

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 IPR2015-00511
Patent 8,631,935 B2

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

CHAGNON, *Administrative Patent Judge*.

DECISION
Denying 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 1–4 and 11–20 (“the challenged claims”) of U.S. Patent No. 8,631,935 B2 (Ex. 1001, “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 not a reasonable likelihood that Petitioner would prevail in establishing that any of the challenged claims of the '935 patent is unpatentable. *See* 35 U.S.C. § 314(a). For the reasons that follow, we deny institution of *inter partes* review.

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* review involving the same parties, related to the '935 patent, as well as to U.S. Patent Nos. 8,448,786 B2 and 8,678,190 B2, are pending as IPR2015-00509, IPR2015-00513, and IPR2015-00514. *See* Pet. 5–6.

B. The '935 Patent

The '935 patent is titled “Catheter Tray, Packaging System, and Associated Methods.” Ex. 1001, 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.

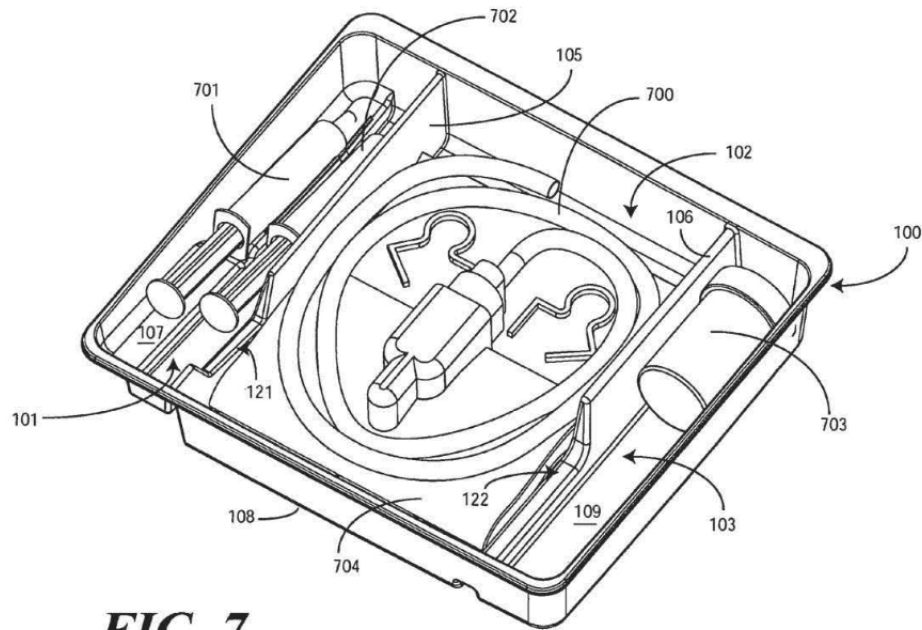


FIG. 7

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. 1001, 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 Claim

Of the challenged claims, claims 1, 17, and 19 are independent. Claims 2–4 and 11–16 depend, directly or indirectly, from claim 1; claim 18 depends from claim 17; and claim 20 depends from claim 19. Claim 1 of the '935 patent, reproduced below, is illustrative of the challenged claims:

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. 1001, 10:12–26.

D. The Applied References

Petitioner relies on the following references. Pet. 8.

Reference	Date	Exhibit No.
U.S. Patent No. 3,978,983 ("Brezette")	Sept. 7, 1976	Ex. 1010
U.S. Patent No. 4,226,328 ("Beddow")	Oct. 7, 1980	Ex. 1012
U.S. Patent No. 6,840,379 B2 ("Franks-Farah")	Jan. 11, 2005	Ex. 1009
U.S. Patent No. 4,160,505 ("Rauschenberger")	July 10, 1979	Ex. 1011

Petitioner further relies on the Declarations of Dr. Robert M. Kimmel (Ex. 1002, "Kimmel Declaration") and Susan Carrow, MSN/Ed, CEN, RN (Ex. 1004).

E. The Asserted Grounds

Petitioner sets forth its challenges to claims 1–4 and 11–20 as follows.

Pet. 8, 17–60.

References	Basis	Claims Challenged
Brezette, Beddow, and Franks-Farah	§ 103	1–4, 11–20
Rauschenberger, Beddow, and Franks-Farah	§ 103	1–4, 11–20

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. *See* 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. 8–16; Prelim. Resp. 7–13. For purposes of this Decision, we need only make explicit the meaning of the phrase “barrier having an opening therein.” 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)).

Claims 1, 17, and 20 each include 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. 1001, 10:14–18, 11:23–27, 11:42–46 (emphasis added). Petitioner does not offer a construction of the phrase “barrier having an opening therein.” Patent Owner proposes a construction of the term “barrier,” in the context of its use in claims 1, 17, and 19, as a

“structure that separates one compartment from another and prevents or blocks movement therebetween.” Prelim. Resp. 8–10. This proposed construction is consistent with the plain meaning of “barrier”—“[a] fence or other obstacle that prevents movement or access.”¹ The plain meaning of “opening” is “[a]n aperture or gap, especially one allowing access.”²

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. 1001, 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” in accordance with its 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.”

B. Obviousness in View of Brezette, Beddow, and Franks-Farah

Petitioner asserts that claims 1–4 and 11–20 would have been obvious in view of Brezette, Beddow, and Franks-Farah. Pet. 19–43. Each of

¹ *See Barrier Definition*, OxfordDictionaries.com, http://www.oxforddictionaries.com/us/definition/american_english/barrier (last accessed July 13, 2015).

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

independent claims 1, 17, and 19 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. 1001, 10:14–18, 11:23–27, 11:42–46. Petitioner relies on Brezette as disclosing this claim feature. *See* Pet. 21–22, 40, 41.

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. 1010, Title, Abstract.

Figures 1, 2, and 3 of Brezette are reproduced below:

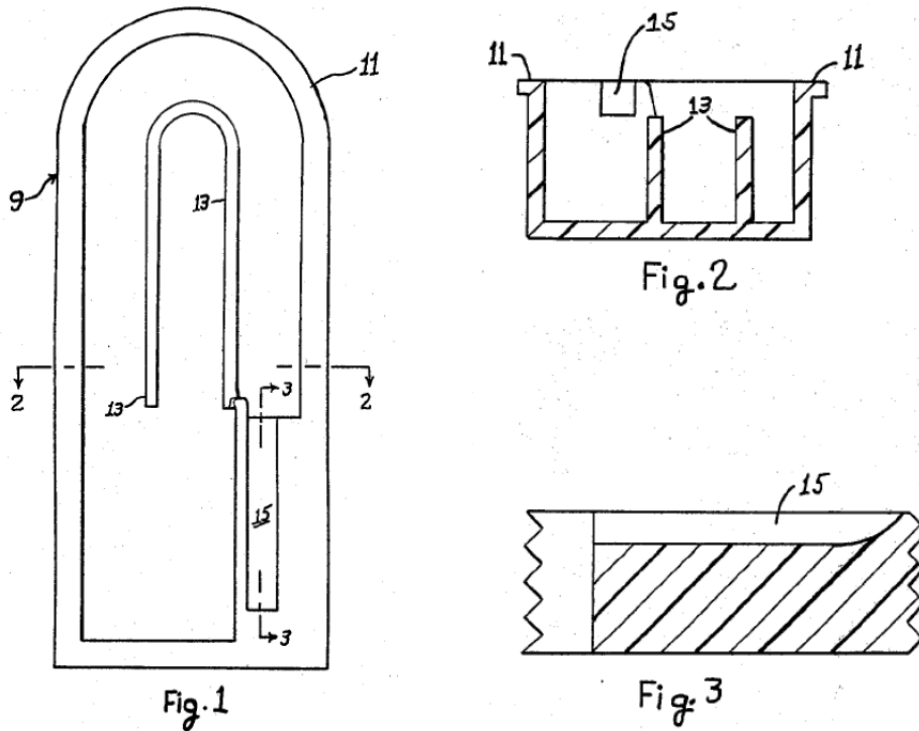
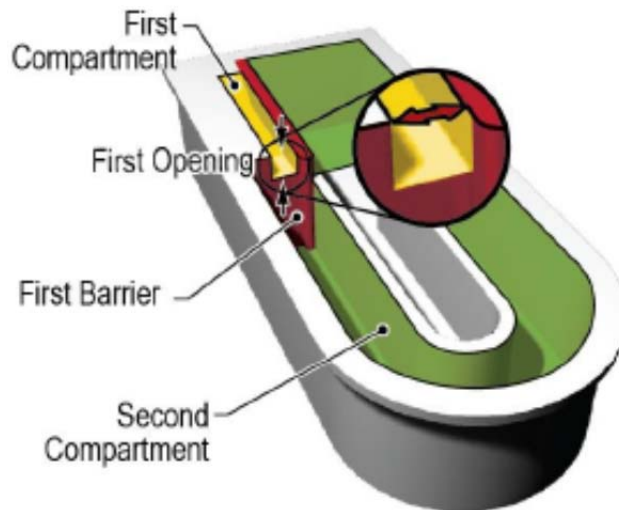


Figure 1 is a top view of catheterization tray 9, and Figures 2 and 3 are cross-sectional views of tray 9 along lines 2–2 and 3–3 of Figure 1, respectively. *See id.* at 2:21–29. Lubrication channel 15 is recessed from upper surface 11. *Id.* at 2:51–53. Tray 9 also includes compartments, separated by 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 through 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.

Petitioner relies on Brezette as teaching “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,” as recited in each of claims 1, 17, and 19. *See* Pet. 21–22, 40, 41. Petitioner provides a rendering, reproduced below, of Brezette’s tray in a perspective view.

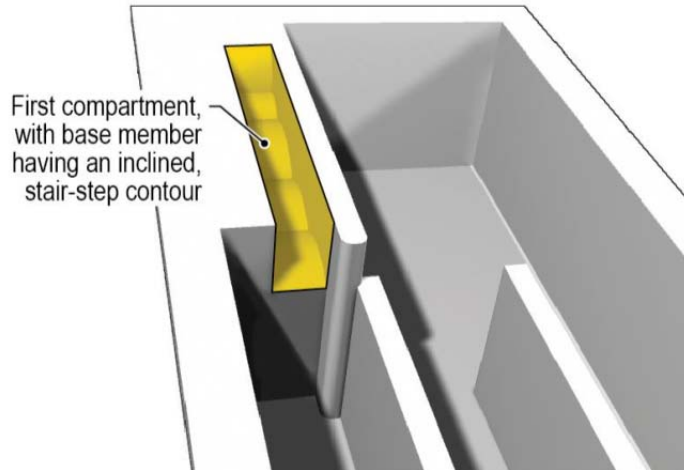


Pet. 21. Petitioner’s rendering illustrates the portions of Brezette’s tray that Petitioner points to as corresponding to the claimed “first compartment” (highlighted in yellow), “second compartment” (highlighted in green), “first

barrier” (highlighted in red), and “opening.” *Id.* at 21–22. Petitioner provides declaration testimony to support the mapping of these claim features. *See* Ex. 1002 ¶ 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. 22 (citing Ex. 1002 ¶ 104).

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 claims 1, 17, and 19. Prelim. Resp. 28–29 (citing Ex. 1010, Fig. 2).

Brezette’s Figures 1–3, as well as Petitioner’s perspective drawing, 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. 1002 ¶ 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. 21. 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. 1010, 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 claims 1, 17, and 19. Petitioner relies on Beddow as showing “placing a sterile wrap.” Pet. 19, 28 (citing Ex. 1012, 2:39–41, 2:47–50). Petitioner relies on Franks-Farah as showing “enclosing printed instructions.” *Id.* at 19, 26–27 (citing Ex. 1009, 2:25–32). 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.” Thus, Petitioner has not demonstrated a reasonable likelihood of prevailing in its challenge of claims 1, 17, and 19 as obvious over Brezette, Beddow, and Franks-Farah.

Each of claims 2–4, 11–16, 18, and 20 depends, directly or indirectly, from one of claims 1, 17, or 19. 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 claims 1, 17, and 19, we also are not persuaded that Petitioner has shown a reasonable likelihood that it would prevail on its assertion that the asserted combination renders obvious claims 2–4, 11–16, 18, and 20.

For the foregoing reasons, we do not authorize institution of *inter partes* review of claims 1–4 and 11–20 under 35 U.S.C. § 103(a) as obvious in view of Brezette, Beddow, and Franks-Farah.

C. Obviousness in View of Rauschenberger, Beddow, and Franks-Farah

Petitioner asserts that claims 1–4 and 11–20 would have been obvious in view of Rauschenberger, Beddow, and Franks-Farah. Pet. 43–58. Each of independent claims 1, 17, and 19 recites “disposing at least one syringe in the first compartment.” Ex. 1001, 10:19, 11:29, 11:48. Petitioner relies on Rauschenberger, in view of Beddow, as teaching this claim feature. *See* Pet. 45–46 (citing *id.* at 22–23); *id.* at 56, 57.

Rauschenberger relates to a sterile, self-contained catheterization tray. Ex. 1011, Abstract. Figure 1 of Rauschenberger is reproduced below:

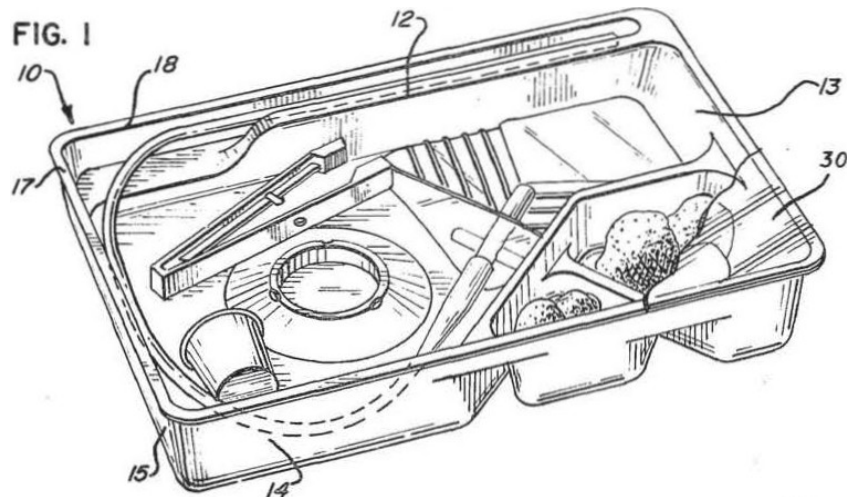


Figure 1 is a perspective view of the catheterization tray of Rauschenberger. *Id.* at 1:47. Tray 10 includes channel 21, which is formed by wall 12. *Id.* at 1:50–61. Rauschenberger discloses that various catheterization components are placed in tray 10, as shown in Figure 1, and sealed with cover sheet 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 are adapted to hold absorbent pads. *Id.* at 2:5–7. 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.

Petitioner admits that “Rauschenberger does not disclose disposing at least one syringe in the first compartment,” but asserts that a person of ordinary skill in the art “would have been motivated by Beddow and the prior art and common sense in general, to modify the Rauschenberger tray to substitute the ‘lubricant packet’ with a syringe and [to] place that syringe in the first compartment.”³ Pet. 45 (citing Ex. 1002 ¶¶ 149–151). Patent Owner argues that Petitioner “uses hindsight to justify significant

³ Petitioner relies on channel 21 of Rauschenberger as teaching the “first compartment.” *See* Pet. 44.

modifications in its attempt to match Rauschenberger to the challenged claims.” Prelim. Resp. 43. Patent Owner enumerates the modifications to Rauschenberger proposed by Petitioner as “(i) replac[ing] the ‘condiment-like packet’ [of lubricant] with a syringe; (ii) widen[ing] the channel of the first compartment specifically to accommodate a syringe; 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 41–42. Patent Owner further asserts that “Petitioner provides no support for its extensive modifications.” *Id.* at 42.

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. 1011, 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 Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). 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 have been motivated by Beddow and the prior art and common sense in general, to modify the Rauschenberger tray to substitute the ‘lubricant packet’ with a syringe and [to] place that syringe in the first compartment” (Pet. 45), Petitioner provides no other analysis of this limitation, nor citations to any portions of Beddow in this regard. Petitioner merely asserts that the “same analysis as to why a [person of ordinary skill] would have reason to modify the first compartment in Brezette to accommodate at least one syringe . . . also applies” to this asserted ground. Pet. 45–46 (citing *id.* at 22–23). However, the referenced analysis merely states that a person of ordinary skill “would have known it may have been necessary to modify the first compartment to adequately hold the syringe (*e.g.*, make the compartment longer or wider, or otherwise modify the configuration . . . within the compartment).” Pet. 23 (citing Ex. 1002 ¶ 105; Ex. 1010, 2:63–64). 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, even the cited portions of the Kimmel Declaration do not provide a sufficient articulated rationale for the modifications necessary to Rauschenberger to teach the claimed step of “disposing at least one syringe in the first compartment.” Dr. Kimmel merely provides a conclusory statement that

a person of ordinary skill in the art would have had reason, in light of Beddow or Brezette,⁴ to put a container of liquid or jelly in the first compartment of the Rauschenberger tray (and move the end of the catheter from the first compartment, as necessary, so the entire catheter assembly is in the second compartment when shipped, until the catheter needs to be lubricated).

Ex. 1002 ¶ 149.

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 claims 1, 17, and 19 of the ’935 patent. *See KSR*, 550 U.S. at 421.

⁴ The portions of Beddow and Brezette to which Dr. Kimmel cites disclose only an “individually sealed foil container 26 of lubricating jelly 27 packed within an elongated rectangular recess 28” and “sterile lubricant packaged [in the lubrication channel 15],” respectively, and provide no teaching with respect to moving the catheter out of channel 21, or changing the size thereof, to accommodate a syringe of lubricant. *See* Ex. 1002 ¶ 149 (citing Ex. 1012, 3:11–14; Ex. 1010, 3:30–31).

Petitioner relies on Franks-Farah as showing “enclosing printed instructions.” *Id.* at 48, 56–57. Petitioner does not assert that Franks-Farah discloses the claim feature missing from the teachings of Rauschenberger and Beddow—“disposing at least one syringe in the first compartment.” Thus, Petitioner has not demonstrated a reasonable likelihood of prevailing in its challenge of claims 1, 17, and 19 as obvious over Rauschenberger, Beddow, and Franks-Farah.

Each of claims 2–4, 11–16, 18, and 20 depends, directly or indirectly, from one of claims 1, 17, or 19. Because we are not persuaded that Petitioner has shown a reasonable likelihood that it would prevail on its assertion that the combination of Rauschenberger, Beddow, and Franks-Farah renders obvious independent claims 1, 17, and 19, we also are not persuaded that Petitioner has shown a reasonable likelihood that it would prevail on its assertion that the asserted combination renders obvious claims 2–4, 11–16, 18, and 20.

For the foregoing reasons, we do not authorize institution of *inter partes* review of claims 1–4 and 11–20 under 35 U.S.C. § 103(a) as obvious in view of Rauschenberger, Beddow, and Franks-Farah.

III. ORDER

Accordingly, it is

ORDERED that pursuant to 35 U.S.C. § 314(a), the Petition is *denied*.

IPR2015-00511
Patent 8,631,935 B2

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