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Paper 10
Entered: June 26, 2015

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 IPR2015-00514
Patent 8,678,190 B2

Before JOSIAH C. COCKS, JENNIFER MEYER CHAGNON, and TIMOTHY J. GOODSON, *Administrative Patent Judges.*

GOODSON, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

C.R. Bard, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 1–7 and 9–18 of U.S. Patent No. 8,678,190 B2 ("the '190 patent"). Medline Industries, Inc. ("Patent Owner") timely filed a Preliminary Response (Paper 9, "Prelim. Resp.")[1] to the Petition. We have jurisdiction under 35 U.S.C. § 314.

To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner will prevail in challenging claims 1–7, 9, and 11–13 of the '190 patent. Pursuant to 35 U.S.C. § 314, we hereby authorize an *inter partes* review to be instituted as to claims 1–7, 9, and 11–13.

Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the full record developed during trial.

A. Related Matters

The '190 patent is the subject of a lawsuit between the parties in the U.S. District Court for the Northern District of Illinois, *Medline Industries,*

[1] It appears that duplicate copies of the Preliminary Response were entered into the Board's electronic Patent Review Processing System as Papers 8 and 9. In this decision, references to the Preliminary Response cite only to Paper 9.

Inc. v. C.R. Bard, Inc., Case No. 1:14-cv-03618. *See* Pet. 6. In addition, three other petitions for *inter partes* reviews involving the same parties and related U.S. Patent Nos. 8,448,786 B2 and 8,631,935 B2 are pending as IPR2015-00509, IPR2015-00511, and IPR2015-00513. *See id.*

B. The '190 Patent (Ex. 1001)

The '190 patent is titled "Catheter Tray, Packaging System, Instruction Insert, and Associated Methods." Ex. 1001, Title. The '190 patent describes tray 100 that holds catheter assembly 700 as well as other items used in catheterization, such as syringes 701, 702 containing sterile water and lubricating jelly. *Id.* at Abstract. Figure 1, reproduced below, is a perspective view of a catheter tray according to an embodiment of the invention. *Id.* at col. 2, ll. 20–22.

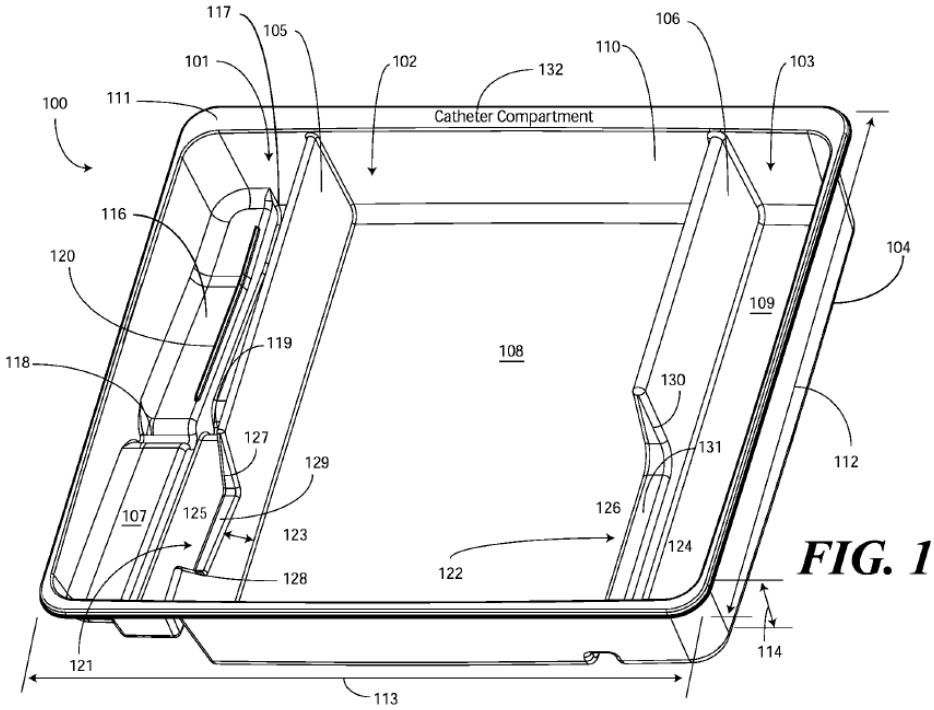


FIG. 1

As shown in Figure 1 above, tray 100 has first compartment 101 for accommodating syringes and second compartment 102 for accommodating the catheter assembly. *Id.* at col. 5, ll. 17–20. The '190 patent explains that

the stair-stepped contour of first compartment base member 107 allows first compartment 101 to be used as a lubricant applicator for the catheter. *Id.* at col. 6, ll. 60–62. Specifically, a medical services provider dispenses lubricating jelly along second step portion 117, which serves as a channel in which the lubricating jelly can spread. *Id.* at col. 6, ll. 63–67. The provider then passes the catheter through opening 121 between first and second compartments 101, 102, through the channel formed by second step portion 117, and out the top of tray 100 to the patient. *Id.* at col. 7, ll. 1–5. According to the '190 patent, this ability to apply lubricating jelly to the catheter while the catheter is contained within tray 100 improves on prior art solutions in both ease of use and reduced risk of contamination. *Id.* at col. 7, ll. 5–7, 20–24.

Figure 10, reproduced below, is a perspective view of a tray with a catheter and other devices disposed therein, along with instructions and packaging. *Id.* at col. 2, ll. 50–54.

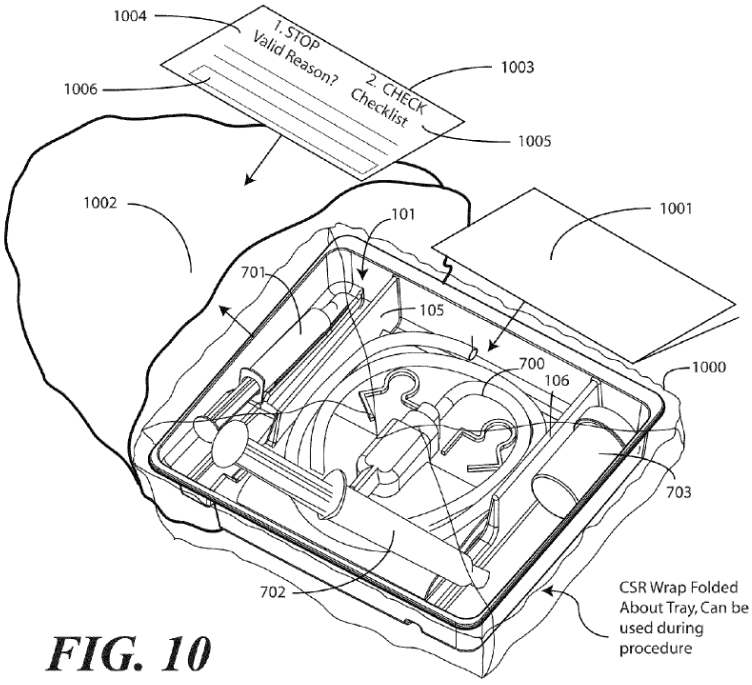


FIG. 10

As shown in Figure 10, tray 100 is sealed with wrap 1000, which can be unfolded and used in the catheter insertion process, such as by providing a sterile field for tray 100 to sit in. *Id.* at col. 9, ll. 42–49. The '190 patent discloses that printed instructions 1001, including a health services portion and a patient portion, can be attached to tray 100. *Id.* at col. 9, ll. 51–54. The health services portion of printed instructions 1001 can provide instructions to health services providers regarding use of the contents of tray 100. *Id.* at col. 9, ll. 55–64. The patient portion of printed instructions 1001 can provide information that is useful for a patient, and it can be detachable from the health services portion so that the provider can detach it and discuss its contents with the patient. *Id.* at col. 9, l. 65–col. 10, l. 14.

C. Illustrative Claims

Claims 1 and 15 are independent method claims. Claims 2–7 and 9–14 depend, directly or indirectly, from claim 1. Claims 16–18 depend, directly or indirectly, from claim 15. Claims 1 and 15 are illustrative of the subject matter at issue, and are reproduced below:

> 1. A method of using a catheter package assembly, comprising:
>
> providing the catheter package assembly, the catheter package assembly comprising:
>
> a tray having a catheter assembly disposed therein;
>
> one or more layers of wrap folded about the tray so as to enclose the tray within the one or more layers of wrap; and
>
> a sealed bag disposed about the tray;
>
> unsealing the sealed bag disposed about the tray to reveal the one or more layers of wrap folded about the tray;
>
> unfolding the one or more layers of wrap to create a sterile field about the tray;

accessing an instruction manual comprising a health care services portion and a patient portion detachably coupled thereto;

detaching the patient portion from the health care services portion; and

delivering the patient portion to the patient.

15. A method, comprising:

providing a catheter package assembly, the catheter package assembly comprising:

a tray having a catheter assembly disposed therein;

one or more layers of wrap folded about the tray so as to enclose the tray within the one or more layers of wrap; and

a sealed bag disposed about the tray;

unsealing the sealed bag disposed about the tray to reveal the one or more layers of wrap folded about the tray;

unfolding the one or more layers of wrap to create a sterile field about the tray;

removing at least one syringe from a first compartment in the tray;

injecting lubricating jelly from the at least one syringe into the first compartment of the tray; and

passing at least a portion of the catheter assembly from a second compartment of the tray through an opening in a first barrier separating the first compartment from the second compartment, thereby passing the at least the portion of the catheter assembly through the lubricating jelly.

D. References Relied Upon

The Petition relies on the following references:

Serany	US 3,329,261	July 4, 1967	Ex. 1008
Brezette	US 3,978,983	Sept. 7, 1976	Ex. 1010
Franks-Farah	US 6,840,379 B2	Jan. 11, 2005	Ex. 1009

McMichael US 7,401,703 B2 July 22, 2008 Ex. 1037

EUROPEAN COMMISSION: PHARMACEUTICAL COMMITTEE, *A Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use* (Sept. 29, 1998), Ex. 1007 (hereinafter "1998 EC Guideline").

ANNE GRIFFITH PERRY & PATRICIA A. POTTER, MOSBY'S POCKET GUIDE TO BASIC SKILLS AND PROCEDURES 524–42 (6th ed. 2007), Ex. 1030 (hereinafter "Mosby's").

E. Alleged Grounds of Unpatentability

Petitioner contends that claims 1–7 and 9–18 of the '190 patent are unpatentable on the following grounds:

References	Basis	Claim(s) Challenged
Serany, Franks-Farah, and 1998 EC Guideline	§ 103	1–7, 9, and 11–13
Serany and Brezette	§ 103	15
Serany, Franks-Farah, 1998 EC Guideline, Mosby's and Brezette	§ 103	10
Serany, Franks-Farah, 1998 EC Guideline, and Brezette	§ 103	14 and 16–18

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1278 (Fed. Cir. 2015). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*,

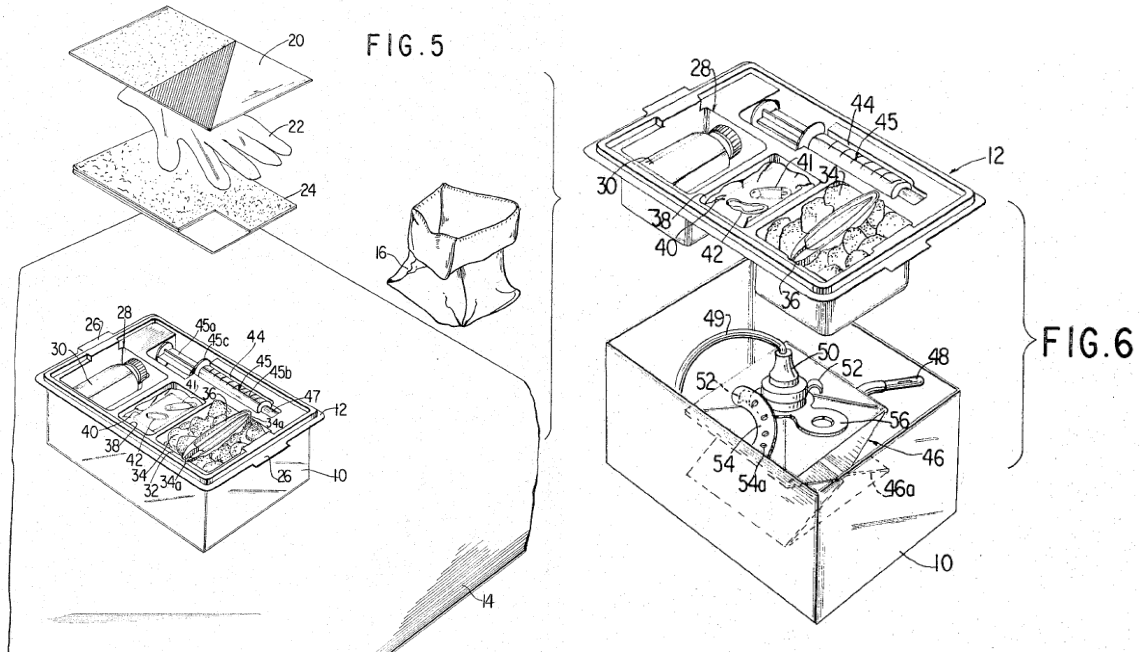
504 F.3d 1249, 1257 (Fed. Cir. 2007). However, "claim terms need only be construed 'to the extent necessary to resolve the controversy.'" *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)); *see also EMI Grp. N. Am., Inc. v. Intel Corp.*, 157 F.3d 887, 895 (Fed. Cir. 1998) (holding that the construction of a given claim term was "irrelevant" because it did not affect the underlying controversy between the parties).

No terms require express construction in order to reach our decision at this stage of the proceeding.

B. Obviousness over Serany, Franks-Farah, and 1998 EC Guideline

Petitioner argues that claims 1–7, 9, and 11–13 are unpatentable under 35 U.S.C. § 103(a) over Serany, Franks-Farah, and 1998 EC Guideline. Pet. 20–40. With respect to independent claim 1, Petitioner asserts that Serany discloses the claimed method except for the "accessing," "detaching," and "delivering" steps. *See id.* at 20–24. Petitioner argues that those steps are directed to nonfunctional printed matter, and, therefore, should not be given patentable weight. *See id.* at 17–19. But if the limitations are given weight, Petitioner argues that they would have been obvious in view of Franks-Farah and 1998 EC Guideline. *See id.* at 26–32.

Serany describes a catheterization package that "provides the convenience of having all the components arranged in logical step-by-step order to facilitate the nurse's or physician's task." Ex. 1008, col. 1, ll. 31–35. Figures 5 and 6 of Serany are reproduced below:



Figures 5 and 6 depict box 10, on the open top of which is mounted tray 12, enclosed within wrap 14. *Id.* at col. 1, ll. 60–62. The entire assembly is enclosed within envelope 16. *Id.* at col. 1, ll. 62–63. Serany describes that the wrap serves as a sterile field when removed from around the box and flattened thereunder. *Id.* at col. 2, ll. 17–20.

Serany further discloses that tray 12 has "compartments or depressions" that accommodate components used in catheterization. *Id.* at col. 2, ll. 40–41. Depression 38 accommodates a plastic pouch, which holds lubricating jelly in individually sealed pouch 40 as well as other items. *See id.* at col. 3, ll. 1–5. Depression 28 accommodates bottle 30 of cleansing solution, depression 32 holds balls 34 of cleansing material, and indentations 34a hold forceps 36, which are used to handle balls 34. *See id.* at col. 2, ll. 42–68. Depression 44 holds a prefilled syringe for inflating the balloon on the catheter. *See id.* at col. 3, ll. 6–7. Beneath tray 12, box 10 holds catheter 48. *Id.* at col. 3, ll. 23–24. Serany describes that "catheter 48 is lubricated with the lubricating jelly 40 while the drainage bottle 46 and

tubing 49 are still in the box. Catheterization is thereafter effected in the usual manner." *Id.* at col. 3, ll. 45–49.

Franks-Farah is directed to a catheter system that can be administered at home by a nonprofessional, such as by the patient himself. *See* Ex. 1009, col. 1, l. 65–col. 2, l. 7. The system includes "step-by-step instructions; . . . clinician step-by-step instructions or self-care documentation; and . . . a box, wherein the above-named items are positioned inside the box." *Id.* at col. 2, ll. 29–32.

The 1998 EC Guideline provides guidance on readability of the label and package leaflet of medicinal products. Ex. 1007, Title, 2. The 1998 EC Guideline states that for a product administered by a health professional, information for the health professional such as 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." *Id.* at 12.

1. Claim 1

In light of the teachings of Serany, including those discussed above, Petitioner contends that Serany discloses the "providing," "unsealing," and "unfolding" steps recited in claim 1. *See* Pet. 21–24. In particular, Petitioner asserts that Serany's box 10, which contains Foley catheter 48, corresponds to the claimed "tray." *Id.* at 21 (citing Ex. 1008, col. 3, ll. 23–26). In support of this assertion, Petitioner cites the testimony of Dr. Robert Kimmel that Serany's box 10 "is flat and has raised sides (raised at a shallow depth compared to the width of the base), making it a tray in the eyes of one skill in the art in June 2009." Ex. 1002 ¶ 211. Petitioner points to Serany's wrap 14 as corresponding to the claimed "one or more layers of wrap," and Serany's envelope 16 as corresponding to the claimed "sealed

bag." Pet. 22–23. Patent Owner's Preliminary Response does not rebut these contentions specifically. For the purposes of this decision, Petitioner's arguments are persuasive.[2]

Petitioner argues that the "accessing," "detaching," and "delivering" steps should not be given patentable weight because they are directed to nonfunctional printed matter. *See* Pet. 8, 17–20. Petitioner analogizes "accessing an instruction manual" in claim 1 to the limitation of "informing a patient" that was found nonfunctional in *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1279–80 (Fed. Cir. 2010). *See* Pet. 19. Petitioner further argues that "[t]he 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." *Id.* (quoting *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1065 (Fed. Cir. 2010)).

Patent Owner counters that Petitioner's printed matter argument "ignore[s] key portions of this limitation, namely that the instructions accessed include 'a health care services portion and a patient portion

[2] We note that the Petition includes an alternative argument that claim 1 would have been obvious even under a construction of "a tray" that excludes Serany's box 10. *See* Pet. 37–40. Although Petitioner denominates this backup position as "Ground 1B," it challenges the same claims based on the same three references as Ground 1A. *See id.* at 37. At this stage of the proceeding, we have not adopted a construction of "a tray" that would exclude Serany's box 10. Thus, we need not address the merits of Petitioner's alternative argument in order to determine whether to institute *inter partes* review of claim 1 based on Serany, Franks-Farah, and 1998 EC Guideline. In later phases of this proceeding, Patent Owner is free to advocate a construction of "a tray" that would exclude Serany's box 10. Likewise, Petitioner is free to oppose such a construction and/or argue that even under such a construction, claim 1 would have been obvious based on Serany, Franks-Farah, and 1998 EC Guideline.

detachably coupled thereto.'" Prelim. Resp. 40 (quoting claim 1). Patent Owner further argues that this limitation transforms the process of using the catheter package assembly, in that both the practitioner's instructions and the patient's instructions can be accessed in one document from the catheter package assembly. *Id.* at 41.

Based on the current record, we are not persuaded that the "accessing," "detaching," and "delivering" steps include only nonfunctional printed matter to which no patentable weight should be given. In *King Pharmaceuticals*, the Federal Circuit explained that the recited step of informing the patient about the benefits of a drug was not functionally related to the method of administering the drug because "[i]rrespective of whether the patient is informed about the benefits, the actual method . . . is the same." *King Pharm.*, 616 F.3d at 1279. Similarly, in *AstraZeneca*, "[t]he instructions in no way function[ed] with the drug to create a new, unobvious product." *AstraZeneca*, 633 F.3d at 1065. Here, however, claim 1 recites that the instructions include a health care services portion detachably coupled to a patient portion. The claim also recites detaching the patient portion and delivering it to the patient. The detachability of the two portions of the instructions appears to be a functional feature affecting how the catheterization package is used in the claimed method, and Petitioner does not persuade us otherwise. Thus, for purposes of this decision, we are not convinced that the "accessing," "detaching," and "delivering" steps of claim 1 should be given no patentable weight.

Petitioner alternatively argues that if the "accessing" step is given weight, it would have been obvious to include instructions in the package because doing so would have furthered Serany's stated goal of "facilitat[ing]

the nurse's or physician's task." Pet. 24–25 (quoting Ex. 1008, col. 1, ll. 31–35). In support of this argument, Petitioners cite the testimony of Susan Carrow that in order to maximize the sterility of the working field, catheter kits have long been designed to include within the kits themselves all components necessary to perform the catheterization, including instructions for use. *See* Pet. 25; Ex. 1004 ¶¶ 16, 34. In addition, Petitioners assert that Franks-Farah teaches including instructions within the catheter package itself. Pet. 28–29 (citing Ex. 1009, col. 2, ll. 25–32).

Petitioner argues that the 1998 EC Guideline discloses instructions that comprise "a health services portion and a patient portion detachably coupled thereto," as recited in claim 1. Pet. 29 (citing Ex. 1007, 12). In particular, Petitioner asserts that the 1998 EC Guideline describes coupling the instruction for the healthcare professional with the patient leaflet. *Id.* Petitioner contends that a skilled artisan following the guidance of the 1998 EC Guideline "with the goal of educating patients about catheters and potential infections" would have been led to include with Serany's tray an instruction manual with a health care services portion and a patient portion detachably coupled thereto. Pet. 31. In support of this contention, Petitioner cites the testimony of Ms. Carrow, who states that including patient-related information within catheter kits makes that information available for distribution to the patient upon completion of the procedure. Ex. 1004 ¶ 39. Petitioner further argues that the 1998 EC Guideline teaches the "detaching" and "delivering" steps of claim 1. *See* Pet. 31–32.

In response, Patent Owner argues that the 1998 EC Guideline is directed to the packaging of medicinal products, which involve different considerations than devices to be used in a sterile environment. Prelim.

Resp. 44. However, Patent Owner does not explain why these different considerations undermine the obviousness of Petitioner's proposed combination. To the extent that Patent Owner intends to argue that the 1998 EC Guideline is nonanalogous art, that argument is not persuasive based on the current record. We note that Petitioner's declarant, Dr. Kimmel, testifies that a skilled artisan would have looked to the 1998 EC Guideline for best practices in designing packaging for catheter trays because medicinal products and medical devices share many of the same design considerations. *See* Pet. 27–28; Ex. 1002 ¶¶ 20, 23. Patent Owner does not rebut this assertion persuasively.

Patent Owner further argues that a skilled artisan would not be motivated to include practitioner and patient instructions in the same manual because practitioner instructions should be accessed first and patient instructions should be accessed last. Prelim. Resp. 45 (citing Pet. 25, 30; Ex. 1004 ¶¶ 34, 39). Thus, Patent Owner contends that including the two sets of instructions in the same manual would result in accessing the patient instructions out of the order of their intended use. *Id.* However, claim 1 does not specify when the patient portion must be detached and delivered to the patient relative to the completion of the catheterization. Accordingly, the claim does not preclude accessing the instruction manual early in the procedure, and detaching and delivering the patient portion at the end of the procedure. Thus, Patent Owner does not persuade us that the prior art "teaches away" from the claimed method. *See id.*

Based on the current record, Petitioner has demonstrated a reasonable likelihood that it will prevail in showing that claim 1 would have been

obvious in view of the teachings of Serany, Franks-Farah, and 1998 EC Guideline.

2. Claims 2–7, 9, and 11–13

Petitioner provides a detailed explanation of how each limitation of dependent claims 2–7, 12, and 13 is taught or suggested by the combination of Serany, Franks-Farah, and 1998 EC Guideline. Pet. 32–36. Based on the record before us, we find these contentions persuasive.

With respect to claim 9, Petitioner argues that the recited steps of obtaining a syringe and forming a test balloon were routine steps of catheterization practice in 2009. *Id.* at 34. In support of that assertion, Petitioner quotes the following from Mosby's: "'[b]efore inserting indwelling catheter, common practice is to test balloon by injecting fluid from prefilled syringe into balloon port.'" *Id.* at 34 (quoting Ex. 1030, 528); *see* Ex. 1004 ¶¶ 23–24.

Regarding claim 11, Petitioner cites Ms. Carrow's testimony that swabsticks were a known substitute for the forceps and rayon balls that Serany uses for cleansing. Pet. 34–35 (citing Ex. 1004 ¶ 59; Ex. 1008, col. 2, ll. 40–72). Petitioner cites McMichael as an exemplary prior art reference teaching the use of swabsticks. *Id.* (citing Ex. 1037).

Patent Owner argues that the Petition fails to specify the combination on which Petitioner's challenge is based, insofar as Petitioner cites numerous prior art references beyond Serany, Franks-Farah, and 1998 EC Guideline. *See* Prelim. Resp. 19–21. With respect to claims 1–7, 12, and 13, we understand Petitioner's challenge to be based on Serany, Franks-Farah, and 1998 EC Guideline alone, as identified in pages 9–10 of the Petition as the grounds for challenge. Although the Petition cites supplementary references

in discussing these claims, we understand those supplementary references to be cited as background reflecting the state of the prior art, and not necessary to the grounds of institution. *See* Pet. 20–40.

However, with respect to claims 9 and 11, the Petition does appear to cite Mosby's and McMichael as more than background references. *See* Pet. 34–35. Rather, the Petition relies on Mosby's and McMichael as teaching limitations in claims 9 and 11, respectively, that Petitioner does not contend are taught in the other three cited references. *See id.* Although the summary of the grounds of challenge on pages 9–10 of the Petition does not cite Mosby's or McMichael explicitly, our review of the Petition as a whole indicates that the challenge to claim 9 is based on Serany, Franks-Farah, 1998 EC Guideline, and Mosby's, and the challenge to claim 11 is based on Serany, Franks-Farah, 1998 EC Guideline, and McMichael.

Based on the current record, we are persuaded that Petitioner has demonstrated a reasonable likelihood that it will prevail in showing that claims 2–7, 12, and 13 would have been obvious in view of the teachings of Serany, Franks-Farah, and 1998 EC Guideline. Petitioner also has demonstrated a reasonable likelihood that it will prevail in showing that claim 9 would have been obvious in view of the teachings of Serany, Franks-Farah, 1998 EC Guideline, and Mosby's, and that claim 11 would have been obvious in view of the teachings of Serany, Franks-Farah, 1998 EC Guideline, and McMichael. We note that Patent Owner is not prejudiced by the inclusion of Mosby's and McMichael in the challenges to claims 9 and 11, respectively, because the Petition provides sufficient notice of Petitioner's reliance on these references for these grounds of unpatentability.

Moreover, Patent Owner will have an opportunity to respond to these grounds it its Patent Owner Response.

C. Obviousness over Serany and Brezette

Petitioner argues that claim 15 is unpatentable under 35 U.S.C. § 103(a) over Serany and Brezette. Pet. 40–45. Petitioner asserts that the "providing," "unsealing," and "unfolding" steps of claim 15 are the same as in claim 1, and relies on Serany as disclosing those limitations. *See id.* at 40. Petitioner argues that Brezette teaches the "removing," "injecting," and "passing" limitations of claim 15. *See* Pet. 41–45.

Brezette is directed to a catheterization tray that includes a lubrication channel for lubricating the portion of the catheter to be inserted into a patient. Ex. 1010, Title, Abstract. Figures 1, 2, and 3 of Brezette are reproduced below:

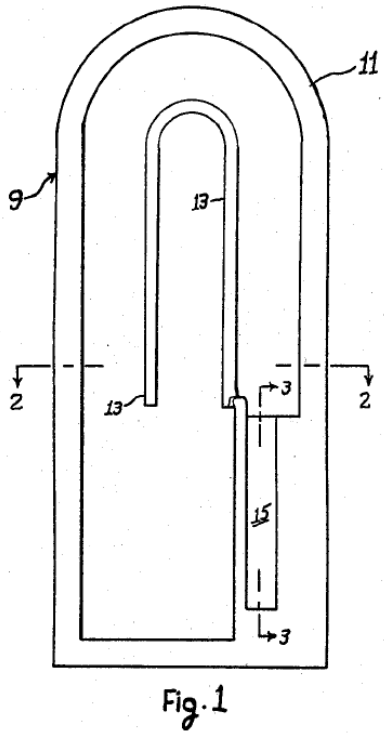


Fig. 1

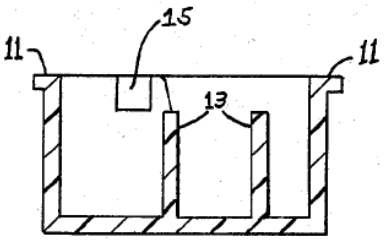


Fig. 2

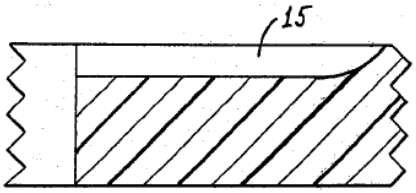
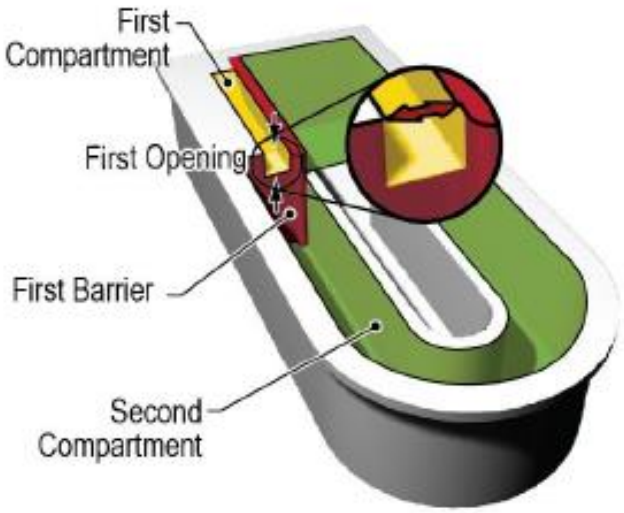


Fig. 3

Figure 1 is a top view, and Figures 2 and 3 are cross-sectional views, of catheterization tray 9. *See id.* at col. 2, ll. 21–29. Lubrication channel 15

is recessed from upper surface 11. *Id.* at col. 2, ll. 51–53. Tray 9 also includes compartments, compartmentalized by divider 13, for receiving a catheter and other catheterization implements. *Id.* at col. 2, ll. 46–50. Brezette describes that "where a packet of lubricating jelly has been provided, it is opened and squeezed into lubrication channel 15" and the catheter is then pushed or swirled though the jelly. *Id.* at col. 3, ll. 16–21. According to Brezette, this approach improved on the prior art technique of squeezing the jelly onto a sterile towel, because the lubrication channel 15 confines the lubricant, and, therefore, less jelly is wasted. *See id.* at col. 1, ll. 45–54, col. 3, ll. 21–25.

In challenging claim 15, Petitioner relies on Brezette as teaching the limitation of "an opening in a first barrier separating the first compartment from the second compartment." *See* Pet. 44–45. The Petition includes a rendering, reproduced below, of Brezette's tray in a perspective view.



Pet. 45.[3] Petitioner's rendering illustrates the portions of Brezette's tray that Petitioner points to as corresponding to the claimed "first compartment," "second compartment," "first barrier," and "opening." As seen in Petitioner's rendering, Petitioner points to Brezette's lubrication channel 15 as the claimed "first compartment." *See* Pet. 41. Dr. Kimmel testifies that the red double-sided arrow shows the claimed "opening" and the "barrier [is] the wall between the first and second compartment." Ex. 1002 ¶ 109.

Patent Owner argues that in Brezette's tray, nothing separates lubrication channel 15 from the rest of the tray, and, therefore, there is no "first barrier separating the first compartment from the second compartment" as recited in claim 15. Prelim. Resp. 32 (citing Ex. 1010, Fig. 2). We agree with Patent Owner. Brezette's Figures 1–3, as well as Petitioner's perspective drawing, show no separation between the lubrication channel 15 and the neighboring portion of the tray, which Petitioner points to as the claimed "second compartment." Accordingly, Petitioner does not persuade

[3] Patent Owner objects to Petitioner's use of models of Brezette's tray that do not appear in Brezette itself. *See* Prelim. Resp. 27–29. According to Patent Owner, the perspective drawing reproduced above improperly relies on the scale and dimensions of Brezette's Figures. *See id.* (citing *Nystrom v. TREX Co.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005)). We are not persuaded that Petitioner's use of the perspective drawing is improper. In *Nystrom*, reliance on a model derived from a prior art reference was improper because the district court relied on the model to determine whether specific ratios recited in the claims were present in the prior art reference. *Nystrom*, 424 F.3d at 1148–49. Here, Petitioner does not rely on the perspective drawing to show that Brezette teaches specific proportions, ratios, or dimensions. Rather, the drawing simply renders Brezette's Figures 1–3 in a perspective view that illustrates more clearly how Petitioner correlates portions of Brezette's tray with the elements recited in claim 15. Moreover, Patent Owner does not identify any inaccuracies in the perspective drawing.

us that Brezette discloses "an opening in a first barrier separating the first compartment from the second compartment," as recited in claim 15.

Thus, Petitioner has not demonstrated a reasonable likelihood of prevailing in its challenge of claim 15 as obvious over Serany and Brezette.

D. Obviousness over Serany, Franks-Farah, 1998 EC Guideline, Mosby's and Brezette

Petitioner argues that claims 10 is unpatentable under 35 U.S.C. § 103(a) over Serany, Franks-Farah, 1998 EC Guideline, Mosby's and Brezette. Pet. 46. Petitioner relies on Brezette as teaching the limitation in claim 10 of "an opening in a first barrier separating the first compartment from the second compartment." *See id.* For the reasons discussed above in Section II.C., Petitioner has not shown that Brezette discloses this limitation. Therefore, Petitioner has not demonstrated a reasonable likelihood of prevailing in its challenge of claim 10 as obvious over Serany, Franks-Farah, 1998 EC Guideline, Mosby's and Brezette.

E. Obviousness over Serany, Franks-Farah, 1998 EC Guideline, and Brezette

Petitioner argues that claims 14 and 16–18 are unpatentable under 35 U.S.C. § 103(a) over Serany, Franks-Farah, 1998 EC Guideline, and Brezette. Pet. 47. Petitioner relies on Brezette as teaching the limitation in claim 14 of "an opening in a first barrier separating the first compartment from the second compartment." *See id.* For the reasons discussed above in Section II.C., Petitioner has not shown that Brezette discloses this limitation. Claims 16–18 depend from claim 15, and Petitioner continues to rely on Brezette as teaching the claim 15 limitation of "an opening in a first barrier separating the first compartment from the second compartment." *See id.* Accordingly, Petitioner has not demonstrated a reasonable likelihood of

prevailing in its challenge of any of claims 14 and 16–18 as obvious over Serany, Franks-Farah, 1998 EC Guideline, and Brezette.

III. CONCLUSION

For the foregoing reasons, upon review of Petitioner's analysis and supporting evidence, as well as the arguments presented in the Preliminary Response, we conclude Petitioner has demonstrated a reasonable likelihood that it will prevail with respect to its challenge to claims 1–7, 9, and 11–13. We further conclude that Petitioner has not demonstrated a reasonable likelihood that it will prevail with respect to its challenge to claims 10 and 14–18. At this stage in the proceeding, we have not made a final determination as to the patentability of any challenged claims.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 1–7, 9, and 11–13 of the '190 patent for the following grounds:

1. Claims 1–7, 12, and 13 as unpatentable under 35 U.S.C. § 103(a) over Serany, Franks-Farah, and 1998 EC Guideline;

2. Claim 9 as unpatentable under 35 U.S.C. § 103(a) over Serany, Franks-Farah, 1998 EC Guideline, and Mosby's; and

3. Claim 11 as unpatentable under 35 U.S.C. § 103(a) over Serany, Franks-Farah, 1998 EC Guideline, and McMichael;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, the trial commencing on the entry date of this decision; and

FURTHER ORDERED that the trial is limited to the grounds identified above.

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