finally, Serany describes a sealed bag disposed about a tray. Serany at 1:60-66. Serany alternates between calling this bag an "envelope" (*id.*) and a "bag" (3:57-58) and Serany teaches the bag was made of a "transparent and flexible plastic film, ha[ving] a heat seal." Serany at 1:60-68.

2. A Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use, Published September 29, 1998 ("1998 EC Guidelines") (Ex. 1007)

The "1998 EC Guidelines" are a 1998 publication by the European Commission, Enterprise and Industry Directorate-General, Consumer Goods; Pharmaceuticals Group. There is also a 2009 version[2] of the 1998 EC Guidelines, which indicate that they supersede the 1998 version. Both Guidelines are identical for purposes of this Petition, though the 1998 EC Guidelines are used in this Petition in the event the Patent Owner attempts to establish an invention date prior

[2] http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm

to January 2009, the publication date for the 2009 EC Guidelines. Neither of the EC Guidelines were of record during prosecution of the application giving rise to the '786 patent.

Although the 1998 EC Guidelines are primarily directed to "medicinal products," *i.e.*, pharmaceuticals, as opposed to "medical products" or "medical devices" a POSA prior to June, 2009 would have looked to the 1998 EC Guidelines to inform what best practices and available guidelines exist for designing packaging for catheterization trays and for guidance on what materials should be included within such packaging. Kimmel Decl. at ¶¶ 20, 23, 110, 158. The 1998 EC Guidelines state that the Guidelines are "for use by applicants for a marketing authorization (MA). It provides guidance on the factors which influence readability . . . [and] gives guidance on how each item on the label should be expressed. . . . [e]nsuring that the label and package leaflet are readable is the primary objective of this guideline." 1998 EC Guidelines at 2.

Section C of the 1998 EC Guidelines is entitled "Leaflet Format." As described in the Guidelines, the "The information contained in the leaflet . . . must be phrased so that it is ***readily understandable for the patient***." 1998 EC Guidelines at 11. Part 6 of Section C deals with a "product administered in hospital" and a "product administered by a health professional." *Id.* at 12 (underlining original). The 1998 EC Guidelines states that:

6.1 For a product administered in hospital additional package leaflets may also be provided separately from the product package; e.g. a pad of tear-off leaflets supplied to the hospital for distribution to patients, as required. In this case the SPC [Summary of Product Characteristics] (e.g. for the hospital staff) could be provided in the product package. When the package leaflet is provided separately, the MA holder should take appropriate measures to enable the hospital staff to provide the patient with the current version of the package leaflet.

6.2 For a product administered by a health professional, information from the SPC for the health professional (e.g. the instructions for use, inter alia) could be included at the end of the patient leaflet in a tear-off portion, to be removed prior to giving the leaflet to the patient..

Id. at 12.

3. U.S. Patent No. 6,840,379 ("Franks-Farah") (Ex. 1009)

Franks-Farah issued on January 11, 2005 and constitutes prior art to the '786 patent under 35 U.S.C. § 102(b).

Franks-Farah describes a method and system for performing intermittent male catheterization by a patient, a patient's caregiver, or a health care provider. *See* Franks-Farah at Abstract. As recited in Franks-Farah, the system "contains at least: (I) infection prevention devices (gloves, disposable wipes, zipper bags, alcohol gel (i.e., a waterless cleaner), soap, and protective underpads); (II) insertion devices (catheter and lubricant); (III) recording devices (urine record card and collection basin); and (IV) information devices (step-by-step instructions,

contents map and self-care documentation) among other items." Franks-Farah at 3:39-46.

Also, the Franks-Farah reference discloses two sets of instructions included within the kit itself. First are step-by-step illustrated instructions for using the catheter kit to perform a catheterization procedure. Franks-Farah at 2:33:37; 7:4-10. The kit also includes "self-care documentation" whereby the "instructor (i.e., a doctor, nurse, clinician or other medical professional) uses the self-care documentation to educate the user in performing an intermittent male catheterization… the medical professional then keeps the self-care documentation documenting that the user was educated in performing the male catheterization." *Id.* at 2:44-55. Such "self-care documentation" is designed to ensure that the physician provides adequate instruction to the catheter patient about the self-catheterization procedure by requiring that the physician memorialize having provided such instructions to the patient. *See also id.* at 7:4-41.

B. Priority date of claims 1 and 2

As a continuation-in-part application, the '786 patent is entitled to the priority date from the earliest application in the chain supporting the claim. *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1360 (Fed. Cir. 2012). The earliest application to which the '786 patent claims priority, application no. 12/495,148, was filed on June 30, 2009. Without conceding that the '148

application supports the claims of the ’786 patent, Bard assumes for purposes of this Petition and proceeding that the priority date of claims 1 and 2 of the ’786 patent is June 30, 2009.

C. Level of ordinary skill in the art

The person of ordinary skill in the art of the ’786 patent 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. In the alternative, the POSA would have had a bachelor’s degree in an alternative technical field and about two years’ experience in the packaging of medical devices. The POSA 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 health care 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). Kimmel Decl. at ¶¶ 21, 23, 47.

D. Statutory grounds for challenge

Cancellation of claims 1 and 2 of the ’786 patent is requested on the following grounds. Although Petitioner presents only two primary grounds for unpatentability (Grounds 1 and 2), each of those grounds has lettered, sub-grounds. Explained in each section below, the application of those sub-grounds depends

upon factors such as the Board's findings concerning the general knowledge of a POSA in June 2009 and the Board's construction of certain terms (*e.g.*, "a" and "tray").

Ground	Reference(s)	Claims	Basis
1A	Serany (U.S. Pat. No. 3,329,261)	1	§ 102/ § 103
1B	Serany in combination with Franks-Farah (U.S. Pat. No. 6,840,379)	1	§ 103
1C	Serany in combination with Franks-Farah and Brezette (U.S. Pat. No. 3,978,983)	1	§ 103
2	Ground 1A, B, or C in combination with The European Commission Guideline On The Readability of the Label And Package Leaflet of Medicinal Products for Human Use ("1998 EC Guidelines")	2	§ 103

E. Claim construction

In this proceeding, claim terms should be given their broadest reasonable interpretation in view of the specification (which may be different from the proper construction in court). 37 C.F.R. § 42.100(b). The terms requiring construction 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. '786 patent at 3:34-38 ("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***."). There is nothing in the context of the '786 patent claims where the word "a" appears (especially in the context of "a tray") that would lead a POSA to believe the Patent Owner intended to deviate from this explicit definition. Kimmel Decl. at ¶ 65.

2. "tray"

The term "tray" is a limitation in both challenged claims of the '786 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 '786 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 ¶¶ 66-76. The background section states that one type of tray can be a "flat plastic tray." '786 patent at 1:62-63.

The specification further provides exemplary dimensions of a tray that is shorter in height than it is wide (*id*. at 4:57-63 (disclosing illustrative height of 1.750 inches and illustrative width of nine inches)), and provides figures that depict a tray as container that is shorter than it is wide (*see* '786 patent, Fig. 1).

Art of record also supports a broad construction of the term "tray." United States Publication No. 2004/0004019 ("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."

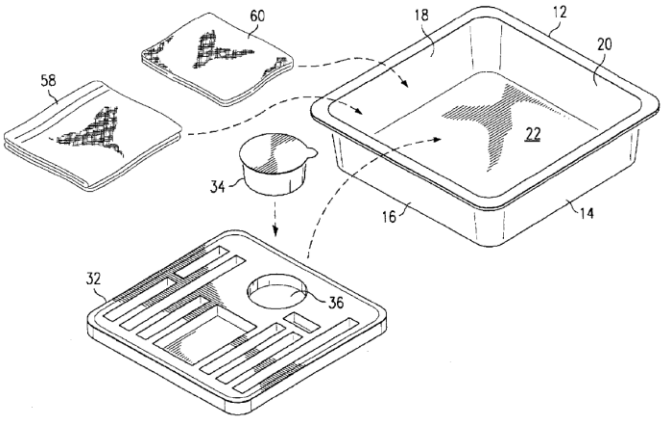


FIG. 3

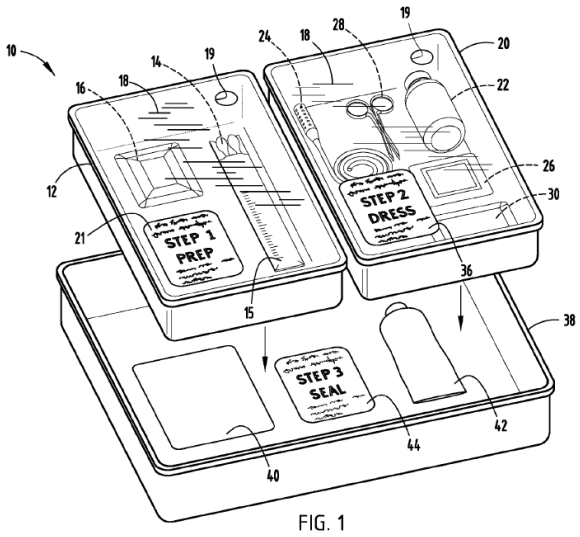
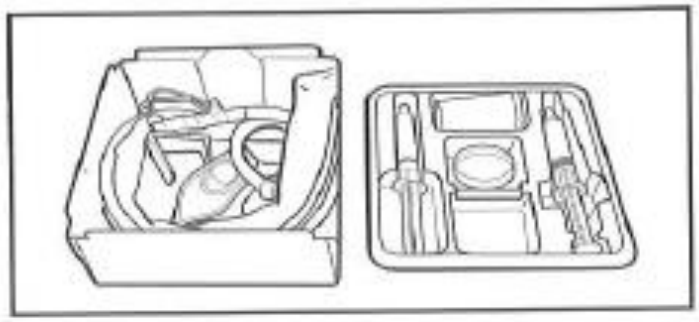


FIG. 1

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. 2 (at left).

Also, neither the ordinary meaning, nor the specification of the '786 patent, limit a tray to a particular manner of manufacture. *See, e.g.*, '786 patent at 4:46-

56. 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 it was 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) ("Bardex DFU 2010") (Ex. 1029); Kimmel Decl. at ¶¶ 74-76.

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. "accessing an instruction manual"

Claim 1 of the '786 patent recites "accessing an instruction manual." The term "accessing an instruction manual" should be given its broadest reasonable construction in view of the specification in which it appears and should be construed to mean **accessing an instruction manual from the catheterization package or elsewhere**.

Claim 1 does not indicate ***from where*** such instruction manual must be accessed. The specification of the '786 patent indicates that "accessing an instruction manual" directly from the contents of the catheter assembly package itself is merely **an embodiment** of the claimed invention. For example, at col. 26 lines 3-11, the '786 patent states, "[t]urning now to FIGS. 31, 32, and 33, illustrated therein is ***one embodiment*** of a method of using the packaged catheter assembly 2901 of FIG. 29 … The health care services provider 3101 can then **access the instruction manual 1001 that is disposed atop the packaged catheter assembly 2901 in this *illustrative embodiment***."

It is axiomatic that a patentee is entitled to the "full scope" of his claims, and should not be limited to a preferred embodiment. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005); *Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009); *see FedEx Corp. v. IPVenture, Inc.*, No. IPR2014-00833, 2014 WL 6847484, at *4 (PTAB Dec. 3, 2014) (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 to that configuration. *Prima Tek II, LLC v. Polypap*, 318 F.3d 1143, 1148 (Fed. Cir. 2003); *see also Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1323 (Fed. Cir. 2008). In fact, even when patentees disclose only a single embodiment, the claims will not be read restrictively unless the patentees have demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion. *Linear Tech. Corp. v. Int'l Trade Comm'n*, 566 F.3d 1049, 1058 (Fed. Cir. 2009).

The language of the '786 patent specification does not limit the term "accessing an instruction manual" to only the case where such manual is accessed from within the catheter assembly package. The '786 patent specification directs that "[p]rinted instructions 1001 **can** then be attached to, disposed upon, or disposed within the tray 100." '786 patent at 18:27-28. The '786 patent envisions this inclusion as "**optional**." *Id.* at 16:47-56 ("Prior to depositing the packaged catheter assembly 2901 into the bag 2902, optional printed instructions 1001 can be attached to or disposed upon the packaged catheter assembly 2901 as well.").

Neither the claims nor the specification of the '786 patent indicates that printed instructions included ***within*** the package itself is a ***required*** element of the invention or should be imparted to the meaning of the term "accessing" as that term appears in claim 1.

Based on the exemplary language used throughout the specification, the claim term "accessing an instruction manual" should not be limited to the case wherein the instruction manual is packaged with the catheter assembly itself and accessed therefrom, although it certainly includes such embodiments. Per the plain language of the claims as further highlighted by the '786 specification, the user carrying out the method recited in claim 1 of the '786 patent may access the instruction manual from the package itself or from any other source.

The term "accessing an instruction manual" should therefore be construed as **accessing an instruction manual from the catheterization package or elsewhere**.

4. "bag"

The term "bag" appears in claim 1 of the '786 patent, reciting "opening a thermally sealed bag disposed about a tray." The term "bag" should be given its broadest reasonable construction in view of the specification in which it appears and should be construed to mean **a flexible container.**

Again, the claims of the '786 patent do not themselves impart a specific meaning to the standalone term "bag" (*e.g.*, without the modifiers "thermally sealed"). The specification of the '786 patent broadly states:

> the assembly can be sealed in a **sterile wrap such as a bag 2902**, which may be thermally or otherwise sealed. The completed assembly 3001 is shown in FIGS. 30 and 37, where an outer

packaging material is shown. In FIGS. 30 and 37, the outer packaging material is a thermally sealed bag 2902.

'786 patent at 17:6-11.

As shown in medical dictionaries accessible in June 2009, the term "bag" refers generally to "a flexible container." *See* Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition, 2003 at 190 (Ex. 1018) ("bag – a flexible container; see also POCKET, POUCH and SAC."); Dorland's Illustrated Medical Dictionary 31st Edition, 2007 (Ex. 1019) (same).

As used in the '786 patent and as understood by one of skill in the art, the term "bag" broadly refers to a flexible container. The term "bag" should be broadly construed to refer to **a flexible container**.

5. "wrap"

The term "wrap" appears in the third limitation, of claim 1 which recites the step of "unfolding one or more layers of wrap." 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 further defined in the claims and the specification uses the term broadly in multiple different ways. For example, the specification references "sterile plastic wrap" ('786 patent at 1:58-59) as being a mode of packaging traditional catheters which suffered from being prone to damage

because the "wrap" provided little physical protection. *Id.* at 1:57-61. The '786 patent goes on to state that the catheter tray presented as the invention,

> can be sealed with a wrap 1000 to keep the internal components sterile. The wrap 1000 can be **any of a number of types of material**. In one embodiment, the wrap 1000 comprises a central sterile reprocessing (CSR) wrap that is widely used by medical professionals…while **CSR wrap is one example** of a wrap that can be used, it will be clear to those of ordinary skill in the art that **other wraps, such as plastic, cotton, linen, paper or combinations thereof**, can be substituted without departing from the spirit and scope of the invention.

Id. at 10:14-24.

The '786 patent specification also contemplates that such wrap can be placed over or under a patient. *Id.* at 14:48-52 ("In many catheterization procedures, a first layer of material will be placed under the patient, while a second layer of material is placed atop the patient. For such applications, the packaged catheter assembly can include an additional layer of wrap material 2701."). Indeed, the '786 patent explicitly contemplates that wrap material 2701 can constitute a patient drape or under-buttocks drape or a combination thereof. *Id.* at 15:45-49 ("Also as with FIG. 27, the packaged catheter assembly can include an additional layer of material 2701, which may be a patient drape, under-buttocks drape, or a combination thereof disposed within one or more layers of wrap material 2200.").

Given this broad use of the term "wrap" in the '786 patent specification, the proper construction for the claim term "wrap" should **a flexible material capable of being placed about an object**.

6. "additional layer of wrap"

The third limitation of claim 1 of the '786 patent recites the step of "unfolding one or more layers of wrap to reveal an *additional layer of wrap* and the catheter assembly." The term "additional layer of 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 the same as "wrap," *i.e.*, **a flexible material capable of being placed about an object**.

None of the claims further define the term "additional layer of wrap." The specification, however, describes that the additional layer of wrap can be made of the same material as the first layer or it can be made of a different material. *Id.* at 14:57-61. Further, the additional layer of wrap does not need to be wrapping or enveloping the catheter assembly to constitute a "wrap":

> In many catheterization procedures, a first layer of material will be placed under the patient, while a second layer of material is placed atop the patient. For such applications, the packaged catheter assembly can include an additional layer of wrap material 2701. ***In the illustrative embodiment of FIG. [27], the additional layer of wrap material 2701 comprises a folded layer of CSR wrap*** measuring 17 by 17.5 inches. ***The additional layer of wrap material 2701 in***

> ***this illustrative embodiment is folded as a 4 by 2 matrix***. The one or more layers of wrap material 2200 and the additional layer of wrap material 2701 can be the same type of material. Alternatively, the one or more layers of wrap material 2200 and the additional layer of wrap material 2701 can be different. In one embodiment, for example, the additional layer of wrap material 2701 can be a fenestrated wrap with one or more pre-formed openings suited to the catheterization procedure.

Id. at 14:46-64.

Given this broad disclosure without further limitation, the term "additional layer of wrap" should be broadly construed to mean the same as "wrap," *i.e.*, **a flexible material capable of being placed about an object**.

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 and 2 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. 1003), an Associate Professor of Packaging Science at Clemson University.

VII. CLAIM-BY-CLAIM EXPLANATION OF GROUNDS FOR UNPATENTABILITY OF CLAIMS 1 & 2

Claim 1, as the only independent claim in the ’786 patent, is representative of the alleged invention described in the claims of the ’786 patent and is reproduced below. The letters in brackets preceding the claim elements—*e.g.*, [A]—will be used throughout this Petition as shorthand references for those elements:

> **[A]** A method of using a catheter package assembly, comprising:
>
> **[B]** Opening a thermally sealed bag disposed about a tray having a catheter assembly disposed therein;
>
> **[C]** accessing an instruction manual;
>
> **[D]** unfolding one or more layers of wrap to reveal an additional layer of wrap and the catheter assembly; and
>
> **[E]** placing one or more layers of wrap or the additional layer of wrap beneath a patient, thereby transforming an area beneath the patient from a non-sterile field to a sterile field.

A. The ’786 patent’s “instruction manual” limitations should be given no patentable weight

Independent claim 1 recites “accessing an instruction manual” and dependent claim 2 puts further limitations on the design of that instruction manual. Neither claim is specific about the subject matter of the instruction manual; the user might access an instruction manual concerning heart surgery and still meet the limitations of the claims. Even assuming that the manual related to use of the catheterization assembly, accessing such instructions during the use of a

catheterization kit also would have been obvious to one skill in the art. *See* Section VII.B.

Absent some "functional relationship"—which is not present here—the mere inclusion or use of an instruction manual 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 "instructions" limitations impart no functional connection between the printed matter (the instructions) and the known method of using a catheterization

kit—let alone a "new and unobvious functional relationship." Indeed, the "accessing instructions" limitation and the further limitation regarding the instructions in claim 2 do not have *any connection with the catheterization kit at all*. *See* Section V.E.3 (construing "accessing an instruction manual"). Independent claim 1 merely recites "accessing" some sort of generic instruction manual—presumably instructions to use a catheterization tray 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 using a catheterization kit, was well known prior to 2009. *E.g.*, Carrow Decl. at ¶¶ 15-30 and section VII.B. The limitation of "accessing an instruction manual," like the limitation of "informing a patient" regarding a drug as analyzed in *King Pharmaceuticals*, falls short of converting this known method of manufacturing into an invention. The use of an instruction manual of any kind "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 "accessing an instruction manual" element and the further limitation on the form of the instruction manual in claim 2 confer no patentable weight to the claims.

B. Ground 1: Claim 1 in light of Serany as the primary obviousness reference

Serany discloses each of the elements of claim 1, except element C, "accessing an instruction manual." *See* Section VII.B.1 below. As explained

above, this "printed material" instruction limitation should be given no weight, so claim 1 should be found unpatentable as anticipated under 35 U.S.C. § 102 in view of Serany.

Should element C be given weight, below are alternative grounds for proposed rejections with Serany as a primary reference under § 103. The secondary references used depend upon the Board's findings concerning the general knowledge of a POSA in June 2009 and the Board's construction of certain claim terms, *e.g.,* "a" and "tray."

1. <u>Ground 1A</u>: Claim 1 is invalid as obvious in view of Serany

It would have been obvious for a POSA by June 2009 to include an instruction manual in the catheterization kit disclosed in Serany, for a user to access and follow while performing a catheterization procedure, and Petitioner requests that the Board find the claim unpatentable under § 103. As shown in the subsections below concerning Elements B, C, and E of claim 1 (see page 24 for the corresponding claim elements), and the subsequent claim chart which addresses Elements A and D of claim 1, Serany discloses all of the claim elements of the '786 patent except element C, "accessing an instruction manual." This latter step adds no patentable weight. It would have been routine for a POSA to have included an instruction manual in Serany's catheterization kit.

a) Claim 1, Element B: "opening a thermally sealed bag disposed about a tray having a catheter assembly disposed therein"

Serany discloses both the step of "opening a thermally sealed bag" ("bag" construed above as a flexible container (Section V.E.4)) and the limitation whereby this bag is "disposed about a tray having a catheter assembly disposed therein." Both of these steps were well known prior to 2009. Carrow Decl. at ¶¶ 17-19, 41-42, 66-68.

Serany alternates between calling the item numbered 16 in Serany's figures an "envelope" (1:60-69) and a "bag" (3:57-58). Serany further describes this bag as made of transparent and flexible plastic film—typical materials for making a bag (Kimmel Decl. at ¶¶ 64, 216)—and being heat sealed. Serany at 1:60-69. Serany explicitly states that the thermally sealed bag is adapted to be "separated" or "opened" and shows this process with arrows in figure 1, and as fully opened in figure 2, below:

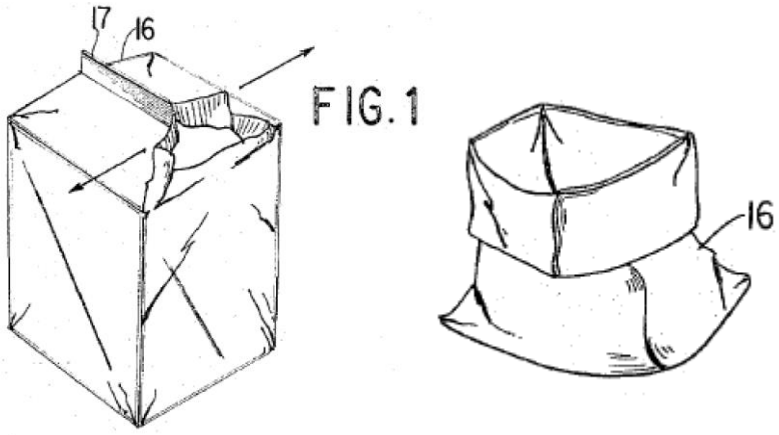
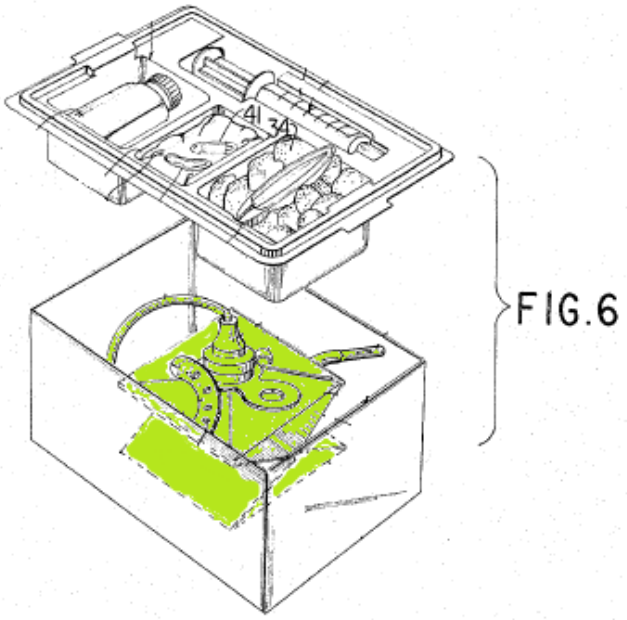


FIG. 1

A POSA would understand that the "envelope" or "bag" referenced in Serany is a "thermally sealed bag." Kimmel Decl. at ¶¶ 64, 215-216; Carrow Decl. at ¶ 18, 41, 67, 69.

Serany further describes that the thermally sealed bag is disposed about a tray having a catheter assembly disposed therein. Serany describes a "tray 12" and a separate tray (Serany calls it a "box 10") and indicates that "the entire assembly [is] encased within an envelope 16." Serany at 1:60-69. A POSA applying the proper constructions of the term "tray," would understand the "box" of Serany to be a "tray" because the "box" disclosed in Serany is a container that is shorter than it is wide. *See* Section 2; Kimmel Decl. at ¶¶ 62-63, 75, 210-211. (In addition, Serany's "box" is identical to the bottom "tray" referred to in Bard's directions for use created around the priority date. *See* Section 2; Kimmel Decl. at ¶ 75).

The bottom tray of Serany contains the catheter assembly, as shown at number 48 in figure 6. Serany at 3:23-26 ("Included in the box 10 beneath the tray 12 are a collapsible drainage bottle 46 and a Foley catheter 48 (partially shown) connected thereto by the drainage tube 49 and ready for use."). Both the lower and upper trays disclosed in Serany constitute "a tray" as that term should be properly construed and this tray includes a catheter assembly disposed therein (shown below in green).



Accordingly, one of ordinary skill in the art would understand Serany to disclose element B of claim 1—"opening a thermally sealed bag disposed about a tray having a catheter assembly disposed therein." Kimmel Decl. at ¶¶ 215-216.

b) ***Claim 1, Element C:*** **"accessing an instruction manual"**

Serany does not explicitly disclose "accessing an instruction manual," whether included within the catheter tray, or accessed from some external source.

Without conceding that it is so entitled, even if the step of "accessing an instruction manual" in claim 1 is given patentable weight, claim 1 is still unpatentable as obvious over the teachings in Serany and the general knowledge of a medical package designer as of June 2009.

The primary object of the invention disclosed in Serany is to "provide[] the convenience of having all the components arranged in a logical step-by-step order

to facilitate the nurse's or physician's task." Serany at 1:31-35. Given that instructions facilitate a task, it would have been obvious to a POSA as of June 2009 to include instructions for performing a catheterization within the Serany kit itself.

Guidance in the field of medical packaging suggested a similar course. The U.S. Food and Drug Administration (FDA) instructed, as early as 1997, manufacturers to include instructions for use in catheter kit packaging. In a document entitled "Guidance for the Content of Premarket Notifications of Conventional and Antimicrobial Foley Catheters" (written prior to February 27, 1997) ("FDA Guidance") (Ex. 1026), the FDA directed that for premarketing approval of Foley catheters and related kits, manufacturers were required to submit "all the information required for a prescription device as noted under 21 CFR 801," including "proposed labels, labeling, and advertisements sufficient to describe the conventional or antimicrobial Foley catheter, its intended use, **and the directions for use**." Such directions for use were recommended to include: "a) **instructions on how to prepare the Foley catheter for patient use**; b) how to insert and remove the Foley catheter [and] . . . **[f]unctional test procedures** for the Foley catheter prior to use should also be provided, **e.g., balloon inflation**/deflation." FDA Guidance at 2.

Thus, as early as 1997, the FDA was instructing that catheter manufacturers comply with the medical device labeling requirements of 21 C.F.R. § 801.5 and include instructions for use along with other device labeling materials.

Furthermore, inclusion of instructions or instruction manuals for access by health care practitioners utilizing medical device kits existed in the general knowledge of a POSA long before June 2009. *See, e.g.,* U.S. Pub. No. 2007/0060908 A1 ("Webster") (Ex. 1031) at [¶ 139] ("The kit can further include, for example, labeling with ***instruction for use*** and/or warnings, such as information specified for inclusion by the Food and Drug administration. Such labeling can be on the outside of the package and/or on separate paper within the package."); U.S. Patent No. 8,628,549 ("To et al.") (Ex. 1032) at 47:18-25 ("The kit 400 also preferably includes ***instructions or directions 404 for using the contents of the kit*** 400 to carry out a desired procedure, as described above.")[3]; U.S. Pub. No. 2007/0299431("Jakubowski et al.") (Ex. 1033) at [¶¶59-60] ("The kit 44 also preferably includes ***directions 48 for using the contents of the kit*** 44 to carry out a desired procedure."); and U.S. Pub No. 2008/0121553 ("Gobel") (Ex.

[3] Issued on Jan. 14, 2014 but the application giving rise to the patent published as U.S. Pub. No. 2009/0018565 A1 on January 15, 2009 and is thus prior art to the '786 patent under 35 U.S.C. § 102(a).

1034) at [¶ 30] ("In the kit 10 depicted in FIG. 1…additional articles (not shown) any of which may be provided may include an ***instruction pamphlet***.").

Considering the prevalence of instruction manuals in medical kits before June 2009, a POSA would have been motivated by her general knowledge to include such instructions in the Serany kit. *Randall Mfg. v. Rea*, 733 F.3d 1355, 1363 (Fed. Cir. 2013) (overturning Board's decision because of failure to consider that it would be common knowledge to use "prevalent, perhaps even predominant, method" of performing claimed method as shown in the prior art).

Even if an instruction manual were not included in a Serany catheterization kit, prior to June 2009 a practitioner would have consulted an instruction manual relating to such a kit—whether provided separately from the kit, published and accessed via the Internet, or otherwise—to ensure proper use of the kit. Carrow Decl. at ¶ 35; Mosby's Pocket Guide to Basic Skills and Procedures (2007) ("Mosby's") (Ex. 1030) at 524-542 (instructing a nurse how to conduct a catheterization procedure).

c) *Claim 1, Element E:* "placing one or more layers of wrap or the additional layer of wrap beneath a patient, thereby transforming an area beneath the patient from a non-sterile field to a sterile field"

Although as a practical matter it is not possible to transform the area directly underneath the patient (particularly the buttocks) from a non-sterile to a sterile field simply by placing a wrap thereunder (Carrow Decl. at ¶ 77), Serany teaches

placing a wrap in the exact manner as described by claim 1. Serany discloses unfolding the enclosing wrap and utilizing the enclosing layer of wrap to create a sterile field. Serany at 2:17-21 ("The wrap, when removed from around the boxes as described above and flattened out thereunder, serves as a sterile field and work area for the remaining operations to be described."). Serany also describes obtaining an underbuttocks wrap ("underpad") from the catheter package assembly and placing the underbuttocks wrap beneath a patient. *Id.* at 2:21-26 ("Upon removal of the wrap 14, there is exposed a waterproof underpad 20 which is folded flat and rests on top of the tray 12. The underpad 20, which may be made of paper with a plastic water-proof coating on one side, is adapted to be placed under the patient."); *see also* Carrow Decl. at ¶ 74-76. The '786 patent describes the exact same type of underpad as the "additional layer of wrap" to be placed beneath the patient:

> [T]he packaged catheter assembly can include an additional layer of material 2701 [elsewhere in the specification called "additional layer of *wrap* material 2701"], which may be a patient drape, under-buttocks drape, or a combination thereof.

Id. at 15:45-48.

The figures from the '786 patent (top) and Serany (bottom) also show this "additional layer of wrap" or underpad as a folded wrap—2701 in the '786 patent and 20 in Serany:

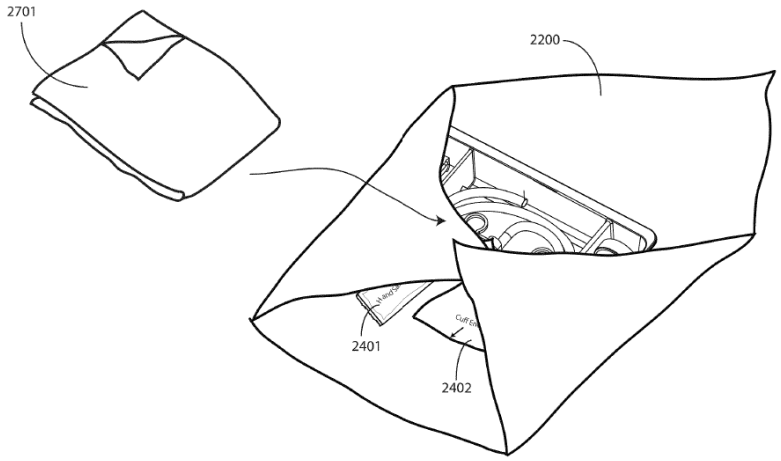
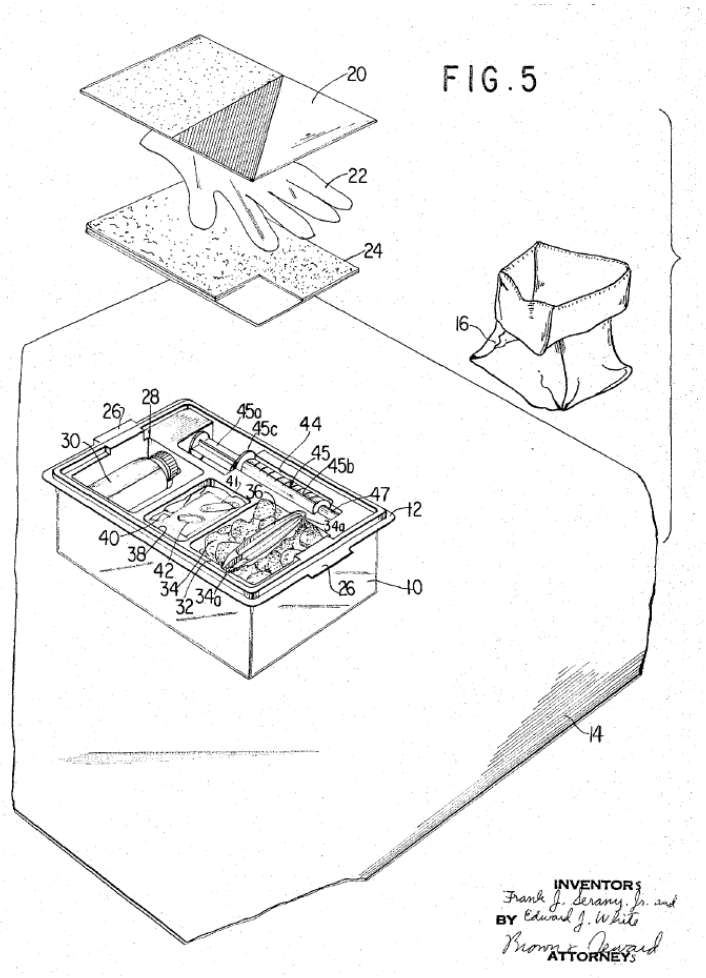


FIG. 27

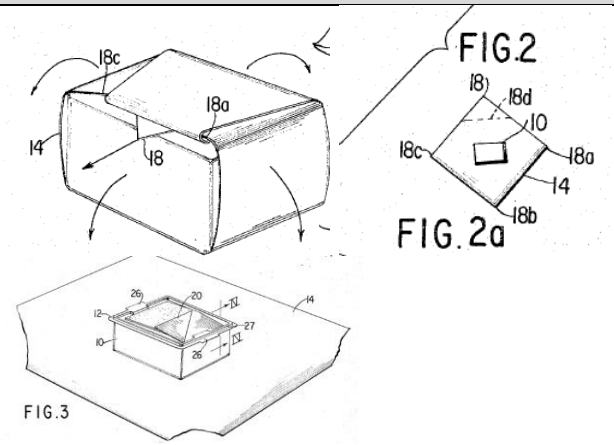


The underbuttocks wrap / underpad disclosed in Serany satisfies element E.

d) Claim 1: Remaining elements A and D

In light of the teaching provided in Serany and the general knowledge of a POSA as of June 2009, claim 1 of the '786 patent is unpatentable as obvious under 35 U.S.C. § 103.

U.S. 8,448,786 Claim 1	**Prior Art**
[A] A method of using a catheter package assembly, comprising:	Serany at 1:9-11 ("The package is adapted to be opened at the patient's bedside to make available such components in their preferred order of use."); *id* at 4:23-24 ("[A]ll the components for catheterization have been included in the package."). Serany discloses various steps in the method of using a catheter package assembly. *See e.g.*, Serany at 2:17-18 ("the wrap, when removed from around the box"); *id.* at 2:21 ("upon removal of the wrap"); *id.* at 2:30-31 ("A fenestrated drape **24** folded flat underneath the gloves is removed…"); *id.* at 2:33 ("The tray **12** is then lifted…").
[B] opening a thermally sealed bag disposed about a tray having a catheter assembly disposed therein;	*See* Section VII.B.1, subsection a), above.
[C] accessing an instruction manual;	No patentable weight. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1065 (Fed. Cir. 2010); *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1280 (Fed. Cir. 2010); *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004) Otherwise, see Section VII.B.1, subsection b), above.
[D] unfolding one or more layers of wrap to reveal an additional layer of wrap and the catheter assembly; and	Serany discloses one or more layers of wrap folded about and enclosing the tray. *See* Serany at 1:60-63 ("[A] box **10** having an open top with a tray **12** mounted thereon is enclosed within a wrap **14.**"); *see also id.* at Figs. 2, 2a and 3.

U.S. 8,448,786 Claim 1	Prior Art
	 Serany discloses unfolding the enclosing wrap to reveal the contents of the catheter assembly. Serany at 2:1-20 ("The wrap 14…is folded around the box 10 in such a way that a slight tug on the corner 18 will release the folds so that the **wrap may thereafter be readily spread out on the flat surface upon which the box rests**…the wrap, when removed from around the box…and flattened out thereunder, serves as a sterile field and work area for the remaining operations to be described.") Serany also discloses an "additional layer of wrap" (or underpad) beneath this enclosing layer of wrap. Serany at 2:21-26 ("Upon removal of the wrap 14, there is exposed a waterproof underpad 20 which is folded flat and rests on top of the tray 12. The underpad 20, which may be made of paper with a plastic water-proof coating on one side, is adapted to be placed under the patient.").
[E] placing one of the one or more layers of wrap or the additional layer of wrap beneath a patient, thereby transforming an area beneath the patient from a non-sterile field to a sterile field.	*See* Section VII.B.1, subsection c)), above.

2. Ground 1B: Claim 1 is invalid as obvious in view of Serany in combination with Franks-Farah

As discussed in Section VII.B.1, each of the elements of claim 1 of the '786 patent is disclosed in Serany, except for limitation [C], "accessing an instruction manual." The disclosure of all such limitations by Serany as discussed in Section VII.B.1 is incorporated here by reference.

Without conceding that the limitation "accessing an instruction manual" confers any patentable weight (*see* Section VII.A), and to the extent the Board finds the general knowledge of a POSA insufficient in combination with Serany to teach use of this element, Franks-Farah discloses a catheterization system that includes instruction manuals—*e.g.*, step-by-step instructions, contents map, and self-care documentation—within the catheter kit itself. Franks-Farah at 2:25-32 ("In a more preferred embodiment of the system, the system contains . . . (I) 4 male intermittent catheters; … **(VI) step-by-step instructions; (VII) clinician step-by-step instructions or self-care documentation**").

Franks-Farah contemplates that the user of the catheterization kit can be the patient himself, the patient's caregiver, an in-home care provider, or a healthcare provider. Franks-Farah at 3:33-36. And the user uses such step-by-step instructions by accessing the same: "the method of the present invention generally comprises using the system 10 in accordance with the detailed step-by-step instructions 34." Franks-Farah at 5:1-3. The claims of the '786 patent are not

limited to "use" by a health care provider and thus are equally met where the "accessing" of instructions is performed by a patient preparing to self-catheterize himself.

As shown above in Section VII.B.1, subsection b), Franks-Farah is not the only example of a prior art medical device package including instructions for use of the medical device within the kit itself. The prevalence of including instructions in medical kits prior to June 2009—and the FDA requirements necessitating the same—is but one reason for a POSA to include instructions as taught by Franks-Farah within the Serany catheterization kit.

Also, Serany itself would have provided a reason for one of skill in the art to include the instructions from Franks-Farah. One object of the invention disclosed in Serany is to "provide[] the convenience of having all the components arranged in a logical step-by-step order to facilitate the nurse's or physician's task." Serany at 1:31-35; 1:20-25. Given this stated goal of "facilitating the nurse's or physician's task" it would have been an obvious step to include in the tray assembly itself instructions for performing that task. Because instructions facilitate a task, and since Serany states that an object of the claimed invention is to "hav[e] all the components arranged" to facilitate such a task, it would have been obvious to include within the catheter kit of Serany the instructions disclosed in other prior art catheter packages. *See e.g.*, Carrow Decl. at ¶¶ 16, 34-39, 43, 70.

In sum, it would have been obvious for a person of skill in the art to include in the catheter kit described in Serany instructions for use such as those described in Franks-Farah.

3. Ground 1C: Claim 1 is unpatentable as obvious in view of Serany combined with Franks-Farah, and using a single-level tray

Petitioner requests that the Board find claim 1 unpatentable as obvious for the reasons explained above in Sections VII.B.1 and VII.B.2. But should the Board construe the term "a" and "tray" narrowly to exclude the lower-level tray or box disclosed in Serany, claim 1 should still be found unpatentable because it would have been obvious to a POSA to substitute Serany's two-level tray with a single-level tray.

Single-level catheterization trays designed to hold the components that were held in the Serany tray were well-known by June 2009. *See, e.g.*, Brezette (Ex. 1010) at Figure 1 (below) and 4:7-12 (claiming a tray to hold "catheter and other implements necessary to said catheterization"); Rauschenberger, U.S. Pat. No. 4,160,505 (Ex. 1011) at Figure 1 (below) and 2:15-27; U.S. Pat. No. 3,542,019 (Ex. 1013) ("Gittens") at 3:30 (disclosing single-level "equipment tray 16" for holding catheterization materials); *see also* U.S. Pat. No. 3,485,352 (Pilger) (Ex. 1024) at Figure 1 & 2 (below) and 2:3-14 (disclosing various catheterization components); and Carrow Decl. at ¶ 20.

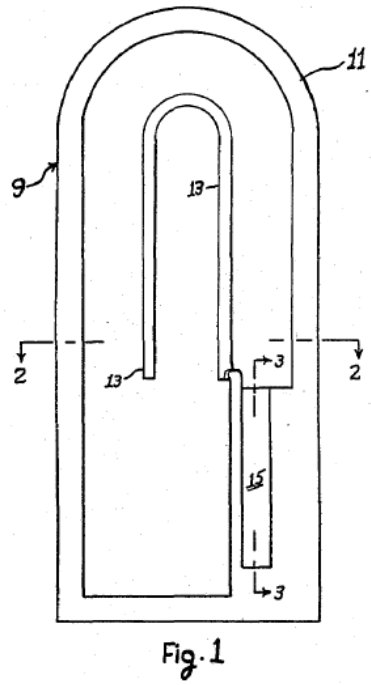
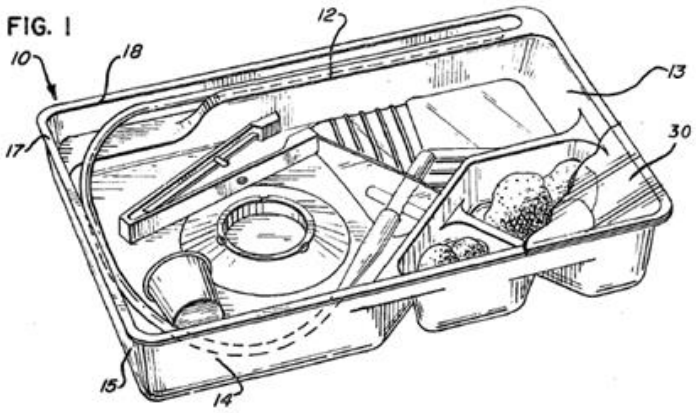
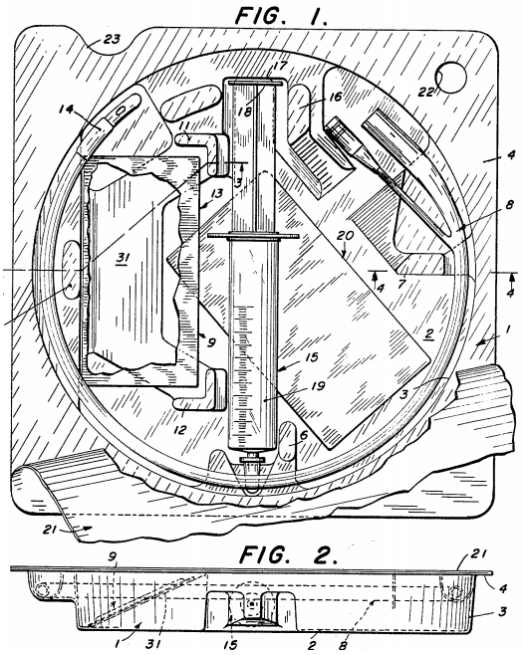


Fig. 1

Brezette



Rauschenberger



Pilger

It would have been obvious to a POSA to utilize a single-level tray instead of Serany's two level tray as the both designs were known to a POSA and such a

substitution would have yielded only predictable results. *KSR Int'l Co.*, 550 U.S. at 416-17 ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results" further recognizing obviousness inquiry simple when it involves "the 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").

A POSA also would have had reason to substitute Serany's two-level tray design for a single-level tray design to gain the advantages of such a configuration. A single-level tray design would reduce the chance of the patient, or the practitioner, inadvertently upsetting the catheterization materials as there would be less things for them to bump. Rauschenberger at 1:30-49. Use of a one-level tray design would also help maintain the sterile field around the tray as nothing would have to be moved from one tray to another—it would all be contained within one tray. Kimmel Decl. at ¶¶ 212-214; *see also* Mosby's at 528 (instructing practitioner to "[o]rganize supplies on sterile field" because that helps maintain "principles of surgical asepsis and organizes work area.").

Having all of the components necessary for a catheterization easily at hand can increase the speed and the efficiency with which a catheterization is

completed. "Reducing the risks associated with urinary catheters," Nursing Standard (2009) ("Nursing Standard") (Ex. 1020) at 52. A POSA would have recognized that such efficiency could only be further increased if a single-level tray was used, giving the practitioner access to all of the necessary components at once and in one place, as opposed to spaced out across different fields around the patient. Kimmel Decl. at ¶ 214.

For particular one-level tray designs, such as Pilger, it may have also been easier for a health care facility to store the package as it could be stored on an end as opposed to flat, saving space in certain situations. Pilger at 3:14-21. A POSA would have recognized this design choice between one tray or two trays and been motivated to use a single level tray design. As a result, for all of the reasons stated above, claim 1 should be found unpatentable as obvious.

C. Ground 2: Claim 2 is invalid in view of Serany in combination with the 1998 EC Guidelines

Claim 2 of the '786 patent depends from claim 1. As discussed in section VII.B above, claim 1 is unpatentable as obvious in light of Serany (and other references).

Claim 2 recites the additional limitation of "wherein the instruction manual comprises a health care services portion and a patient portion detachably coupled thereto." Claim 2 is unpatentable in light of the art and combinations identified in section VII.B above, in further combination with the 1998 EC Guidelines.

As discussed above, it was well documented in the prior art before June 2009 that instructions (for both patients and health care providers) should be accessible during administration of medical and medicinal products. As discussed above in section VII.B.1.b), the FDA required as early as 1997 making instructions for use available in catheter kit packaging.

Such inclusion was also a directive in the 1998 European Commission's "Guideline On the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use." The 1998 EC Guidelines are a prior art document designed to "to provide guidance on the factors which influence readability . . . [and] on how each item on the label should be expressed." 1998 EC Guideline at 2. Even though the 1998 EC Guidelines are primarily directed to "medicinal products," *i.e.*, pharmaceuticals, as opposed to "medical products," one of skill in the art of packaging design in 2009 would have looked to the 1998 EC Guidelines to inform what best practices existed for designing packaging for catheterization trays and for guidance on what materials should be included within such packaging. Kimmel Decl. at ¶¶ 20, 23.

This is particularly true given that users of both products are utilizing a medical treatment. The need for adequate instruction on how to use these medical products applies across these closely related arts and renders the 1998 EC Guidelines a reasonably pertinent reference in considering the obviousness of the

claims of the ’786 patent. *Innovention Toys, LLC v. MGA Entertainment, Inc.*, 637 F.3d 1314, 1321 (Fed. Cir. 2011) (“A reference is reasonably pertinent if ... it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem. If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection.”).

As discussed in the 1998 EC Guidelines, two pieces of product information are critical in packaging medicinal products: the product label and the package leaflet. The stated purpose of the EC Guideline is to provide guidance on how to ensure that the information on the label and package leaflet is readable and can be understood by those who receive it. *Id.* at 2. A POSA designing a catheterization package and its contents (both instruments and written documents) would have referenced the 1998 EC Guidelines for guidance on how to best present such information. Kimmel Decl. at ¶ 23.

The 1998 EC Guidelines teach an instruction manual with two portions: a health care services portion (*e.g.*, the SPC (or, "summary of product characteristics") "for the health professional" (*e.g.*, the instructions for use) and a patient portion (*e.g.*, "package leaflet" which must be "phrased so that it is readily understandable to the patient."). 1998 EC Guidelines at 11-12. These Guidelines also disclose that the two are detachably coupled, teaching that the instructions be included "in a tear-off portion" of the patient leaflet. *Id.* at 12.[4]

[4] The 2009 EC Guidelines, published nearly a decade later and superseding the 1998 EC Guidelines are, in relevant substance, identical. Section 9.2 of the 2009 EC Guidelines concerns product inserts for "products administered by a healthcare professional or in a hospital." 2009 EC Guidelines 11. Catheters are one such type of product administered by a healthcare professional. The 2009 EC Guidelines instruct that for such products, "information from the summary of product characteristics for the healthcare professional **(*e.g., the instructions for use***) could be included at the end of the patient leaflet e.g. in a tear-off portion, to be removed prior to giving the leaflet to the patient." *Id.*

Disclosures in both Serany and the 1998 EC Guidelines provide justification for why a POSA armed with the teachings in Serany and the 2009 EC Guidelines would have combined such teachings together such that the instruction manual comprises "a health care services portion an a patient portion detachably coupled thereto." Serany's explicit goal is to enable a practitioner to perform a catheterization procedure "in the usual manner" (Serany, col. 3:48-49), by "containing components for a catheterization procedure…[in a] package [that] is adapted to be opened at the patient's bedside to make available such components in their **preferred order of use**…and include items which assure that a sterile field may be maintained as the components are removed from the package and used." *Id.* at 1:8-16.

One of skill in the art in 2009, designing a catheter assembly kit per the disclosures provided in Serany and per Serany's goal of including all necessary catheterization components, would have understood that a health care practitioner would have found it desirable to be able to access information for themselves and for their patient, if necessary, in the form of an instruction manual or instructions for use as discussed in the 1998 EC Guidelines. Carrow Decl. at ¶ 16, 34-39, 43-45, 70, 78. The 1998 EC Guidelines further describe coupling the instruction manual (instructions for use) directed to the healthcare professional (*i.e.*, the health care services portion) **with** the patient leaflet (directed to the patient/user, *i.e.*, the

patient portion) and provides the example that such coupling can be accomplished to facilitate easily detaching each part from the other, "*e.g.*, in a tear-off portion." 1998 EC Guidelines at 12. ("[I]nformation from the SPC (summary of product characteristics) for the health professional (e.g. the instructions for use, inter alia) could be included at the end of the patient leaflet in a tear-off portion, to be removed prior to giving the leaflet to the patient"). The 1998 EC Guidelines, therefore, disclose the additional limitation found in dependent claim 2, namely an "instruction manual compris[ing] a health care services portion and a patient portion detachably coupled thereto."

Also, it was known before June 2009 that it was important to instruct patients about their catheter and the catheterization procedure in order to avoid infections and other complications. CAUTI Maintenance Bundle (Feb. 2008) (Ex. 1035) at 1 ("***Ensure patients are aware*** of their role in preventing urinary tract infection.") (emphasis in original); "FAQs about 'Catheter-Associated Urinary Tract Infection" (dated Oct. 2008) (Ex. 1036) (pamphlet to be provided to patients about catheter infections); Nursing Standard at 52 ("Whenever catheterization is undertaken, to provide informed consent patients should be made aware of the procedure, aftercare and the possible complications that may arise."); *See e.g.*, Carrow Decl. at ¶ 39.

A POSA in 2009, therefore, following the guidance provided by the 1998 EC Guidelines, with the goal of educating patients about catheters and potential infections, would have had reason to include with Serany's tray an instruction manual comprising a health care services portion and a patient portion detachably coupled thereto.

VIII. CONCLUSION

For the reasons given above, *inter partes* review of U.S. Patent No. 8,448,786, claims 1 and 2, under 35 U.S.C. § 311 and 37 C.F.R. § 42.101 is hereby requested.

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Respectfully submitted,

/Jason M. Honeyman/____

Richard F. Giunta (Reg. No. 36,149)
Jason M. Honeyman (Reg. No. 31,624)
WOLF GREENFIELD & SACKS, P.C.
600 Atlantic Ave.
Boston, MA 02210-2206
Tel: 617-646-8000/Fax: 617-646-8646

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:

Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC
222 12th Street NE
Suite 1803
Atlanta GA 30309

Date: December 30, 2014 /Jason M. Honeyman/