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Paper No. 9
Entered: July 15, 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 IPR2015-00513
Patent 8,631,935 B2

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

CHAGNON, *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 for *inter partes* review of claims 7, 8, 10, 21–23, 25, 27, 28, and 30–34 ("the challenged claims") of U.S. Patent No. 8,631,935 B2 (Ex. 1101, "the '935 patent"). Paper 2 ("Pet."). Medline Industries, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 7 ("Prelim. Resp.").

We have authority to determine whether to institute *inter partes* review. *See* 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). Having considered the Petition and the Preliminary Response, we determine that there is a reasonable likelihood that Petitioner would prevail with respect to its challenge to claim 21, but that there is not a reasonable likelihood that Petitioner would prevail in establishing that claims 7, 8, 10, 22, 23, 25, 27, 28, and 30–34 are unpatentable. *See* 35 U.S.C. § 314(a). Accordingly, we institute trial only as to claim 21 of the ’935 patent.

Our 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 the claim for which *inter partes* review is instituted. Our final decision will be based on the full record developed during trial.

A. Related Proceedings

The ’935 patent has been asserted against Petitioner in *Medline Industries, Inc. v. C.R. Bard, Inc.*, Case No. 1:14-cv-03618 (N.D. Ill.). Paper 4, 2. Three other petitions for *inter partes* reviews involving the same parties, related to the ’935 patent, as well as related U.S. Patent Nos. 8,448,786 B2 and 8,678,190 B2, are pending as IPR2015-00509, IPR2015-00511, and IPR2015-00514. *See* Pet. 5–6.

B. The ’935 Patent

The ’935 patent is titled “Catheter Tray, Packaging System, and Associated Methods.” Ex. 1101, Title. The ’935 patent describes a tray that holds a catheter assembly, as well as other items used in catheterization, such as syringes containing sterile water and lubricating jelly and/or a specimen container. *Id.* at Abstract. Figure 7, reproduced below, is a

perspective view of a catheter tray according to an embodiment of the invention. *Id.* at 2:22–25.

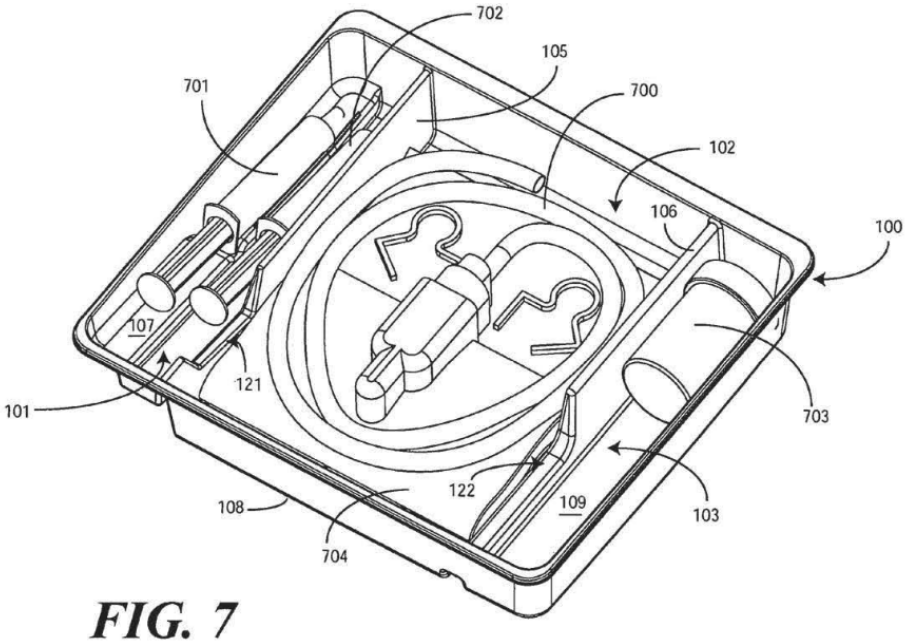

FIG. 7

As shown in Figure 7 above, tray 100 has first compartment 101 for accommodating syringes 701, 702, second compartment 102 for accommodating catheter assembly 700, and third compartment 103 for accommodating specimen jar 703. *Id.* at 4:51–55. First and second compartments 101, 102 are separated by first barrier 105, and second and third compartments 102, 103 are separated by second barrier 106. *Id.* at 4:6–10. First compartment base member 107 includes stair-stepped contour 115 (*see, e.g.*, *id.* at Figs. 2, 4), such that syringes 701, 702 may be held at different depths in tray 100, to facilitate ease of use. *Id.* at Abstract, 4:60–5:15. First compartment base member 107 may also be inclined relative to the other compartment base members. *Id.* at 5:16–41. Larger syringes may

be accommodated by nesting such a syringe within openings 121, 122 provided in barriers 105, 106, respectively. *Id.* at 6:13–24, Fig. 10.

The ’935 patent explains that during a catheterization procedure, a medical services provider may dispense lubricating jelly into first compartment 101. *Id.* at 6:31–35. The provider then passes catheter 700 through opening 121 in first barrier 105, through the lubricating jelly dispensed in first compartment 101, and out the top of tray 100 to the patient. *Id.* at 6:35–40. According to the ’935 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 and infection. *Id.* at 6:40–42, 6:53–59.

Tray 100 is sealed with central supply room (“CSR”) wrap 1000 to keep the internal components sterile. Ex. 1101, 8:53–54. The ’935 patent discloses that printed instructions 1001, which can provide instructions to medical services providers regarding use of the contents of tray, can be attached to tray 100. *Id.* at 8:55–58. The entire assembly can then be sealed in a sterile wrap. *Id.* at 9:11–13.

C. Illustrative Claims

Of the challenged claims, claims 21 and 22 are independent. Claims 23, 25, 27, 28, and 30–34 depend, directly or indirectly, from claim 22. Claims 7, 8, and 10 depend from independent claim 1, which is not challenged in the present Petition.[1] Claims 1, 21, and 22 of the ’935 patent, reproduced below, are illustrative of the challenged claims:

[1] Claim 1 is challenged in Petitioner’s IPR2015-00511.

> 1. A method of manufacturing a packaged catheter assembly, comprising:
>
> providing a tray having at least a first compartment with a first compartment base member having an inclined, stair-step contour and a second compartment, wherein the first compartment and the second compartment are separated by a first barrier having an opening therein;
>
> disposing at least one syringe in the first compartment;
>
> disposing a catheter assembly in the second compartment;
>
> sealing the tray;
>
> enclosing printed instructions directing a user to discharge contents of the at least one syringe into the first compartment and to pass at least a portion of the catheter assembly through the opening and into the contents; and
>
> placing a sterile wrap about the tray.

Ex. 1101, 10:12–26.

> 21. A method of manufacturing a packaged catheter assembly, comprising:
>
> providing a tray having at least a first and a second compartment separated by a first barrier having an opening therein;
>
> disposing at least one syringe in the tray;
>
> sealing the tray; and
>
> enclosing with the tray printed instructions directing a user to discharge contents of the at least one syringe into the first compartment and to pass at least a portion of the catheter assembly into the contents.

Id. at 11:62–12:5.

> 22. A tray configured to accommodate a catheter assembly and medical devices corresponding to catheter use, the tray comprising:
>
> a contoured surface defining at least three compartments separated by barriers and a perimeter wall, the at least three compartments comprising:
>
> a first compartment comprising a first compartment base member having at least one inclined stair-stepped contour defining a ramp upon which syringes may be placed so that a plunger of each syringe is predisposed to project upward and out of the tray;
>
> a second compartment comprising a second base member;
>
> a first barrier separating the first compartment from the second compartment, wherein the first barrier defines a first opening between the first compartment and the second compartment, the first opening having a first opening depth;
>
> a third compartment comprising a third base member: and
>
> a second barrier separating the second compartment from the third compartment, wherein the second barrier defines a second opening between the second compartment and the third compartment, the second opening having a second opening depth.

Id. at 12:6–29.

D. The Applied References

Petitioner relies on the following references. Pet. 8.

Reference	**Date**	**Exhibit No.**
U.S. Patent No. 3,329,261 ("Serany")	July 4, 1967	Ex. 1108
U.S. Patent No. 6,840,379 B2 ("Franks-Farah")	Jan. 11, 2005	Ex. 1109
U.S. Patent No. 3,978,983 ("Brezette")	Sept. 7, 1976	Ex. 1110

Reference	Date	Exhibit No.
U.S. Patent No. 4,160,505 ("Rauschenberger")	July 10, 1979	Ex. 1111
U.S. Patent No. 4,226,328 ("Beddow")	Oct. 7, 1980	Ex. 1112

Petitioner further relies on the Declarations of Dr. Robert M. Kimmel (Ex. 1102, "Kimmel Declaration") and Susan Carrow, MSN/Ed, CEN, RN (Ex. 1104).

E. The Asserted Grounds

Petitioner sets forth its challenges to claims 7, 8, 10, 21–23, 25, 27, 28, and 30–34 as follows. Pet. 8, 19–60.

References	Basis	Claims Challenged
Rauschenberger and Franks-Farah	§ 103	21
Brezette, Beddow, and Franks-Farah	§ 103	7, 8
Brezette	§ 103	22, 23, 25, 27, 28, 30–34
Rauschenberger	§ 103	22, 23, 25, 31–34
Brezette, Beddow, Franks-Farah, and Serany	§ 103	10

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, a "claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, No. 2014-1301, 2015 WL 4097949, at *5–*8 (Fed. Cir. July 8, 2015). Under the broadest reasonable construction standard, claim terms generally 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. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

The parties propose constructions for several claim terms. Pet. 8–17; Prelim. Resp. 8–15. For purposes of this Decision, we need only make explicit the meaning of the phrases "barrier having an opening therein," in claims 1 and 21, and "barrier [that] defines a[n] . . . opening," in claim 22. No other terms require express construction. *See, e.g., Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Claim 1 includes the following step: "providing a tray having . . . a first compartment . . . and a second compartment, wherein the first compartment and the second compartment are separated by a first *barrier having an opening therein*." Ex. 1101, 10:14–18 (emphasis added). Claim 21 includes the step "providing a tray having at least a first and a second compartment separated by a first *barrier having an opening therein*." *Id.* at 11:64–66 (emphasis added). Claim 22 includes the features "a first *barrier* separating the first compartment from the second compartment . . . [and that] *defines a first opening* between the first compartment and the second compartment" and "a second *barrier* separating the second compartment from the third compartment, . . . [and that] *defines a second opening* between the second compartment and the third compartment." *Id.* at 12:18–21, 12:25–28 (emphases added).

We discuss these similar phrases together. Petitioner does not offer a construction of the phrase "barrier having an opening therein" or "barrier

[that] defines a[n] . . . opening." Patent Owner proposes a construction of the term "barrier," in the context of its use in claims 1, 21, and 22, as a "structure that separates one compartment from another and prevents or blocks movement therebeteween." Prelim. Resp. 10–11. This proposed construction is consistent with the plain meaning of "barrier"—"[a] fence or other obstacle that prevents movement or access."[2] The plain meaning of "opening" is "[a]n aperture or gap, especially one allowing access."[3]

As seen in each of the embodiments described in the '935 patent, the barriers separating the compartments include a structure physically separating one compartment from another. *See, e.g.*, Ex. 1101, Figs. 1, 7 (barrier 105 that separates compartment 101 from compartment 102; barrier 106 that separates compartment 102 from compartment 103). These barriers each include a gap therein, allowing access between the compartments at the location of the gap. *See, e.g.*, *id.* (opening 121 in barrier 105; opening 122 in barrier 106).

Thus, consistent with the Specification of the '935 patent, we construe "barrier having an opening therein" and "barrier [that] defines a[n] . . . opening" in accordance with the ordinary and customary meaning, to mean "structure that prevents or blocks movement from or access between one compartment to another, the structure including a gap therein."

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[2] *See Barrier Definition*, OxfordDictionaries.com, http://www.oxforddictionaries.com/us/definition/american_english/barrier (last accessed July 13, 2015).
[3] *See Opening Definition*, OxfordDictionaries.com, http://www.oxforddictionaries.com/us/definition/american_english/opening (last accessed July 13, 2015).

B. Obviousness of Claim 21 in View of Rauschenberger and Franks-Farah

Petitioner asserts that claim 21 would have been obvious in view of Rauschenberger and Franks-Farah. Pet. 19–24. We have reviewed the parties' contentions and supporting evidence. Given the evidence on this record, and for the reasons explained below, we determine that the information presented shows a reasonable likelihood that Petitioner would prevail on its assertion that claim 21 is unpatentable as obvious in view of Rauschenberger and Franks-Farah.

1. Overview of Rauschenberger

Rauschenberger relates to a "sterile, self-contained catheterization package[,] which permits the catheterization procedure to take place within the sterile work area defined by the tray." Ex. 1011, 1:4–7. Figure 1 of Rauschenberger is reproduced below:

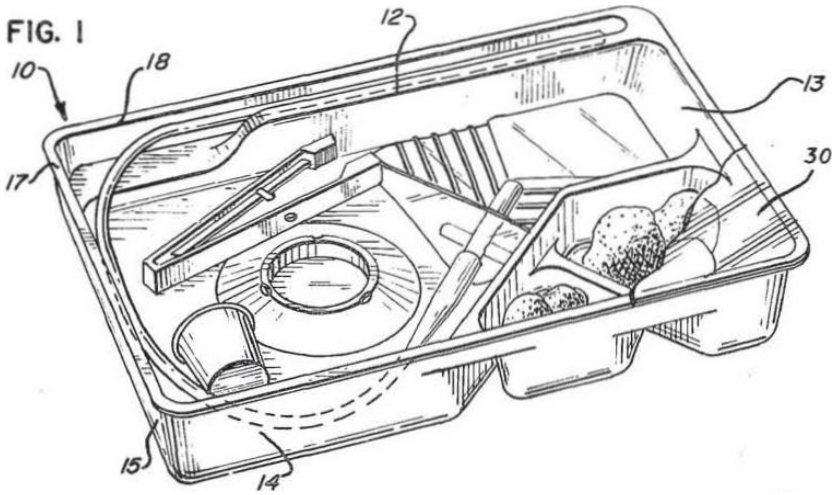


Figure 1 is a perspective view of the catheterization tray of Rauschenberger. *Id.* at 1:47. Tray 10 includes channel 21, which is formed by wall 12. *Id.* at 1:50–61. Rauschenberger discloses that various catheterization components are placed in tray 10, as shown in Figure 1, and sealed with cover sheet 30. *Id.* at 2:15–17. In particular, channel 21 is adapted to receive an insertion

end of a catheter; the remainder of the catheter extends into the main compartment of tray 10. *Id.* at 1:62–66. Compartments 23, 24, defined by walls 27, 28, 29, are adapted to hold absorbent pads. *Id.* at 2:1–7. According to Rauschenberger, the "remaining compone[nt]s generally are arranged sequentially from the top of the tray on down in the order: gloves, lubricant, antiseptic solution, fenestrated drape, forceps, drainage bag and specimen container." *Id.* at 2:22–26.

During use, a lubricant packet is used to put lubricant on the catheter in channel 21, and the catheter is rotated within channel 21 to spread lubricant on its insertion end. *Id.* at 2:30–33. The configuration of channel 21 is such that the danger of the catheter being dislocated from channel 21 is minimized. *Id.* at 2:33–36.

2. Overview of Franks-Farah

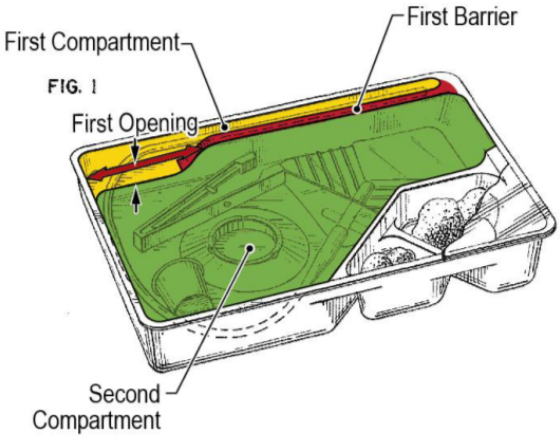
Franks-Farah is directed to a catheter system that can be administered at home by a nonprofessional, such as by the patient himself. *See* Ex. 1109, 1:65–2:7. The system includes "catheters; . . . step-by-step instructions; . . . clinician step-by-step instructions or self-care documentation; and . . . a box, wherein the above-named items are positioned inside the box." *Id.* at 2:27–32.

3. Analysis

Petitioner's Arguments and Evidence

Claim 21 recites a "method of manufacturing a packaged catheter assembly." As noted above, Rauschenberger discloses a sterile, self-contained catheterization tray, and discusses the packaged configuration thereof. Ex. 1111, 1:4–7, 2:15–27.

Petitioner relies on Figure 1 of Rauschenberger as disclosing the claimed "tray having at least a first and a second compartment separated by a first barrier having an opening therein." Petitioner provides an annotated version of Figure 1 of Rauschenberger, reproduced below:



Pet. 20. Petitioner's annotated figure illustrates the portions of Rauschenberger's tray that Petitioner points to as corresponding to the claimed "first compartment" (highlighted in yellow), "second compartment" (highlighted in green), "first barrier" (highlighted in red), and "[first] opening." *Id.* (citing Ex. 1102 ¶ 186).

Petitioner admits that Rauschenberger does not disclose "disposing at least one syringe in the tray," but asserts that Rauschenberger "does disclose disposing implements for catheterization in the tray," including a "lubricant packet." Pet. 20 (citing Ex. 1111, 2:22–27, 2:30). Petitioner further asserts that "[i]t was common knowledge well before [the filing date of the '935 patent] that liquid or jelly could be stored in a syringe instead of a packet." *Id.* (citing Ex. 1104 ¶¶ 24–25, 82; Ex. 1102 ¶¶ 187–188; Ex. 1120,[4]

[4] M. Madeo & A. J. Roodhouse, *Reducing the Risks Associated with Urinary Catheters*, 23 NURSING STANDARD 47–55 (2009).

Ex. 1122[5]). On the current record, we agree with Petitioner that "[s]ubstituting one container for another type of container (*e.g.*, substituting a lubricant in a 'packet' with a lubricant in a syringe) would have been an obvious substitution of components known to be suitable to yield predictable results." *Id.* at 20–21 (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007); Ex. 1102 ¶ 188; Ex. 1104 ¶¶ 25, 82; Ex. 1101, 4:40–44).

Petitioner relies on the disclosure that tray 10 of Rauschenberger is sealed with cover sheet 30 about flange 17, as teaching the claimed step of "sealing the tray." *Id.* at 21 (citing Ex. 1111, 2:15–20; Ex. 1102 ¶ 190).

With respect to the "enclosing with the tray printed instructions directing a user to discharge contents of the at least one syringe into the first compartment and to pass at least a portion of the catheter assembly into the contents" limitation of claim 21, Petitioner argues that "[t]his 'printed matter' limitation should be given no patentable weight." *Id.* at 22, 17–19. Petitioner argues, in the alternative, that "even if this limitation is given patentable weight, it would have been obvious for a [person of ordinary skill] to include the claimed instructions with Rauschenberger." *Id.* at 22.

Petitioner asserts that Rauschenberger teaches discharging lubricant into the first compartment and passing at least a portion of the catheter assembly into the lubricant. *Id.* (citing Ex. 1111, 2:30–33, Fig. 1). Petitioner further asserts that the "inclusion of instructions with a urethral catheter assembly[,] such as the one described in Rauschenberger[,] in order to help a user understand how to use the assembly was well known—if not universally adopted across the industry," prior to the filing date of the '935

[5] Instructions for BARDEX® I.C. (BARD Infection Control System) Infection Control Foley Tray (2006).

patent. *Id.* (citing Ex. 1104 ¶¶ 16, 34–39, 43, 85; Ex. 1102 ¶¶ 191–192). Petitioner points to Franks-Farah as teaching a catheterization system including instructions within the kit itself. *Id.* at 22–23 (citing Ex. 1109, 2:25–32). On the current record, we agree with Petitioner that it would have been "standard and customary in light of Franks-Farah to enclose printed instructions" in the Rauschenberger tray. *Id.* at 22–24.

We are persuaded, on the current record and taking into account Patent Owner's arguments, discussed below, that Petitioner has shown sufficiently that the combination of Rauschenberger and Franks-Farah teaches or suggests all of the limitations of claim 21, and has articulated sufficient reasoning why it would have been obvious to combine these references in the proposed manner.

Patent Owner's Arguments

Patent Owner argues that (1) Petitioner does not specify which combination of references it asserts; (2) the "enclosing . . . instructions" limitation should be given patentable weight; and (3) the cited combination does not disclose "pass[ing] at least a portion of the catheter assembly into the contents." Prelim. Resp. 18–20, 28–30, 55–57. We address each of Patent Owner's arguments in turn.

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 Rauschenberger and Franks-Farah. *See* Prelim. Resp. 18–20. We understand Petitioner's challenge to claim 21 to be based on Rauschenberger and Franks-Farah alone, as identified at page 8 of the Petition as the ground for the challenge. Although the Petition cites supplementary references in discussing this claim, 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. 19–24.

With respect to the "enclosing . . . instructions" limitation, because we determine that Petitioner has made a sufficient showing on the present record with respect to the obviousness of this claim feature, we do not, at this time, reach the question of whether the limitation should be given patentable weight for purposes of this decision.

With respect to the "pass[ing] at least a portion of the catheter assembly into the contents," limitation, Patent Owner argues that the cited combination does not teach a "catheter assembly," and that "[b]ecause the catheter is packaged already located within the lubrication channel, Rauschenberger does not teach or suggest passing a portion of the catheter assembly through the opening into the contents of the first compartment." Prelim. Resp. 56–57.

With respect to the catheter assembly, Patent Owner argues that because, for example, the catheter and drainage bag are not disclosed as being connected via tubing in Rauschenberger, Rauschenberger cannot disclose a tray for a *catheter assembly*. *See id.* at 50. Patent Owner argues that "catheter assembly" must be construed as "a medical device including a catheter connected to a drainage receptacle via tubing." *Id.*; *see also id.* at 11–13 (Patent Owner's discussion of claim construction). While Patent Owner provides citations to the Specification purporting to distinguish "catheter" from "catheter assembly" (*id.*), Patent Owner does not direct us to any portion of the Specification of the '935 patent that provides direct support for its proposed construction. Further, Patent Owner's proposed construction appears to be inconsistent with at least one other portion of the

Specification. *See, e.g.*, Ex. 1101, 3:12–15 (referring to catheter assembly and fluid bag (for samples obtained from a patient via the catheter) as separate components to be accommodated in the tray). We are persuaded, on the present record, that the catheter of Rauschenberger is sufficient to teach or suggest the catheter assembly portion of this limitation.

We also are not persuaded that Rauschenberger does not suggest *passing* at least a portion of the catheter assembly *into the contents of the first compartment* (e.g., the lubricant). We note that claim 21 does not require passing a portion of the assembly *through the opening* into the contents of the first compartment, as argued by Patent Owner. *See* Prelim Resp. 57. Claim 21 merely requires "pass[ing] at least a portion of the catheter assembly into the contents." Ex. 1101, 12:4–5. We are persuaded, on the present record, that Rauschenberger's disclosure of "rotat[ing the catheter] within channel 21 to spread lubricant about its insertion end" (Ex. 1111, 2:31–33) is sufficient to teach "pass[ing] at least a portion of the catheter assembly into the contents" (e.g., into the lubricant in the first compartment).

Conclusion

For the foregoing reasons, we authorize institution of *inter partes* review of claim 21 under 35 U.S.C. § 103(a) as obvious in view of Rauschenberger and Franks-Farah.

C. Obviousness Grounds Based on Brezette

Petitioner asserts that claims 7 and 8 would have been obvious in view of Brezette, Beddow, and Franks-Farah; claim 10 would have been obvious in view of Brezette, Beddow, Franks-Farah, and Serany; and claims 22, 23, 25, 27, 28, and 30–34 would have been obvious in view of Brezette.

Pet. 24–46, 57–59. We have reviewed the parties' contentions and supporting evidence. Given the evidence on this record, and for the reasons explained below, we determine that the information presented does not show a reasonable likelihood that Petitioner would prevail on any of the grounds based on Brezette. Specifically, we are not persuaded that Petitioner has made a sufficient showing that Brezette, or the other cited references, teaches or suggests "the first compartment and the second compartment are separated by a first barrier having an opening therein," as recited in claim 1, or "a first barrier separating the first compartment from the second compartment . . . [and that] defines a first opening between the first compartment and the second compartment," as recited in claim 22.

1. Overview of Brezette

Brezette relates to a catheterization tray that includes a compartment for receiving a catheter and a lubrication channel for lubricating the portion of the catheter to be inserted into a patient. Ex. 1110, Title, Abstract. Figures 1, 2, and 3 of Brezette are reproduced below:

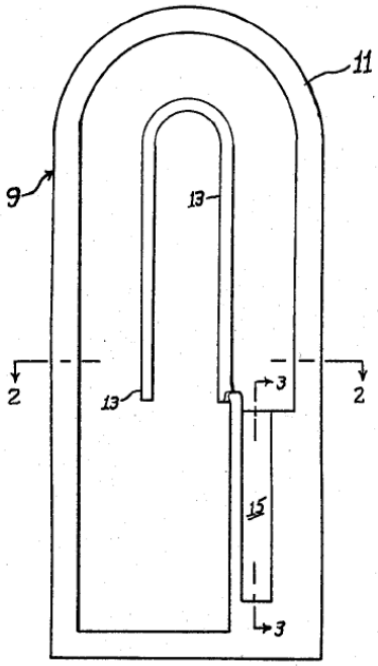


Fig. 1

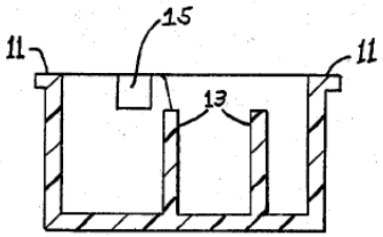


Fig. 2

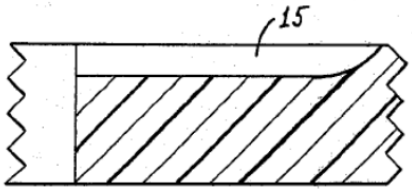


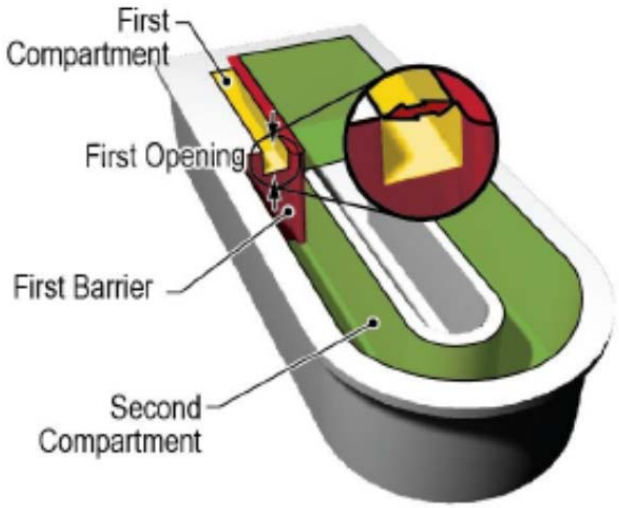
Fig. 3

Figure 1 is a top view of catheterization tray 9, and Figures 2 and 3 are cross-sectional views of tray 9 along lines 2–2 and 3–3 of Figure 1, respectively. *See id.* at 2:21–29. Lubrication channel 15 is recessed from upper surface 11. *Id.* at 2:51–53. Tray 9 also includes compartments, separated by divider 13, for receiving a catheter and other catheterization implements. *Id.* at 2:46–50. Sterile lubricant is either packaged in lubrication channel 15, or provided in a packet that is squeezed into lubrication channel 15, and the catheter is then pushed or swirled though the lubricant. *Id.* at 3:16–21, 3:30–31. According to Brezette, providing lubricating jelly in lubrication channel 15 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 1:45–54, 3:21–25.

2. Analysis

Independent claim 1, from which claims 7, 8, and 10 depend, recites "providing a tray having . . . a first compartment . . . and a second compartment, wherein the first compartment and the second compartment are separated by a first barrier having an opening therein." Ex. 1101, 10:14–18. Independent claim 22, recites "a first barrier separating the first compartment from the second compartment . . . [and that] defines a first opening between the first compartment and the second compartment." *Id.* at 12:18–21, 12:25–28.

In each of the above-referenced grounds based on Brezette, alone or in combination with other references, Petitioner relies on Brezette as disclosing the above-noted claim features pertaining to a "first barrier." *See* Pet. 26–27, 38. Petitioner provides a rendering, reproduced below, of Brezette's tray in a perspective view.

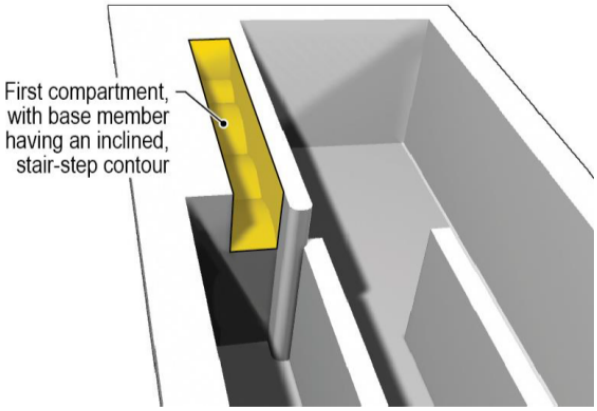


Pet. 27, 38. Petitioner's rendering illustrates the portions of Brezette's tray that Petitioner points to as corresponding to the claimed "first compartment" (highlighted in yellow), "second compartment" (highlighted in green), "first

barrier" (highlighted in red), and "[first] opening." *Id.* at 26–27, 38. Petitioner provides declaration testimony to support the mapping of these claim features. *See* Ex. 1102 ¶ 104. Dr. Kimmel testifies that the "first barrier separating the first compartment and the second compartment is shown in red on the right hand side of the first compartment and turning the corner along the front of the first compartment." *Id.* Petitioner further cites to Dr. Kimmel's assertion that that the "red, double-sided arrow in the close-up view identifies the opening in the barrier." Pet. 27 (citing Ex. 1102 ¶ 104), 38 (citing Ex. 1102 ¶ 204).

Patent Owner argues that in Brezette's tray, nothing separates lubrication channel 15 from the rest of the tray, and, therefore, there is no disclosure of "the first compartment and the second compartment [being] separated by a first barrier having an opening therein," as recited in claim 1. Prelim. Resp. 33–35 (citing Ex. 1110, Fig. 2). Patent Owner makes similar arguments with respect to claim 22. *See id.* at 46.

Brezette's Figures 1–3, as well as Petitioner's perspective rendering, show no single "structure that prevents or blocks movement from or access between" lubrication channel 15 and the neighboring portion of the tray, which Petitioner points to as the claimed "second compartment," where the structure also "includ[es] a gap therein," as required by our construction. Dr. Kimmel testifies that the first barrier is "on the right hand side of the first compartment and turning the corner along the front of the first compartment." Ex. 1102 ¶ 104. However, as can be seen more clearly from a further rendering provided by Petitioner, reproduced below, these portions appear to be two distinct features in Brezette.



Pet. 26. The rendering provided by Petitioner is consistent with Figure 1 of Brezette, in which the portion of Brezette along the right side of lubrication channel 15 is shown to protrude past the face of the wall at the front of lubrication channel 15. Beyond Dr. Kimmel's conclusory statement above, the Petition does not include any explanation, or any citation to the Kimmel Declaration, as to why these two distinct features of Brezette should be considered together as the claimed "first barrier." Aside from the two features in Brezette being structurally distinct from one another, there also is no apparent reason why a skilled artisan would consider the face of the wall at the front of lubrication channel 15 to be part of a "barrier," insofar it plays no role in preventing or blocking movement from or access between lubrication channel 15 and the neighboring portion of the tray. Because only the wall along the right side of lubrication channel 15 prevents or blocks movement from or access between lubrication channel 15 to the neighboring compartment, that is the only feature that a skilled artisan would consider to be a barrier separating lubrication channel 15 and the neighboring compartment. Thus, we are not persuaded that a skilled artisan would understand *both* of the features identified by Dr. Kimmel as *together* being the claimed "first barrier."

Moreover, neither of the two features individually can be considered the claimed "first barrier." The face of the wall at the front of Brezette's lubrication channel 15 cannot be considered the claimed barrier because the space between lubrication channel 15 and the neighboring portion of the tray is *entirely open*, and does not include a "structure that prevents or blocks movement from or access between" compartments so as to form a barrier. *See, e.g.*, Ex. 1110, Figs. 1–3. The portion of Brezette along the right side of lubrication channel 15 cannot be considered the claimed barrier because it is completely solid and does not "includ[e] a gap therein."

Accordingly, Petitioner does not persuade us that Brezette discloses "the first compartment and the second compartment are separated by a first barrier having an opening therein," as recited in claim 1, or "a first barrier separating the first compartment from the second compartment . . . [and that] defines a first opening between the first compartment and the second compartment," as recited in claim 22.

With respect to claim 1, Petitioner relies on Beddow as showing "placing a sterile wrap" (Pet. 32 (citing Ex. 1112, 2:39–41, 2:47–50)), and relies on Franks-Farah as showing "enclosing printed instructions" (*id.* at 29–31). Petitioner does not assert that Beddow or Franks-Farah discloses the claim feature missing from Brezette—that "the first compartment and the second compartment are separated by a first barrier having an opening therein." The challenge to claim 22 is based on Brezette alone. Thus, Petitioner has not demonstrated a reasonable likelihood of prevailing in showing claim 1 would have been obvious over Brezette, Beddow, and Franks-Farah, or on its challenge of claim 22 as obvious over Brezette.

Each of claims 7, 8, 10, 23, 25, 27, 28, and 30–34 depends, directly or indirectly, from one of claims 1 or 22. Because we are not persuaded that Petitioner has shown a reasonable likelihood that it would prevail on its assertion that the combination of Brezette, Beddow, and Franks-Farah renders obvious independent claim 1, or on its assertion that Brezette renders obvious claim 22, we also are not persuaded that Petitioner has shown a reasonable likelihood that it would prevail on its assertion that the asserted references or combinations thereof render obvious claims 7, 8, 10, 23, 25, 27, 28, and 30–34.

Conclusion

For the foregoing reasons, we do not authorize institution of *inter partes* review of claims 7 and 8 under 35 U.S.C. § 103(a) as obvious in view of Brezette, Beddow, and Franks-Farah; of claim 10 under 35 U.S.C. § 103(a) as obvious in view of Brezette, Beddow, Franks-Farah, and Serany; or of claims 22, 23, 25, 27, 28, and 30–34 under 35 U.S.C. § 103(a) as obvious in view of Brezette.

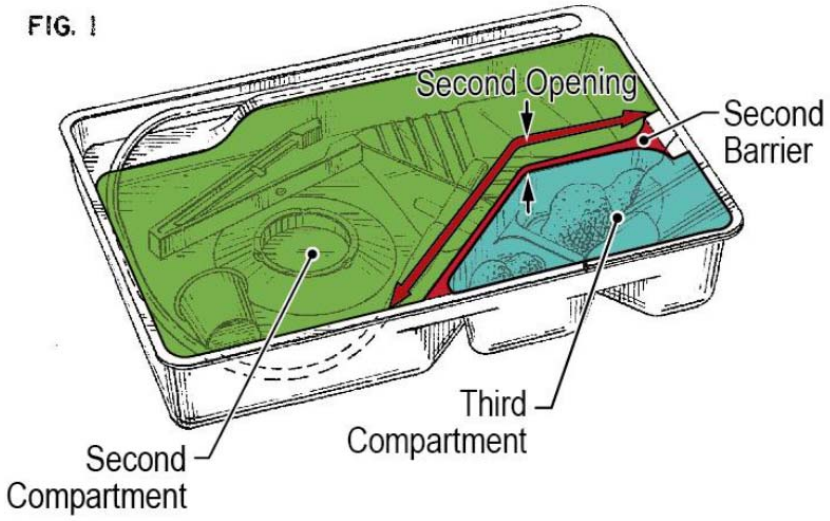
D. Obviousness in View of Rauschenberger

Petitioner asserts that claims 22, 23, 25, and 31–34 would have been obvious in view of Rauschenberger. Pet. 47–57. We have reviewed the parties' contentions and supporting evidence. Given the evidence on this record, and for the reasons explained below, we determine that the information presented does not show a reasonable likelihood that Petitioner would prevail on this ground. Specifically, we are not persuaded that Petitioner has made a sufficient showing that Rauschenberger teaches or suggests "a second barrier separating the second compartment from the third compartment . . . [and that] defines a second opening between the second

compartment and the third compartment," or "a first compartment comprising a first compartment base member . . . upon which syringes may be placed," as recited in claim 22.

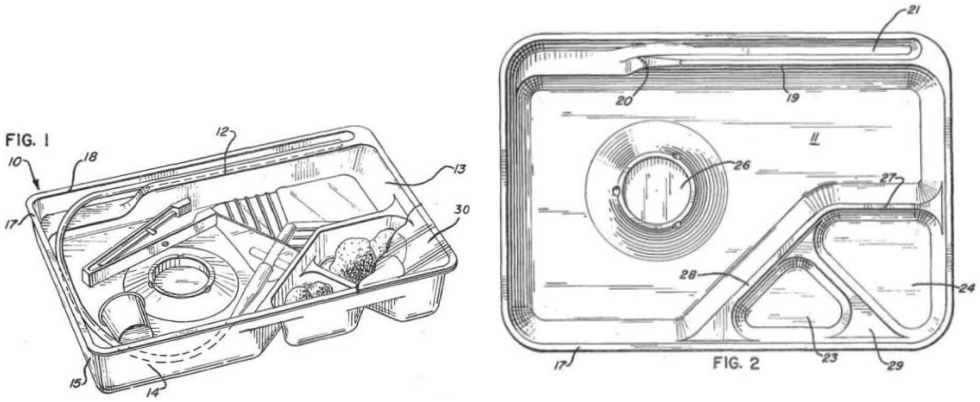
> *a second barrier separating the second compartment from the third compartment . . . [and that] defines a second opening between the second compartment and the third compartment*

Independent claim 22 recites both a "first barrier separating the first compartment from the second compartment . . . [and that] defines a first opening between the first compartment and the second compartment" *and* a "second barrier separating the second compartment from the third compartment . . . [and that] defines a second opening between the second compartment and the third compartment." Ex. 1101, 12:18–21, 12:26–28. As discussed above, with respect to claim 21, we are persuaded that wall 12 of Rauschenberger discloses the claimed "first barrier." *See supra* Section II.B.3. Petitioner provides an annotated version of Figure 1 of Rauschenberger, reproduced below:



Pet. 53. Petitioner's annotated figure illustrates the portions of Rauschenberger's tray that Petitioner points to as corresponding to the claimed "second compartment" (highlighted in green), "third compartment" (highlighted in blue), "second barrier" (highlighted in red), and "second opening." *Id.* As seen in Petitioner's annotated figure, Petitioner points to the main compartment of Rauschenberger's tray 10 as the claimed "second compartment," and Rauschenberger's compartments 23, 24 as the claimed "third compartment." *See id.* Petitioner asserts that the combination of walls 27, 28 of Rauschenberger teaches the claimed "second barrier." Pet. 53. Petitioner cites to the Kimmel Declaration, asserting that the "double-sided red arrow" identifies the opening in the second barrier. *Id.* (citing Ex. 1102 ¶ 206).

Figures 1 and 2 of Rauschenberger are reproduced below:



Figures 1 and 2 illustrate perspective and top views of tray 10 of Rauschenberger, respectively. Ex. 1111, 1:47–48. As seen in these figures, walls 27, 28 are flat on top and do not include an opening or gap defined thereby. Petitioner alleges that the space above walls 27, 28 defines the claimed "opening." Pet. 53 (indicating, e.g., that the "area beneath the double-sided red arrow" corresponds to the claimed "second opening depth"). We are not persuaded however, that this alleged "opening" teaches

a "gap" *in* the barrier structure, as required by our construction of a "barrier [that] defines a[n] . . . opening." *See supra* Section II.A.

Accordingly, Petitioner does not persuade us that Rauschenberger teaches "a second barrier separating the second compartment from the third compartment . . . [and that] defines a second opening between the second compartment and the third compartment," as recited in claim 22.

> *a first compartment comprising a first compartment base member having at least one inclined stair-stepped contour defining a ramp upon which syringes may be placed so that a plunger of each syringe is predisposed to project upward and out of the tray*

Independent claim 22 also recites "*a first compartment comprising a first compartment base member* having at least one inclined stair-stepped contour defining a ramp *upon which syringes may be placed* so that a plunger of each syringe is predisposed to project upward and out of the tray." Petitioner admits that "Rauschenberger does not disclose disposing at least one syringe in the tray," (with respect to claim 21) and asserts that a person of ordinary skill in the art "would be led to replace the lubrication packet in Rauschenberger with a syringe of lubricant and dispose that syringe in the first compartment."[6] Pet. 49 (referring back to Pet. 20–21). Patent Owner argues that Petitioner "uses hindsight to justify significant modifications in its attempt to match Rauschenberger to the challenged claims." Prelim. Resp. 52. Patent Owner enumerates the modifications to Rauschenberger proposed by Petitioner as "(i) replac[ing] the 'lubrication packet' disclosed in Rauschenberger with a syringe; (ii) widen[ing] the channel of the first compartment specifically to accommodate a syringe '***if***

[6] Petitioner relies on channel 21 of Rauschenberger as teaching the "first compartment." *See* Pet. 48.

necessary;' and (iii) mov[ing] the syringe from the tray—which contains all other components—to the first compartment—which contains only the end of the catheter." *Id.* at 50–51. Patent Owner further asserts that "Petitioner provides no support for these extensive modifications." *Id.* at 51.

Rauschenberger does not disclose channel 21 being configured such that syringes may be placed therein, but instead discloses channel 21 being configured to hold only the catheter. *See, e.g.*, Ex. 1111, 1:62–64 ("Channel 21 is adapted to receive a conventional urethral catheter which is positioned within channel 21 with its insertion end in the horizontal section."), 2:33–36 ("Ramp section 20 supports the catheter during its rotational movement and minimize[s] the danger of the catheter being dislocated from channel 21."). We agree with Patent Owner that Petitioner has not articulated sufficient reasoning why it would have been obvious to modify Rauschenberger in the proposed manner, particularly with respect to why one of ordinary skill would have moved the syringe (that replaces the lubricant packet of Rauschenberger) from the main compartment of tray 10 of Rauschenberger to channel 21, in which the catheter is disposed.

The Federal Circuit has made clear that an obviousness determination "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR*, 550 U.S. at 418. Similarly, an obviousness analysis must "avoid hindsight reconstruction by using the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit." *In re NTP, Inc.*, 654 F.3d 1279, 1299 (Fed. Cir. 2011).

Beyond the conclusory assertion that a person of ordinary skill "would be led to replace the lubrication packet in Rauschenberger with a syringe of lubricant and dispose that syringe in the first compartment" (Pet. 49), Petitioner provides no other analysis of this limitation. The Petition merely refers back to the discussion of Rauschenberger with respect to claim 21, which only asserts it would have been obvious to replace the lubricant packet of Rauschenberger with a syringe. *Id.* (referring to *id.* at 20–21). Claim 21, however, only requires the syringe be disposed in the *tray*, and not that the syringe be disposed in the *first compartment*. *See*, Ex. 1101, 11:67. An articulated reasoning of why a person of ordinary skill would *move the syringe* from the main compartment of tray 10 of Rauschenberger to channel 21 of Rauschenberger, and *then change the size* of channel 21 to accommodate the syringe, is still missing.

To the extent Petitioner relies on arguments presented only in the Kimmel Declaration, incorporation by reference is impermissible under our rules. *See* 37 C.F.R. § 42.6(a)(3) ("Arguments must not be incorporated by reference from one document into another document."); *Cisco Sys., Inc. v. C-Cation Techs., LLC*, Case IPR2014-00454, slip op. at 7–10 (PTAB Aug. 29, 2014) (Paper 12) (informative). In any case, Petitioner has not pointed us to anywhere in the Kimmel Declaration that provides a sufficient articulated rationale for the modifications necessary to Rauschenberger to teach the claimed step of "first compartment comprising a first compartment base member having at least one inclined stair-stepped contour defining a ramp *upon which syringes may be placed*."

We are not persuaded that the Petition sufficiently explains why a person of ordinary skill simultaneously would make all of the particular

proposed changes to Rauschenberger. Rather, we agree with Patent Owner that the Petition improperly "reli[es] upon *ex post* reasoning" and impermissible hindsight reconstruction to modify Rauschenberger to read on claim 22 of the '935 patent. *See KSR*, 550 U.S. at 421.

Conclusion

Accordingly, we are not persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing in showing claim 22 would have been obvious over Rauschenberger. Each of claims 23, 25, and 31–34 depends, directly or indirectly, from claim 22. Because we are not persuaded that Petitioner has shown a reasonable likelihood that it would prevail on its assertion that Rauschenberger renders obvious independent claim 22, we also are not persuaded that Petitioner has shown a reasonable likelihood that it would prevail on its assertion that Rauschenberger renders obvious claims 23, 25, and 31–34.

For the foregoing reasons, we do not authorize institution of *inter partes* review of claims 22, 23, 25, and 31–34 under 35 U.S.C. § 103(a) as obvious in view of Rauschenberger.

III. CONCLUSION

For the foregoing reasons, we institute an *inter partes* review of claim 21, but do not authorize institution of *inter partes* review of claims 7, 8, 10, 22, 23, 25, 27, 28, and 30–34. At this preliminary stage in the proceeding, we have not made a final determination with respect to the patentability of any challenged claim or the construction of any claim term.

IV. ORDER

Accordingly, it is

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claim 21 under 35 U.S.C. § 103(a) as obvious in view of Rauschenberger and Franks-Farah;

FURTHER ORDERED that no other ground of unpatentability asserted in the Petition is authorized for this *inter partes* review; and

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 will commence on the entry date of this decision.

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