

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C.R. BARD, INC.,
Petitioner,

v.

MEDLINE INDUSTRIES, INC.,¹
Patent Owner.

IPR2019-00035
Patent 9,745,088 B2

Before JOSIAH C. COCKS, MITCHELL G. WEATHERLY, and
ALYSSA A. FINAMORE, *Administrative Patent Judges*.

WEATHERLY, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision on Remand
Determining Some Challenged Claims Unpatentable
35 U.S.C. §§ 144, 318

¹ Patent Owner was previously identified as Medline Industries, Inc., but it states that it changed its legal form from a corporation to a limited partnership on September 7, 2021. Paper 82, 2. As of the same date, Medline Industries, LP was also the record owner of the '088 patent. Ex. 3004.

I. INTRODUCTION

A. TRIAL BACKGROUND

C.R. Bard, Inc. (“Petitioner”) filed a petition (Paper 2, “Pet.”) to institute an *inter partes* review of claims 1, 2, 6–10, 16–19, and 25–44 (the “challenged claims”) of U.S. Patent No. 9,745,088 B2 (Ex. 1001, “the ’088 patent”). 35 U.S.C. § 311. Medline Industries, LP (“Patent Owner”) timely filed a Preliminary Response. Paper 12 (“Prelim. Resp.”). Based on our review of the record at that preliminary stage, we concluded that Petitioner was reasonably likely to prevail with respect to at least one of the challenged claims, and we therefore instituted *inter partes* review of all challenged claims on all the grounds set forth in the Petition. *See* Paper 18, 26–27.

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. § 103 based on the following grounds (Pet. 23–87):

Claims challenged	35 U.S.C. §	References
1, 2, 6–10, 16, 17, 25–32, 36–41	103	Solazzo, ² Serany ³
18, 19, 35	103	Solazzo, Serany, Franks-Farah ⁴
33, 34, 42	103	Solazzo, Serany, Disston ⁵
43, 44	103	Solazzo, Serany, Disston, Franks-Farah

² U.S. Patent No. 7,278,987 B2 (Ex. 1005, “Solazzo”).

³ U.S. Patent No. 3,329,261 (Ex. 1006, “Serany”).

⁴ U.S. Patent No. 6,840,379 B2 (Ex. 1007, “Franks-Farah”).

⁵ U.S. Patent No. 3,166,189 (Ex. 1008, “Disston”).

After we instituted this review, Patent Owner filed a Patent Owner Response in opposition to the Petition. Paper 36 (“PO Resp.”). Petitioner filed a Reply in support of the Petition. Paper 55 (“Reply”). Patent Owner filed a Sur-reply. Paper 64 (“Sur-reply”). With our authorization, each party filed a brief addressing a recent decision from our reviewing court, *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366 (Fed. Cir. 2019). Papers 69, 70. Patent Owner did not move to amend any claim of the ’088 patent.

We heard oral argument on January 6, 2020, a transcript of which appears in the record (Paper 71, “Tr.”).

We entered a Final Written Decision (“Decision” or “Dec.”) in which we concluded that Petitioner had failed to demonstrate by a preponderance of evidence that claims 1, 2, 6–10, 16–19, and 25–44 were unpatentable. Paper 73, 5–30. Our Decision was based solely upon our determinations that Petitioner had failed to demonstrate that the prior art described or suggested all limitations of each independent claim. *Id.* at 12–28. We did not separately address the patentability of any dependent claim, *id.* at 28, or weigh the objective evidence of nonobviousness adduced by Patent Owner, *id.* at 28–29.

B. THE APPEAL TO THE FEDERAL CIRCUIT

Petitioner appealed our Decision to the Federal Circuit. *C.R. Bard, Inc. v. Medline Indus., Inc.*, No. 2020-1900, 2021 WL 3574043 (Fed. Cir. Aug. 13, 2021) (“Op.”). Briefly, the Federal Circuit disagreed with our determinations that the prior art did not teach all limitations of independent

claims 1, 25, and 37.⁶ *Id.* at *5–7. More specifically, the Federal Circuit vacated our Decision that claims 1, 2, 6–10, 16–19, and 25–44 of the '088 patent were not unpatentable. *Id.* at *7. Therefore, the Federal Circuit remanded the case to us for further proceedings consistent with its opinion. *Id.* at *10.

On remand, we must (1) determine whether and to what extent, if any, Patent Owner's actions in IPR2019-00208,⁷ collaterally estop Patent Owner from arguing that objective evidence of nonobviousness warrants a conclusion that its claims remain patentable; and (2) reconsider the patentability of the challenged claims, including dependent claims not separately analyzed in the Decision, in view of the objective evidence of nonobviousness adduced by Patent Owner. *Id.* at *9–10. We did not separately address any dependent claims in our Decision. Accordingly, we must now reconsider whether Petitioner has proven that dependent claims 2, 6–10, 16–19, 26–36, and 38–44 are unpatentable.

C. REMAND BACKGROUND

On remand, we authorized the parties to concurrently file an opening brief on the merits and concurrently file a responsive reply brief. Paper 84, 4–5. Neither party asked nor did we allow either party to submit new evidence during the remand proceeding. *Id.* at 3. Accordingly, we decide

⁶ Although the Federal Circuit did not separately and expressly analyze independent claim 37, it did instruct us to include that claim and its dependent claims in our analysis on remand. *Op.* *10.

⁷ IPR2019-00208 involves U.S. Patent No. 9,808,400 B2, which is owned by Patent Owner, “share[s] similar disclosures with” the '088 patent, and has “similar” claims to the claims challenged in this proceeding. IPR2019-00208, Paper 3, 3. The final written decision in IPR2019-00208 was not appealed.

the issues on remand based on the record that was submitted during the original trial.

Petitioner filed an opening brief (Paper 87, “Pet. Remand Br.”). Patent Owner filed an opening brief (Paper 89, “PO Remand Br.”). Petitioner filed a Reply responding to Patent Owner’s opening brief (Paper 95, “Pet. Remand Reply”). Patent Owner filed a Reply responding to the Remand Reply (Paper 92, “PO Remand Reply”).

Patent Owner, but not Petitioner, requested an oral hearing, and we denied Patent Owner’s request. Paper 96. This Final Written Decision is issued pursuant to 35 U.S.C. §§ 144, 318(a) and 37 C.F.R. § 42.73. For the reasons expressed below, we conclude that Petitioner has demonstrated by a preponderance of evidence that claims 1, 2, 6, 8–10, 16, 25–27, 29–37, and 39–44 are unpatentable as obvious but has failed to do so for claims 7, 17–19, 28, and 38.

D. RELATED PROCEEDINGS

The parties identified as a related proceeding the co-pending district court proceeding of *Medline Industries, Inc. v. C. R. Bard, Inc.*, Case Number 1:17-cv-07216 (N.D. Ill.). Pet. 90; Paper 4, 2. The parties also identify IPR2019-00036, in which Petitioner challenges claims 45–58, 60–74, 76–90, and 92 of the ’088 patent, as a related matter. Pet. 90; Paper 4, 2. Patent Owner further identifies as related matters U.S. Patent Application Nos. 15/684,787 and 15/803,383, which are continuations of the application leading to issuance of the ’088 patent. Paper 4, 2. Patent Owner further identifies U.S. Patent Application Nos. 14/265,920; 15/804,520; 15/051,964; 13/374,509; 15/640,224; and 15/703,514 as related matters because these applications “share similar disclosures and claim language” with the

'088 patent. *Id.* Patent Owner further identifies U.S. Patent Application Nos. 16/833,575; 16/944,667; and 17/180,680 as “continuation applications” claiming priority to the '088 patent and U.S. Patent Application Nos. 16/986,803; 16/258,231; 16/688,185; 16/721,718; 17/372,149; 17/483,608; 17/483,610; and 63/247,733 as related matters because these applications “share similar disclosures and in at least some instances similar claim language” with the '088 patent. Paper 82, 2–3.

E. THE '088 PATENT

The '088 patent is directed to “storage containers for medical devices, and more particularly to a storage container for a long, flexible medical implement, such as a catheter, and related medical devices.” Ex. 1001, 1:34–37. The Specification describes tray 100 shown in Petitioner’s annotated and colorized version of Figure 7 (Pet. 14), which we reproduce below.

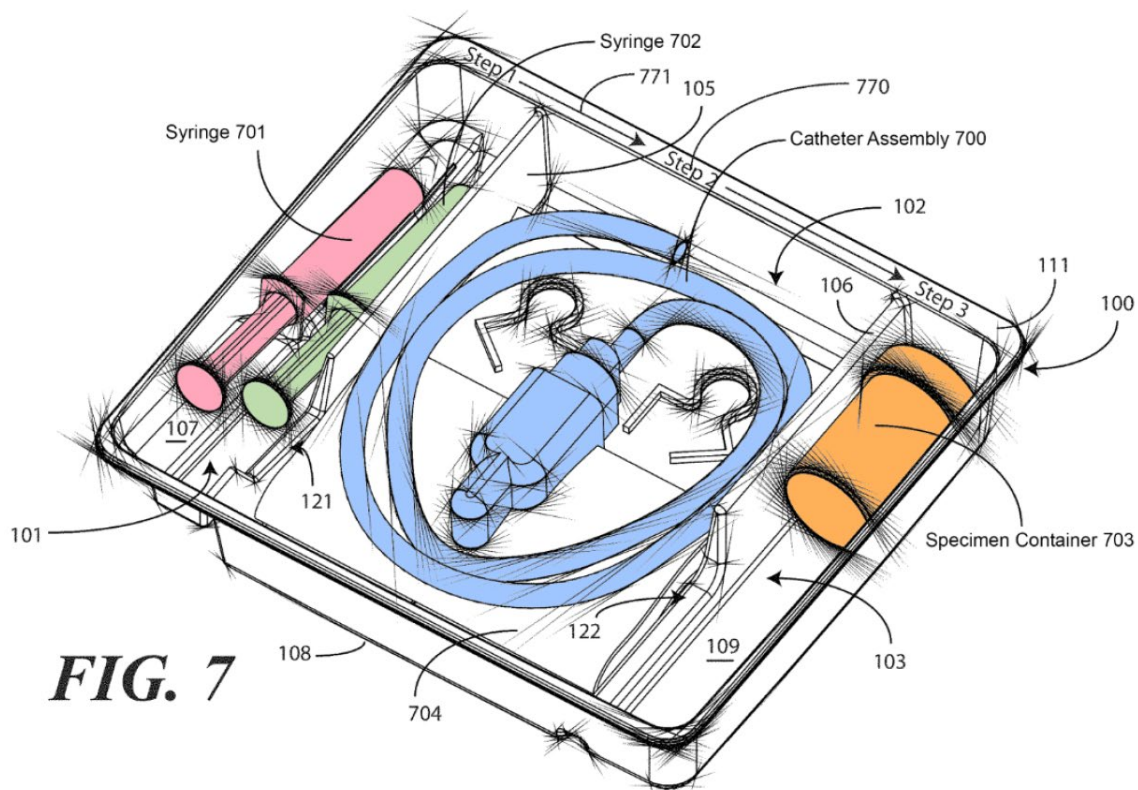


Figure 7 illustrates a catheter, two syringes, and a specimen bottle located within single level tray 100. Ex. 1001, 2:45–49.

Before use, tray 100 is double-wrapped to ensure that components in the tray remain sterile up to and through their initial use with tray 100 being wrapped in CSR wrap 1000 and then outer sterile wrap 1002. *Id.* at 11:45–46, 11:51–52, Fig. 10. Tray 100 includes three compartments 101, 102, 103 adapted to receive various items used in a catheterization procedure. *Id.* at 5:12–18. First compartment 101 accommodates syringes 701, 702 (red, green) containing sterile water or lubricants. *Id.* at 4:18–21, 9:24–26. Second compartment 102 accommodates catheter assembly 700 (blue) and towel 704. *Id.* at 9:26–28. Third compartment 103 accommodates specimen container 703 (orange) for capturing samples taken from the patient via catheter 700. *Id.* at 4:22–23, 5:64–65. Additional objects can be included with the tray, including one or more towels, a drape

to cover the patient, rubber gloves, hand sanitizing materials, swab sticks, a securement device, printed instructions, and so forth. *Id.* at 5:46–51.

Claims 1, 25, and 37 are the independent claims among the challenged claims. *Id.* at 27:47–30:57. The text of each independent claim is reproduced below in Parts VI.A, VII.A, and VIII.A below respectively.

II. CLAIM INTERPRETATION

“A claim in an unexpired patent that will not expire before a final written decision is issued 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) (2018);⁸ *see also* *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (affirming that USPTO has statutory authority to construe claims according to Rule 42.100(b)). When applying that standard, we interpret the claim language as it would be understood by one of ordinary skill in the art in light of the specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Thus, we give claim terms their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) (“The ordinary and customary meaning ‘is the meaning that the term would have to a person of ordinary skill in the art in question.’”). Only terms that are in controversy need to be construed, and

⁸ In 2018, this Rule was amended to require that we interpret claims in the same manner used in a civil action under 35 U.S.C. § 282(b). However, the amended Rule does not apply in this proceeding because the Petition was filed before the effective date of the new Rule, November 13, 2018. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,344 (Oct. 11, 2018).

then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

In our Decision, we did not express an opinion about the meaning of any specific claim language because we determined that the controversy between the parties does not require it. Dec. 6. In their respective remand briefing, neither party proffers any express interpretation of the claims. However, resolving the parties' dispute over claim 1 now requires us to interpret "a compartment" and "a second compartment" as recited in claim 1. We address the meaning of both phrases in Part VI.A below. We interpret all language in the claims according to the principles set forth above.

III. LEGAL STANDARDS

To prevail in its challenges to the patentability of the claims, Petitioner must establish facts supporting its challenges by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). "In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim"))). This burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)) (discussing the burden of proof in *inter partes* review).

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* that we apply in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103(a) as follows: (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, (3) resolving the level of ordinary skill in the pertinent art, and (4) considering objective evidence indicating obviousness or nonobviousness. *KSR*, 550 U.S. at 406 (citing *Graham*, 383 U.S. at 17–18). In an *inter partes* review, Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Thus, to prevail Petitioner must explain how the proposed combinations of prior art would have rendered the challenged claims unpatentable. With these standards in mind, we address each challenge below.

IV. LEVEL OF ORDINARY SKILL IN THE ART

The parties generally agree that a person having an ordinary level of skill in the relevant art would have a bachelor’s degree in packaging engineering, mechanical engineering, or industrial design. Pet. 18 (citing Ex. 1002 ¶¶ 14–16); PO Resp. 15 (citing Ex. 2026 ¶ 38). Alternatively, such a person could have an engineering degree in another technical field along with about two years of experience designing medical packaging. Pet. 18 (citing Ex. 1002 ¶¶ 14–16); PO Resp. 15 (citing Ex. 2026 ¶ 38). Neither party contends that a person of ordinary skill needs to be a medical practitioner, but both parties agree that the person of ordinary skill would

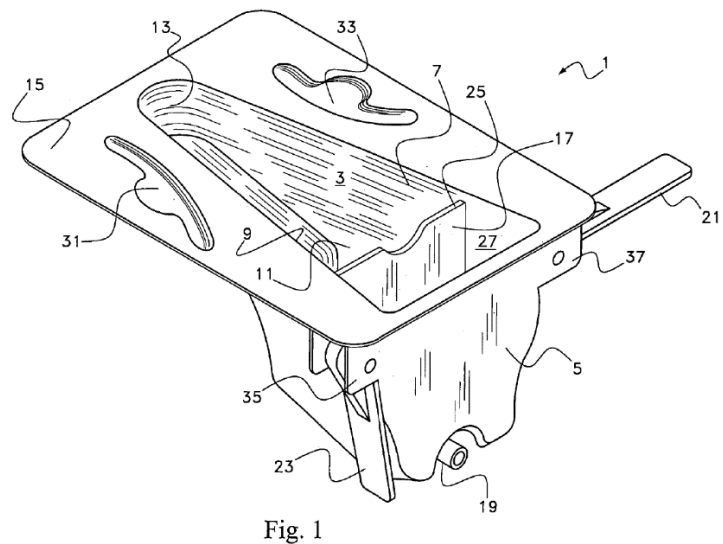
consult with medical practitioners familiar with catheterization procedures.
Pet. 18; PO Resp. 15 (citing Ex. 2027 ¶ 78).

Slight differences exist in the formulation of the level of ordinary skill between the parties. We, however, discern no meaningful difference because none of those differences would affect the outcome of our analysis. Accordingly, we apply the level of skill set forth in the preceding paragraph.

V. OVERVIEW OF PERTINENT PRIOR ART

A. SOLAZZO

Solazzo is directed to an ergonomic, single layer catheterization/irrigation tray 1 having multiple compartments, including recessed area 3, compartment 27, and wells 31, 33 as shown in Figure 1, which we reproduce below right. Ex. 1005, 4:15–25, Fig.1. Solazzo's Figure 1 is a perspective view of the catheterization and irrigation tray illustrating its major features. *Id.* at 3:31–33. Divider wall 17 is optional and, when present, divides recessed area 3 into two compartments, with compartment 27 being configured to receive fluid passing over top 25 of wall 17. *Id.* at 4:15–20.



Recessed area 3 is trapezoidal-shaped with a “non constant depth” provided by terraced bottom 11 having low area 11A and shallow area 11B as shown in Figure 2, reproduced at right. *Id.*

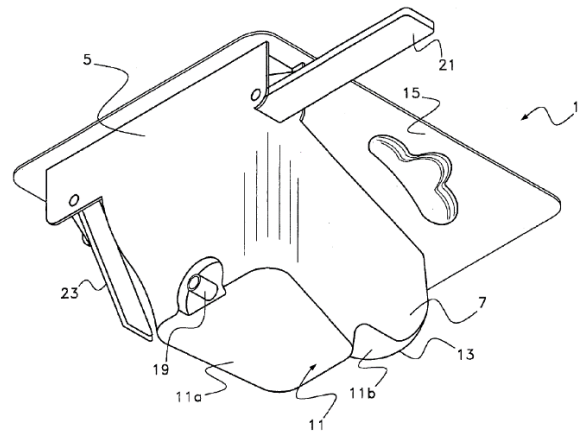


Fig. 2

at 3:61–66, Fig. 2. Recessed area 3 and compartment 27 store medical devices of tray kit 100, including Foley catheter 120, urinary tract lubricant 140, surgical gloves 130, inflation syringe 110, irrigation syringe (not shown), evacuation tubing, and antiseptic solutions as shown in Solazzo’s Figure 8, which is a top view of kit 100 that we reproduce below. *Id.* at 3:14–24, 4:1–8, Fig. 8.

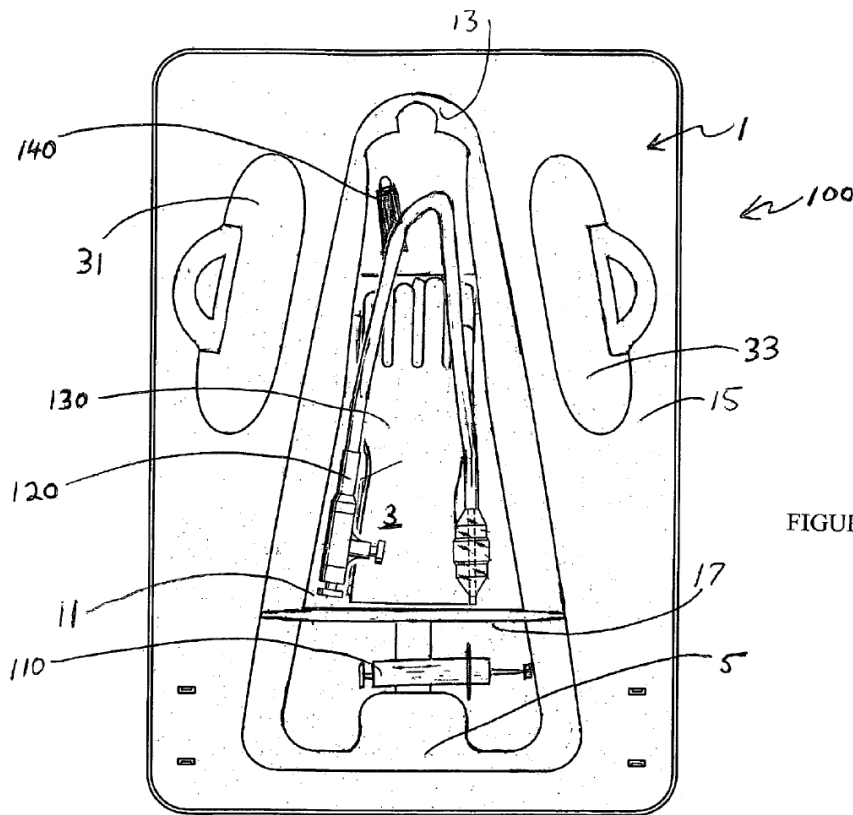


FIGURE 8

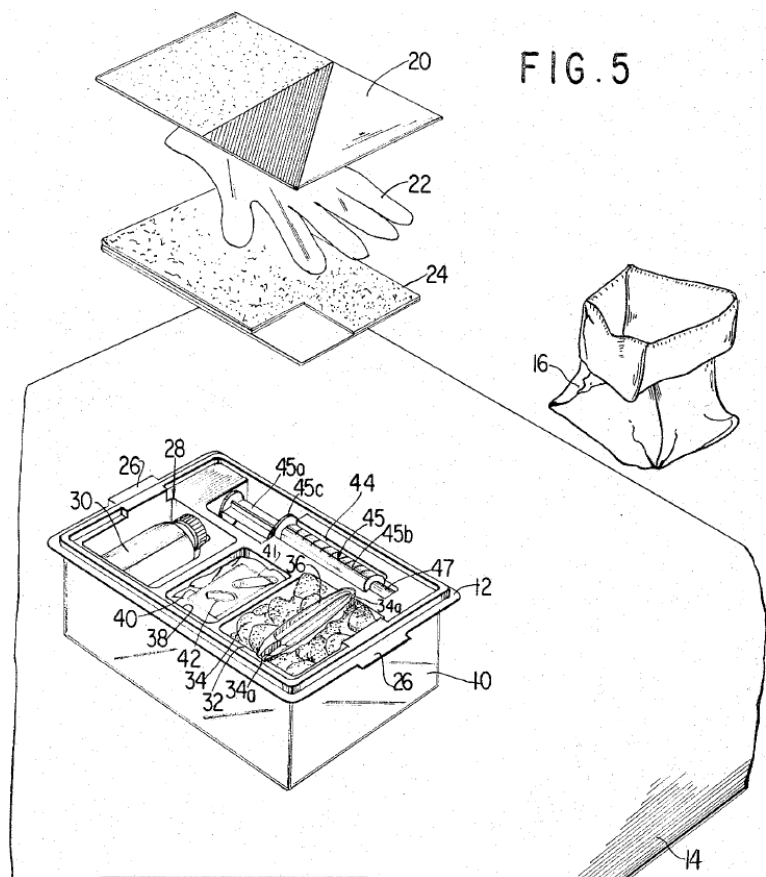
Solazzo’s Figure 8 is a top view of kit 100 illustrating various components stored in compartments of tray 1. *Id.* at 4:41–48.

Inflation syringe 110 is stored at low area 11A, and lubricant 140 is stored at shallow area 11B. *Id.* at 4:41–45, Fig. 8.

In use, recessed area 3 and compartment 27 fit between the legs of a “patient requiring an urological procedure” while flange 15 and wing supports 21, 23 rest atop the legs while the patient is seated. *Id.* at 1:8–12, 3:66–4:10, 4:26, 4:32–33, Fig. 1. A surgeon proceeds to “evacuate the bladder of its contents, urine and/or clots” using kit 100, e.g., by wearing the gloves, lubricating and inserting the catheter, and inflating it with inflation syringe 110. *Id.* at 4:32–33, 4:46–48.

B. SERANY

Serany is directed to a double-wrapped, sterile package providing catheterization components ready for use in the order needed. Ex. 1006, 1:8–16, 1:60–63, 3:63–4:2; Figs. 1–3, 5. Serany’s Figure 5 (reproduced at right in pertinent part) is an exploded view illustrating how various compartments are positioned within Serany’s box 10. The package includes multi-compartment single layer tray 12 mounted on box 10 and enclosed with



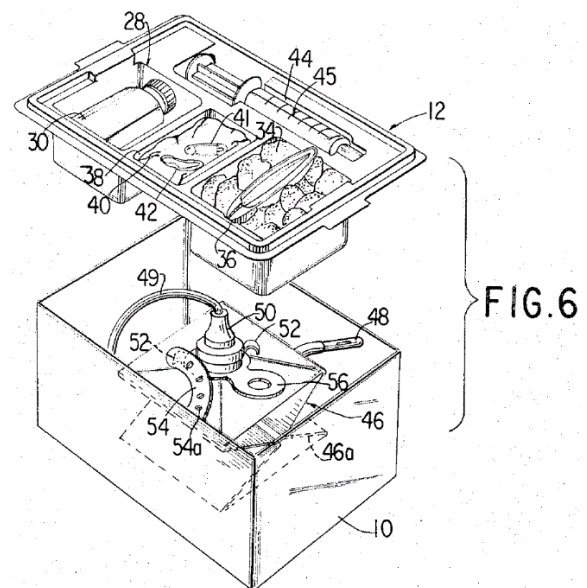
sealed outer envelope 16 and inner wrap 14 that unfolds to provide a sterile field work area. *Id.* at 1:60–72, 2:17–20; Figs. 1–5.

For example, prefilled syringe 45 of sterile water fits in depression 44, which includes indentations 44d along the sides to accommodate the syringe's flange. *Id.* at 2:40–41, 3:6–22; Figs. 6–7. Serany's package further includes waterproof underpad 20, gloves 22, fenestrated drape 24, cleansing solution bottle 30, rayon balls 34, forceps 36, lubricating jelly pouch 40, safety pin 41, and rubber band 42. Serany describes its package as containing "all the essential equipment, . . . for a complete catheterization procedure. . . . Everything is available in the proper order of use and in a sterile condition." *Id.* at 1:16–25.

Box 10 also includes Foley catheter 48 that is preconnected to collapsible drainage bottle 46 via tube 49 and "ready for use" as shown in Serany's Figure 6, which is reproduced at right. *Id.* at 2:22–

33, 2:57–70, 3:1–5, 3:23–26, Figs. 5–6. Collapsible drainage "bottle 46 is made of flexible plastic material having fold lines 46a . . . so that it may be folded flat for storage . . . and expanded into cube form

when in use. The bottle is shown in FIG. 6 partially expanded for illustration purposes." *Id.* at 3:26–31, Fig. 6. Catheter 48 and tubing 49 are coiled in the box about bottle 46 as shown in Figure 6. *Id.* at 3:33–35.



VI. CLAIMS 1, 2, 6–10, AND 17–19

A. INDEPENDENT CLAIM 1

Independent claim 1 recites:

1. A medical procedure kit, comprising:
 - [a] a tray having a compartment for receiving a medical assembly;
 - [b] a first syringe and a second syringe disposed within the tray;
 - [c] at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material; and
 - [d] an outer packaging disposed about both the tray and the at least one layer of wrap material, wherein:
 - [e] the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure; and
 - [f] the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe; and
 - [g] the first compartment comprising a base member that defines a mnemonic device indicating which of the first syringe or the second syringe should be used first in the catheterization procedure.

Ex. 1001, 27:47–67 (with added letter designations a–g to ease discussion).

Previously, we concluded that Petitioner had failed to prove by a preponderance of evidence that the combination of Solazzo and Serany described elements 1e and 1g and thus failed to establish that claim 1 was obvious. Dec. 12–21. The Federal Circuit found that: “Given the prior art disclosures, a skilled artisan would have been motivated to design a compartment with a bottom portion that would elevate one syringe above another, without the aid of other items.” Op. *6. On this basis, the Federal Circuit found that we erred in our “determination that the prior art did not

teach the claim limitation of a compartment that supports syringes at different heights according to order of use.” *Id.* at *7. Thus, the Federal Circuit has found in Petitioner’s favor that the combined teachings of Solazzo and Serany suggest limitations 1e and 1g. The Federal Circuit vacated our conclusion that claim 1 remained patentable and remanded for further proceedings consistent with its opinion. *Id.* at *7, 10. On remand, we must (1) address whether the combination of Solazzo and Serany describes or suggests all other elements of claim 1 and (2) consider and weigh Patent Owner’s objective evidence of nonobviousness.

Petitioner contends that Solazzo alone or in combination with Serany describes all limitations of claim 1. Pet. 31–49. Because the Federal Circuit resolved issues relating to limitations 1e and 1g, we address limitations 1a–1d and 1f below.

1. Limitation 1a

Limitation 1a refers to the following text from claim 1: “[a] medical procedure kit⁹], comprising: a tray having a compartment for receiving a medical assembly.” Ex. 1001, 27:47–49. Petitioner contends that Solazzo describes a single level tray having multiple compartments, one of which is configured for holding a medical assembly including “catheter 120.” Pet. 32–33 (citing Ex. 1005, 2:48–51, 3:17, 3:52–57, 4:41–46, Fig. 8; Ex. 1002 ¶¶ 157–161). Petitioner contends that the medical assembly comprises a catheter and Y-connector. Alternatively, Petitioner contends

⁹ The preamble recitation of a “medical procedure kit” is not in dispute in this proceeding. Additionally, as discussed below, we determine that the prior art accounts for the preamble recitation of a “medical procedure kit,” and thus need not determine whether that recitation is limiting.

that Serany describes placing a “medical assembly” in a tray by disclosing the combination of Foley catheter 48, pre-connected to collapsible bottle 46 via tubing 49 in its tray. *Id.* at 33 (citing Ex. 1006, 1:31–32, 3:23–26, Fig. 6; Ex. 1002 ¶¶ 162–166; Ex. 1003 ¶ 15). For the reasons expressed below, Petitioner persuades us that Solazzo alone describes limitation 1a.

Patent Owner argues that limitation 1a requires that “a compartment for receiving the medical assembly” must be a separate and distinct compartment from the “first compartment” for supporting the syringes that is recited in limitation 1f. PO Resp. 20–21 (citing Ex. 1001, 3:60–4:11, 5:61–65, 9:22–30, Figs. 7–8). For context, limitation 1f recites: “the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe.” Ex. 1001, 27:60–62. Among “at least two compartments,” limitation 1f only specifies a functional purpose for the “first compartment” without reciting any functional or structural limitation on the other compartment among the “at least two compartments.” However, we understand Patent Owner to imply that the unnamed compartment among “at least two compartments” recited in limitation 1f refers to “a compartment for receiving a medical assembly” recited in limitation 1a. Tr. 58:18–59:4. Patent Owner argues that Petitioner fails to demonstrate that Solazzo meets limitation 1a because Petitioner relies upon Solazzo’s “no divider wall” embodiment to meet limitation 1f, which places the medical assembly in the same compartment as the syringes. PO Resp. 20–21. According to Patent Owner, claim 1 requires that the syringes be disposed within the “first compartment” and the medical assembly be

disposed within “a compartment” from limitation 1a that is distinct and separate from the “first compartment.” *Id.*

Even if we were to agree with Patent Owner’s interpretation of limitation 1a, Petitioner contends that Solazzo describes “a compartment for receiving a medical assembly” in the form of Solazzo’s lubrication wells 31, 33. Reply 6 (citing Ex. 1074, 170:18–23). These wells are separate and distinct from compartment 3/27 of Solazzo’s “no divider wall” embodiment, which holds two syringes. *Id.*; Pet. 43–44 (citing Ex. 1005, 4:21–25, Fig. 1; Ex. 1002 ¶¶ 204–207). Wells 31, 33 also can receive a catheter, a type of medical assembly, to lubricate the catheter. Ex. 1005, 4:21–25. For this reason alone, we find that Petitioner has proven by a preponderance of evidence that Solazzo describes limitation 1a as Solazzo’s lubricating wells 31, 33.

However, we disagree with Patent Owner’s interpretation of limitation 1a as requiring that the compartment for receiving the medical assembly be “distinct” from the first compartment or that the medical assembly be disposed within the “compartment” of limitation 1a. Limitation 1f requires “at least two compartments,” but expressly recites a functional limitation for only “a first compartment” among the “at least two compartments.” Ex. 1001, 27:60–62. Claim 1 does not further limit the unspecified compartment among the “at least two compartments” or specify what items, if any, are placed within it. *See id.* at 27:47–67. Two unchallenged dependent claims, claims 4 and 11, further recite that “the at least two compartments” further comprise “a second compartment.” Claim 4 depends directly from claim 1 and further recites, in pertinent part: “the at least two compartments further comprising *a second compartment* separated from the

first compartment by a wall with an opening, further comprising a catheter assembly disposed within the second compartment, the catheter assembly comprising a fluid bag.” *Id.* at 28:21–25 (emphasis added). Claim 11 depends from claim 10, which depends from claim 1, and similarly recites: “the at least two compartments further comprising *a second compartment* separated from the first compartment by a wall with an opening, further comprising a catheter assembly disposed within the second compartment.” *Id.* at 28:47–51 (emphasis added).

The panel questioned Patent Owner extensively regarding the scope of “a compartment” as recited in limitation 1a as compared to the scope of the unspecified compartment among “the at least two compartments” and the “second compartment” introduced, for example, in claim 11. Tr. 54:6–60:9. More specifically, we asked why we should not interpret “a compartment” (from limitation 1a) as simply referring to any compartment adapted for “receiving a medical assembly” that, for example, could encompass both the first compartment and the second compartment within it. *Id.* at 58:13–17. Patent Owner did not persuasively explain why such an interpretation of “a compartment” was incorrect. *Id.* at 54:6–60:9.

The Specification illustrates at least one embodiment of the tray that is inconsistent with Patent Owner’s argument that claim 1 requires that the “medical assembly” and “first and second syringes” be placed in two distinct compartments. Figures 8 and 10, reproduced below left and right respectively, illustrate an embodiment in which syringe 702 is placed within the larger perimeter of tray 100, but not wholly within “first compartment 101.” However, syringe 702 and another syringe 701 are placed within a compartment defined by the outer perimeter of tray 100.

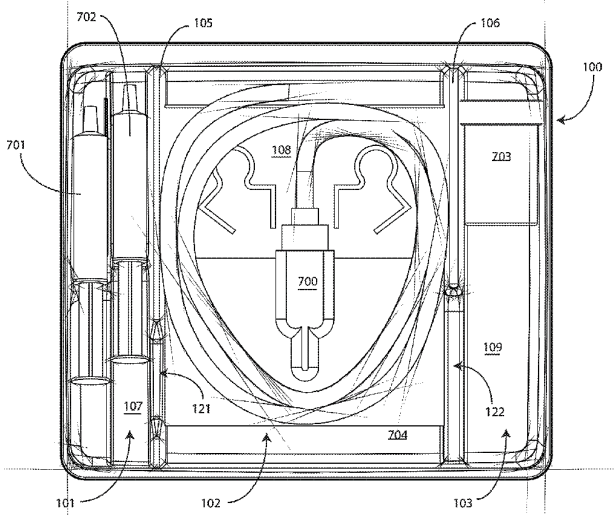


FIG. 8

Figure 8 is a plan view of tray 100.
Ex. 1001, at 3:50–53.

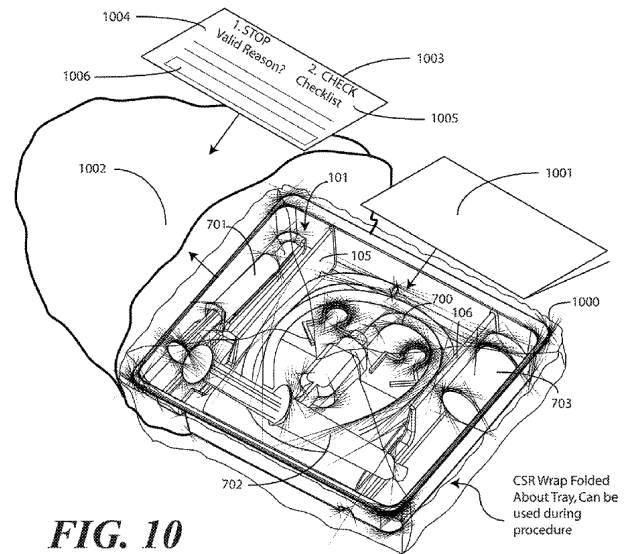


FIG. 10

Figure 10 is a perspective view of tray 100. *Id.* at 10:15–16.

The Specification explains: “In the configuration of FIG. 10, rather than having both syringes 701,702 disposed within the first compartment 101, one syringe 702 is disposed laterally in the first opening 121 and the second opening 122 of the first barrier 105 and second barrier 106, respectively.” *Id.* at 10:30–34. In this instance, syringe 701 is disposed in first compartment 101, but second syringe 702 spans second compartment 102, which holds catheter assembly 700 (i.e., a type of medical assembly). Syringe 702 is also disposed within first compartment 101 and third compartment 103. *Id.* Accordingly, syringe 702 is disposed in all three compartments 101, 102, and 103, and thus is disposed in “a compartment” defined by the outer perimeter of tray 100. At the same time, all parts of catheter assembly 700 are disposed within the same compartment defined by the perimeter of tray 100. In this way, the Specification describes “a compartment for receiving a medical assembly” and other compartments (e.g., first 101, second 102, and third 103) that are (1) separate from each

other (i.e., non-overlapping), but also (2) located within “a compartment” defined by the perimeter of the tray.

Based on our review of claims 1, 4, and 11, and the Specification, we find that Patent Owner’s interpretation of “a compartment” as referring only to a compartment that is “distinct” (i.e., not overlapping to any extent) and separate from the “first compartment” to be too restrictive. Rather, “a compartment” merely refers to any compartment within the tray “for receiving a medical assembly.” Such a compartment could include, for example, the compartment defined by the outer perimeter of tray 100 illustrated in Figures 8 and 10 or some other compartment that is merely capable of “receiving the medical assembly.”

Petitioner contends that Solazzo describes “a compartment for receiving a medical assembly” as recited in claim 1 by illustrating catheter 120 disposed within Solazzo’s compartment 3. Pet. 32–33 (citing Ex. 1005, 2:48–51, 3:17, 3:52–57, 4:41–46, Fig. 8; Ex. 1002 ¶¶ 157–161). When discussing limitation 1f, Petitioner alternatively contends that Solazzo’s lubricating wells 31, 33, which are configured to “receive” a catheter while the user lubricates it, can constitute “a compartment” (i.e., limitation 1a). Pet. 43–44 (citing 4:21–25, Fig. 1; Ex. 1002 ¶¶ 204–207); *see also* Reply 5–6 (citing Ex. 1074, 170:18–23).

Even if we were to accept Patent Owner’s interpretation of “a compartment” in limitation 1a, we find that Petitioner persuasively demonstrates by a preponderance of evidence that either (1) Solazzo’s “no divider wall” embodiment describes limitation 1a as its lubricating wells 31, 33 or (2) Solazzo describes limitation 1a as Solazzo’s compartment 3 of its “divider wall” embodiment. Under our interpretation of “a compartment” of

limitation 1a, we find that Petitioner persuasively demonstrates by a preponderance of evidence that Solazzo's compartment 3/27 of its "no divider wall" embodiment describes limitation 1a.

2. Limitation 1b

Limitation 1b refers to the following text from claim 1: "a first syringe and a second syringe disposed within the tray." Ex. 1001, 27:50–51.

Petitioner contends that Solazzo meets limitation 1b by describing that its catheterization kit includes "(e.) an inflation syringe for inflation of a catheter with fluid; (f.) irrigation syringe." Pet. 34 (citing Ex. 1005, 3:15–24).

Petitioner also contends that Solazzo meets limitation 1b because Solazzo illustrates syringe 110 in compartment 27 and lubricant tube 140 in compartment 3 and an ordinarily skilled artisan would have considered it obvious to put the lubricant in a syringe rather than a tube. *Id.* at 34–35 (citing Ex. 1005, 4:41–46, Fig. 8; Ex. 1002 ¶¶ 167–173; Ex. 1003 ¶ 22).

Patent Owner argues that Petitioner fails to demonstrate that Solazzo teaches the combination of limitations 1b and 1e without specifically addressing the requirements of limitation 1b alone. PO Resp. 24–31.

Limitation 1e further requires that "the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure." Ex. 1001, 27:57–59. That is, Patent Owner argues that Petitioner fails to demonstrate that the combination of Solazzo and Serany teaches arranging first and second syringes in their order of use, but it proffers no argument that Solazzo alone fails to describe placing two syringes in a catheter tray. PO Resp. 24–31. Accordingly, we find that Patent Owner does not oppose Petitioner's showing that Solazzo discloses limitation 1b.

The Federal Circuit has already held that Petitioner demonstrated that the combination of Solazzo and Serany teaches limitation 1e, which requires that the two syringes recited here in limitation 1b be arranged according to their order of use. Op. *6–7. Based upon Petitioner’s argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that Solazzo teaches limitation 1b.

3. Limitation 1c

Limitation 1c refers to the following text from claim 1: “at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material.” Ex. 1001, 27:52–54. Petitioner recognizes that Solazzo does not describe how its catherization kit is packaged. Pet. 36. Petitioner relies upon Serany to describe limitation 1c because Serany discloses that its Foley catheter tray is “enclosed within a wrap 14.” *Id.* at 36–37 (citing Ex. 1006, 1:13–16, 1:60–63, 2:1–20, Figs. 2, 2a, 3). Petitioner argues that an ordinarily skilled artisan would have been motivated to wrap Solazzo’s kit as suggested by Serany to preserve the sterility of items in Solazzo’s kit including at least the catheter and surgical gloves. *Id.* at 37 (citing Ex. 1005, 3:15–24). Based on the combined teachings of Solazzo and Serany, Petitioner argues that an ordinarily skilled artisan would have found it obvious to wrap Solazzo’s kit as suggested by Serany and would have expected that doing so would have been successful.

Patent Owner does not respond to Petitioner’s showing for limitation 1c. *See* PO Resp. 20–32 (arguing in favor of claim 1 with respect to limitations 1a, 1e, and 1g only). Based upon Petitioner’s argument and reasoning, which we adopt as our own, and the evidence cited in the

Petition, Petitioner persuades us by a preponderance of evidence that the combination of Solazzo and Serany teaches limitation 1c.

4. Limitation 1d

Limitation 1d refers to the following text from claim 1: “an outer packaging disposed about both the tray and the at least one layer of wrap material.” Ex. 1001, 27:55–56. Petitioner recognizes that Solazzo does not describe how its tray is packaged. Pet. 38. Petitioner relies upon Serany to describe limitation 1d because Serany discloses that its Foley catheter tray is “encased within an envelope 16.” *Id.* at 38–39 (citing Ex. 1006, 1:13–16, 1:63–72, Fig. 1). Based on the combined teachings of Solazzo and Serany, Petitioner argues that an ordinarily skilled artisan would have found it obvious to combine the outer packaging of Serany with Solazzo’s tray. *Id.* at 39. Petitioner argues that both references relate to Foley catheters and related medical devices, Serany’s packaging and Solazzo’s tray were well known items that could have been combined while performing their known functions, and the combination would have yielded predictable results. *Id.* (citing Ex. 1002 ¶¶ 184–194).

Patent Owner does not respond to Petitioner’s showing for limitation 1d. *See* PO Resp. 20–32 (arguing in favor of claim 1 with respect to limitations 1a, 1e, and 1g only). Based upon Petitioner’s argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that the combination of Solazzo and Serany teaches limitation 1d.

5. Limitation 1f

Limitation 1f refers to the following text from claim 1: “the tray comprises a surface defining at least two compartments, the at least two

compartments comprising a first compartment to support the first syringe and the second syringe.” Ex. 1001, 27:60–63. Petitioner contends that Solazzo describes the “first compartment” as compartment 3/27 of Solazzo’s “no divider wall” embodiment. Pet. 43–44 (citing Ex. 1005, 4:21–25, Fig. 1; Ex. 1002 ¶¶ 204–207). Petitioner contends that compartment 3/27 supports two syringes on its bottom 11, syringe 110 and tube 140 (“replaceable with a syringe”). *Id.* at 44–45 (citing Ex. 1005, Figs. 1, 2, 8; Ex. 1002 ¶¶ 208–209). However, limitation 1f recites “at least two compartments” including the “first compartment” just discussed, but the claim does not limit the scope of the unnamed one of these “two compartments.” Petitioner contends that Solazzo describes the unnamed compartment of the “at least two compartments” as Solazzo’s lubricating wells 31, 33. *Id.*

For the reasons expressed in Part VI.A.1 above, we find that Petitioner proves by a preponderance of evidence that Solazzo describes the “at least two compartments” of limitation 1f as the combined compartment 3/27 of Solazzo’s “no divider wall” embodiment (i.e., the first compartment) and Solazzo’s wells 31, 33 as the other compartment.

6. Objective Evidence of Nonobviousness

For the reasons expressed *infra* in Part IX, we find that Patent Owner’s objective evidence of nonobviousness, considered in conjunction with all other evidence of record, does not weigh against a conclusion of obviousness for claim 1.

7. Conclusion

For all the reasons expressed above including weighing objective evidence of nonobviousness, we conclude that Petitioner has proven by a

preponderance of evidence that the combined teachings of Solazzo and Serany render claim 1 unpatentable as obvious.

B. DEPENDENT CLAIM 2

Claim 2 depends from claim 1 and further recites: “the first syringe and the second syringe ordered within the tray in accordance with their use during the catheterization procedure.” Ex. 1001, 28:1–3. Petitioner argues that its showing that Solazzo and Serany taught limitation 1e (along with the other limitations of claim 1) is sufficient to prove obviousness of claim 2. Pet. 49. The Federal Circuit expressly agreed with Petitioner regarding its showing for limitations 1e and 1g. Op. *6–7. Patent Owner does not separately argue that claim 2 remained patentable in view of Petitioner’s challenge. PO Resp. 16–37 (arguing expressly about only claims 1, 6, 7, and 17). Based upon Petitioner’s argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 2 unpatentable as obvious.

C. DEPENDENT CLAIM 6

Claim 6 depends from claim 1 and further recites: “the first compartment defining one or more contours for accommodating flanges of one or more of the first syringe or the second syringe.” Ex. 1001, 28:29–32. Petitioner argues that claim 6 is obvious in view of Solazzo and Serany. Pet. 49–50. Patent Owner argues that neither Solazzo nor Serany describes “contours for accommodating flanges” of at least one of the syringes. PO Resp. 33–36. Patent Owner contends that the claimed contours refer to recesses 118, 119 shown in Figure 5 (reproduced below) and that the contours must “prevent syringes from dislodging.” *Id.* at 33.

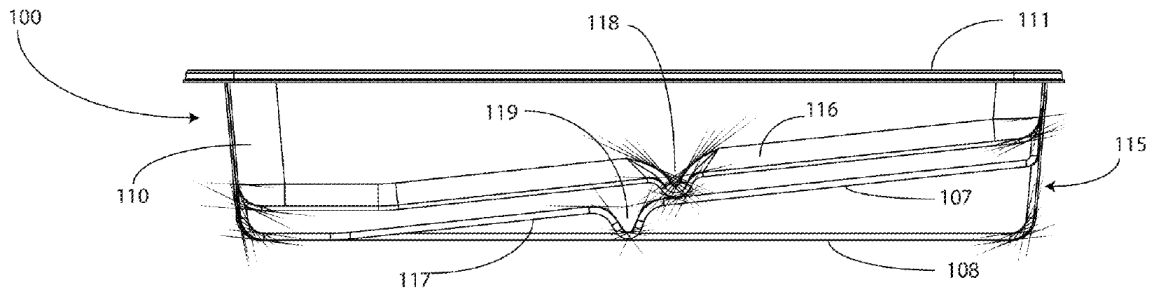


FIG. 5

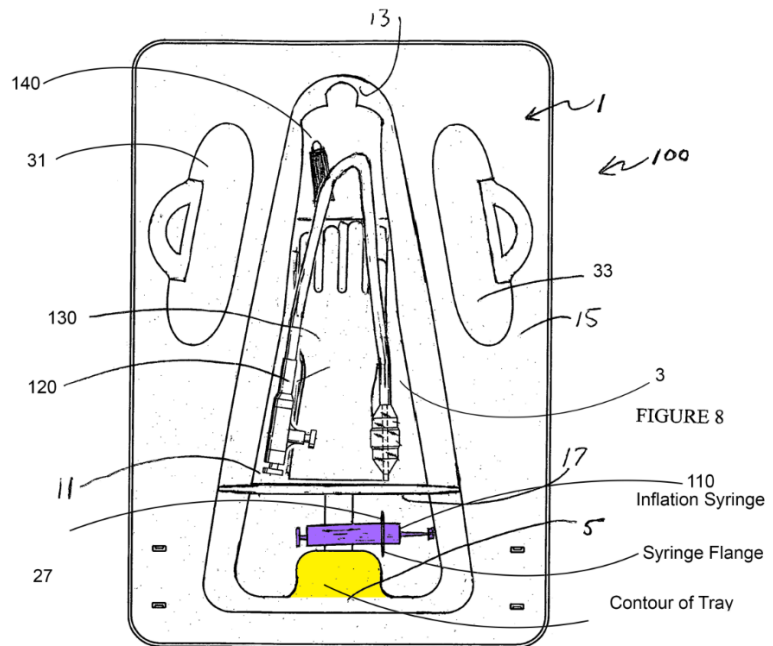
FIG. 5 illustrates a cut-away, left elevation view of one embodiment of a tray. Ex. 1001, 2:39–40.

Patent Owner cites the following passage of the Specification as supporting its interpretation of “contours for accommodating flanges” as requiring that the contours prevent the syringes from moving:

The first compartment base member 107 may include other features suitable for accommodating one or more syringes as well. In one embodiment, one or both of the first step portion 116 and second step portion 117 include recesses 118, 119 for accommodating a syringe flange. *These recesses 118, 119 generally function to prevent the syringes from sliding lengthwise within the first compartment 101.*

PO Resp. 33 (emphasis added) (citing Ex. 1001, 6:52–58). Patent Owner also implies that “accommodating” is akin to “receiving” the syringes, which prevents the syringes from moving. *Id.* at 34 (citing Ex. 2026 ¶¶ 113–114).

Petitioner identifies a contour in Solazzo's compartment 27 as the claimed contour and highlights that contour yellow in the annotated version of Solazzo's Figure 8, which we reproduce at right. Petitioner contends that the yellow-colored portion of Solazzo's tray constitutes a contour that



creates space for accommodating the flange of syringe 110, which is highlighted in purple. Pet. 49–50; Reply 10–11. Even if Patent Owner's interpretation were correct, Petitioner argues that Patent Owner's expert, Dr. Singh, indicates that a contour materially similar to the one in Solazzo's tray would restrict a syringe from moving. Reply 11 (citing Ex. 1070 ¶¶ 21–23; Ex. 1075, 408:21–410:20, 446:5–447:22; Ex. 1048; Ex. 1049).

Alternatively, Petitioner argues that it would have been obvious to modify Solazzo in view of Serany, which expressly describes a compartment with a contour to “accommodate the flange” of a syringe and that an ordinarily skilled artisan would modify Solazzo to “allow the syringe to be easily grasped and removed from the tray.” Pet. 50 (citing Ex. 1002 ¶¶ 224–225 (citing Ex. 1006, 2:40–41, 3:16–22)); Reply 12 (citing Ex. 1002 ¶ 224; Ex. 1070 ¶¶ 26–27; Ex. 1075, 387:19–288:9).

We find Petitioner's argument to be persuasive regardless of whether we interpret “accommodating” to require restricting the movement of a

syringe. Based on testimony from experts for both parties, we find that the contour in Solazzo's tray that Petitioner identifies does restrict movement to a degree. Ex. 1070 ¶¶ 21–23; Ex. 1075, 408:21–410:20, 446:5–447:22; Ex. 1048; Ex. 1049. We also find that Serany expressly describes close-fitting contours in its tray for accommodating flange 45c on syringe 45 that serve to restrict movement of syringe 45. Ex. 1006, 3:12–22, Fig. 6. Petitioner persuasively argues that an ordinarily skilled artisan would have been motivated to incorporate Serany's contours into Solazzo's tray to “allow the syringe to be easily grasped and removed from the tray.” Ex. 1002 ¶ 224; Ex. 1006, 3:16–20. For all these reasons, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 6 unpatentable as obvious.

D. DEPENDENT CLAIM 7

Claim 7 directly depends from claim 1 and further recites: “the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a catheter assembly.” Ex. 1001, 28:33–35. The Federal Circuit found that Petitioner's reliance on Solazzo's “no divider wall” embodiment in combination with teachings from Serany taught limitations 1e and 1g of claim 1. Op. *5–7. Thus, Petitioner's reliance on Solazzo's “no divider wall” embodiment for dependent claims 7 and 17–19 similarly meets the requirements of limitations 1e and 1g. However, on remand, we must determine whether Petitioner has demonstrated that Solazzo's combined compartment 3/27 meets the claimed “lubricating jelly application chamber.” *See id.* at *10 (“[T]he Board should also evaluate the dependent claims that it did not separately analyze in the first instance.”). For the reasons that follow, we determine that Petitioner has failed to do so.

We note that the Federal Circuit affirmed our conclusion that Petitioner had failed to demonstrate that a similar claim, claim 9 of the '596 patent, was unpatentable. Op. *8–9. That claim requires that first and second syringes be disposed within a first compartment that also serves as a “lubricating chamber” and further requires a “coiled medical device . . . including a Foley catheter” disposed within a distinct second compartment. IPR2019-00223, Ex. 1001, 18:54–57. Petitioner mapped claim 9 of the '596 patent to Solazzo’s “divider wall” embodiment. IPR2019-00223, Paper 2, 45–48. By contrast, Petitioner maps claim 7 to Solazzo’s “no divider wall” embodiment. Pet. 50–52.¹⁰ Petitioner argues persuasively that the Federal Circuit’s opinion does not address whether Solazzo’s “no divider wall” embodiment includes the “lubricating jelly application chamber” of claim 7. Pet. Remand Br. 24–27. The Federal Circuit affirmed our conclusion that claim 9 of the '596 patent remained patentable primarily because we found that Solazzo’s compartment 27 in the “divider wall” embodiment (as distinct from compartment 3 or combined compartment 3/27) was “too deep” to serve as a lubricating chamber. Op. *7–8. However, Federal Circuit has not addressed Petitioner’s argument that shallow area 11B of Solazzo’s combined compartment 3/27 in its “no divider wall” embodiment can constitute the claimed lubricating chamber. Pet. 51–52 (citing Ex. 1005, 3:63–66, Figs. 1, 2; Ex. 1002 ¶¶ 228–236). For the reasons that follow, we find Petitioner’s argument to be unpersuasive.

¹⁰ Petitioner argues that Solazzo’s low area 11A discloses a lubricating chamber. Pet. 52. Petitioner also argues that “[a]lternatively, the catheter could be lubricated in the ‘shallow area 11B’ where the catheter and lubricant tube are supported.” *Id.*

Solazzo's tray 1 is illustrated in Figure 1 (reproduced at right). For a patient requiring a urological procedure, tray 1 is positioned between the patient's legs with "back 13 below the scrotum and penis" so that a health care provider can

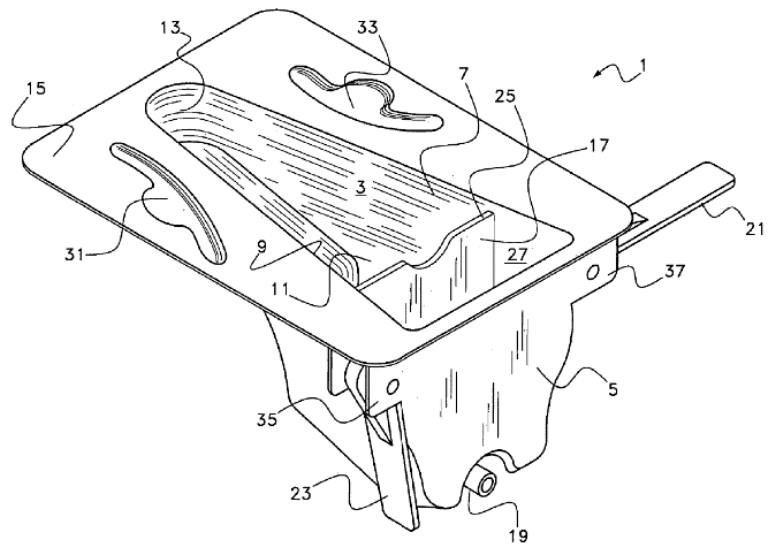


Fig. 1

"evacuate the bladder of its contents, urine and/or clots." Ex. 1005, 4:26–33. When Solazzo's optional divider wall 17 is present, compartment 27 fills with fluid only after the patient fills compartment 3 such that fluid overflows divider wall 17. *Id.* at 4:15–20. Thus, we find that Solazzo describes collecting fluid from the bladder including urine in the entirety of compartment 3/27 (of the "no divider wall" embodiment. *Id.* at 4:15–20, 4:26–33. Furthermore, Solazzo expressly states that "lubricating material could be applied to the catheter" by filling one of the lubricating wells 31 and 33 with lubricant and "sliding the device through the lubricant in the well." *Id.* at 4:21–25. We find, therefore, that Solazzo expressly contemplates using the entire compartment 3/27 to collect fluids, including urine, and a different compartment, i.e., either one or both of lubricating wells 31, 33, as a "chamber to lubricate at least a portion of a catheter assembly."

Petitioner argues that shallow area 11B "facilitates easy lubrication of the catheter" simply because it is shallow and "it was well-known to '(a) apply lubricant directly on the catheter; and (b) use the same

compartment where lubricant is stored to lubricate the catheter.” Pet. Remand Br. 28–29 (citing Pet. 32, 34; Ex. 1002 ¶ 231). Patent Owner persuasively responds, however, that a practitioner would not use the same compartment to collect urine and lubricate the catheter because the lubricant would contaminate the urine specimen collected in the compartment. PO Remand Br. 3–4 (citing PO Resp. 36; Op. *8); *see also* Ex. 2027 ¶ 175 (Ms. Chiappetta testifying that “lubrication in the portion of the tray that collects urine will contaminate the urine,” which would invalidate any testing of the patient’s urine). Although it may be easier to lubricate a catheter in shallow area 11B than in deep area 11A, we find that Solazzo’s shallow area 11B is not well-suited, configured, or intended for lubricating a catheter; rather, Solazzo recommends using lubricating wells 31 and 33 for that purpose. We credit Ms. Chiappetta’s supporting testimony to that effect. *See* Ex. 2027 ¶ 175. Accordingly, we conclude that Petitioner has failed to prove by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 7 unpatentable as obvious.

E. DEPENDENT CLAIMS 8–10

Each of claims 8–10, all of which depend directly from claim 1, recites various ways in which the syringes be arranged at different heights in the tray. Claim 8 depends from claim 1 and further recites: “the first compartment to support the first syringe at a shallower depth within the tray than the second syringe.” Ex. 1001, 28:36–38. Claim 9 depends from claim 1 and further recites: “the first compartment to support the first syringe and the second syringe at different heights based upon use during the catheterization procedure.” *Id.* at 28:39–42. Claim 10 depends from claim 1 and further recites: “wherein a higher of the first syringe or the second

syringe is for use in the catheterization procedure before a lower of the first syringe or the second syringe.” *Id.* at 28:43–46.

Petitioner argues that its showing that Solazzo and Serany taught limitations 1b, 1e, and 1g (along with the other limitations of claim 1) is sufficient to prove obviousness of claims 8–10. Pet. 53–54. The Federal Circuit expressly agreed with Petitioner regarding its showing for limitations 1e and 1g. Op. *6–7. Patent Owner does not separately argue that claims 8–10 remained patentable in view of Petitioner’s challenge. PO Resp. 16–37 (arguing expressly about only claims 1, 6, 7, and 17). Based upon Petitioner’s argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that the combined teachings of Solazzo and Serany render claims 8–10 unpatentable as obvious.

F. DEPENDENT CLAIM 16

Claim 16 depends from claim 1 and further recites: “the tray comprising a surface defining at least two compartments, the at least two compartments comprising the first compartment to support the first syringe.” Ex. 1001, 28:61–64. Petitioner equates the limitation introduced in claim 16 with limitation 1f and argues that its showing for limitation 1f is sufficient to prove obviousness of claim 16. Pet. 54. Patent Owner does not separately argue that claim 16 remained patentable in view of Petitioner’s challenge. PO Resp. 16–37 (arguing expressly about only claims 1, 6, 7, and 17). Based upon Petitioner’s argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 16 unpatentable as obvious.

G. DEPENDENT CLAIM 17

Claim 17 depends from claim 16, which depends from claim 1, and further recites: “the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a catheter assembly.” Ex. 1001, 28:65–67. Petitioner argues that claim 17 is unpatentable as obvious in view of Solazzo and Serany for the same reasons proffered for claim 7. Pet. 54. For the same reasons expressed in connection with claim 7, we conclude that Petitioner fails to prove by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 17 unpatentable as obvious.

H. DEPENDENT CLAIMS 18 AND 19

Claim 18 depends from claim 17, and claim 19 depends from claim 18. Claim 18 recites, in pertinent part: “further comprising printed instructions for using the tray,” Ex. 1001, 29:1–2, and claim 19 adds: “the printed instructions to instruct application of lubricating jelly to the catheter assembly using the lubricating jelly application chamber,” *id.* at 29:3–6.

Petitioner contends that the combined teachings of Solazzo, Serany, and Franks-Farah render claims 18 and 19 unpatentable as obvious. Pet. 54–59. Petitioner relies on Franks-Farah as including printed instructions in a catheter tray and instructing the user to lubricate the tip of the catheter. *Id.* (citing Ex. 1007, 2:5–14, 4:12–17, Figs. 1, 1A, 2A, 2B; Ex. 1002 ¶¶ 146–150, 258–271). However, Petitioner relies on the teachings of Solazzo as suggesting that the compartment holding the first and second syringes should be used as a lubrication chamber. *Id.*

For the reasons expressed immediately above relating to claim 17, we conclude that Petitioner has failed to establish that Solazzo describes the claimed lubrication chamber introduced in claim 17. Accordingly, we also

conclude that Petitioner has failed to prove that claims 18 and 19 are unpatentable as obvious.

VII. CLAIMS 25–32, 35, AND 36

A. INDEPENDENT CLAIM 25

Independent claim 25 recites:

25. A medical procedure kit, comprising:

- [a] a tray having a compartment for receiving a medical assembly;
- [b] a first syringe and a second syringe disposed within the tray;
- [c] at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material; and
- [d] an outer packaging disposed about both the tray and the at least one layer of wrap material,
- [e] wherein: the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure; and
- [f] the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe;
- [g] the first compartment to support the first syringe and the second syringe at different heights according to predetermined steps of the catheterization procedure.

Ex. 1001, 29:29–48 (with added letter designations a–g to ease discussion).

Previously, we concluded that Petitioner had failed to prove by a preponderance of evidence that the combination of Solazzo and Serany described element 25g and thus failed to establish that claim 25 was obvious. Dec. 21–26. The Federal Circuit found that: “Given the prior art disclosures and the finite number of predictable options, a skilled artisan would have

been motivated to stack the syringes by height according to their order of use.” Op. *7. On this basis, the Federal Circuit found that we erred in our “determination that the prior art did not teach the claim limitation of a compartment that supports syringes at different heights according to order of use.” *Id.* Thus, the Federal Circuit has found in Petitioner’s favor that the combined teachings of Solazzo and Serany suggest limitations 25e and 25g. *Id.* at *6–7. The Federal Circuit vacated our decision that claim 25 remained patentable and remanded for further proceedings consistent with its opinion. *Id.* at *7, 10. On remand, we must (1) address whether the combination of Solazzo and Serany describes or suggests all other elements of claim 25 and (2) consider and weigh Patent Owner’s objective evidence of nonobviousness.

Petitioner contends that Solazzo alone or in combination with Serany describes all limitations of claim 25. Pet. 59–69. Because the Federal Circuit resolved issues relating to limitations 25e and 25g, we address limitations 25a–25d and 25f below.

1. Limitation 25a

Limitation 25a refers to the following text from claim 25: “A medical procedure kit, comprising: a tray having a compartment for receiving a medical assembly.” Ex. 1001, 29:29–31. This language is identical to the language of limitation 1a from claim 1. *Compare id.*, with *id.* at 27:47–49. When addressing limitation 25a, Petitioner cross-references its showing for limitation 1a. Pet. 59 (cross-referencing *id.* at 32 (citing Ex. 1005, 2:48–51, 3:17, 3:52–57, 4:41–46, Figs. 1, 8)). Patent Owner does not contest Petitioner’s showing for limitation 25a. PO Resp. 38–40 (contesting Petitioner’s showing only for limitation 25g).

As we explain above with respect to limitation 1a, based upon Petitioner's argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that Solazzo teaches limitation 25a.

2. Limitation 25b

Limitation 25b refers to the following text from claim 25: "a first syringe and a second syringe disposed within the tray" and is identical to the language of limitation 1b. *Compare* Ex. 1001, 29:32–33, *with id.* at 27:50–51. When addressing limitation 25b, Petitioner cross-references its showing for limitation 1b. Pet. 59–60 (cross-referencing *id.* at 34–35 (citing Ex. 1005, 4:41–46, Fig. 8; Ex. 1002 ¶¶ 167–173; Ex. 1003 ¶ 22)). Patent Owner does not contest Petitioner's showing for limitation 25b. PO Resp. 38–40 (contesting Petitioner's showing only for limitation 25g).

Based upon Petitioner's argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that Solazzo teaches limitation 25b.

3. Limitation 25c

Limitation 25c refers to the following text from claim 25: "at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material" and is identical to the language of limitation 1c. *Compare* Ex. 1001, 29:34–36, *with id.* at 27:52–54. When addressing limitation 25c, Petitioner cross-references its showing for limitation 1c. Pet. 60 (cross-referencing *id.* at 35–38 (citing Ex. 1006, 1:13–16, 1:60–63, 2:1–20, Figs. 2, 2a, 3)). Patent Owner does not contest Petitioner's showing for limitation 25c. PO Resp. 38–40 (contesting Petitioner's showing only for limitation 25g).

Based upon Petitioner’s argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that Solazzo teaches limitation 25c.

4. Limitation 25d

Limitation 25d refers to the following text from claim 25: “an outer packaging disposed about both the tray and the at least one layer of wrap material” and is identical to the language of limitation 1d. *Compare* Ex. 1001, 29:37–38, *with id.* at 27:55–56. When addressing limitation 25d, Petitioner cross-references its showing for limitation 1d. Pet. 60 (cross-referencing *id.* at 38–39 (citing Ex. 1006, 1:13–16, 1:63–72, Fig. 1)). Patent Owner does not contest Petitioner’s showing for limitation 25d. PO Resp. 38–40 (contesting Petitioner’s showing only for limitation 25g).

Based upon Petitioner’s argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that Solazzo teaches limitation 25d.

5. Limitation 25f

Limitation 25f refers to the following text from claim 1: “the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe” and is identical to the language of limitation 1f. *Compare* Ex. 1001, 29:39–42, *with id.* at 27:60–63. Petitioner contends that Solazzo describes the “first compartment” as compartment 3/27 of Solazzo’s “no divider wall” embodiment. Pet. 61 (cross-referencing showing for limitation 1f at *id.* 43–44 (citing Ex. 1005, 4:21–25, Fig. 1; Ex. 1002 ¶¶ 204–207)). Petitioner contends that compartment 3/27 supports two syringes on its bottom 11, syringe 110 and tube 140 (“replaceable with a

syringe”). *Id.* at 61 (cross-referencing showing for limitation 1f at *id.* 44–45 (citing Ex. 1005, Figs. 1, 2, 8; Ex. 1002 ¶¶ 208–209)). However, limitation 25f recites “at least two compartments” including the “first compartment” just discussed, but the claim does not limit the scope of the unnamed one of these “two compartments.” Petitioner contends that Solazzo describes the unnamed compartment of the “at least two compartments” as Solazzo’s lubricating wells 31, 33. *Id.* (citing Ex. 1005, 4:21–25, Figs. 1, 8; Ex. 1002 ¶ 278).

For the reasons expressed in Part VI.A.1 above, we find that Petitioner proves by a preponderance of evidence that Solazzo describes the “at least two compartments” of limitation 25f as the combined compartment 3/27 of Solazzo’s “no divider wall” embodiment (i.e., the first compartment) and Solazzo’s wells 31, 33 as the other compartment.

6. Objective Evidence of Nonobviousness

For the reasons expressed *infra* in Part IX, we find that Patent Owner’s objective evidence of nonobviousness, considered in conjunction with all other evidence of record, does not weigh against a conclusion of obviousness for claim 25.

7. Conclusion

For all the reasons expressed above including weighing objective evidence of nonobviousness, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 25 unpatentable as obvious.

B. DEPENDENT CLAIM 26

Claim 26 directly depends from claim 25 and further recites: “the first syringe and the second syringe ordered within the tray in accordance with

their use during the catheterization procedure.” Ex. 1001, 29:49–52.

Petitioner argues that its showing that Solazzo and Serany taught limitation 25e (along with the other limitations of claim 25) is sufficient to prove obviousness of claim 26. Pet. 70. The Federal Circuit expressly agreed with Petitioner regarding its showing for limitations 25e and 25g. Op. *6–7.

Patent Owner does not separately argue that claim 26 remained patentable in view of Petitioner’s challenge. PO Resp. 38–49 (arguing expressly about only claims 25, 28, and 29). Based upon Petitioner’s argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 26 unpatentable as obvious.

C. DEPENDENT CLAIM 27

Claim 27 directly depends from claim 25 and further recites: “further comprising one or more of an instruction set, one or more medical devices, or combinations thereof.” Ex. 1001, 29:53–55. Petitioner relies upon Solazzo, which describes a kit containing multiple medical devices. Pet. 70. Patent Owner does not separately argue that claim 27 remained patentable in view of Petitioner’s challenge. PO Resp. 38–49 (arguing distinctly about only claims 25, 28, and 29). Based upon Petitioner’s argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 27 unpatentable as obvious.

D. DEPENDENT CLAIM 28

Claim 28 directly depends from claim 25 and further recites: “the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a Foley catheter.” Ex. 1001, 29:56–58. For independent claim 25, Petitioner argues that Solazzo or the combination of Solazzo and Serany describes or suggests limitations 25a–25e for the same reasons proffered for limitations 1a–1e of claim 1. Pet. 59–60. Petitioner relies on Solazzo’s “divider wall” and “no divider wall” embodiments as teaching limitations 25f and 25g. *Id.* at 60–69.

For claim 28, Petitioner argues that each of Solazzo’s “divider wall” and “no divider wall” embodiments describes the lubrication chamber. Pet. 70–73. For the “no divider wall” argument, Petitioner cross-references its showing for claim 7, which identifies Solazzo’s shallow area 11B as the claimed lubrication chamber. *Id.* at 70 (cross-referencing *id.* at 52 (citing Ex. 1002 ¶¶ 228–236)). For the reasons expressed in Part VI.D above, we conclude that Petitioner fails to prove that the combined teachings of Solazzo’s “no divider wall” embodiment and Serany render claim 28 unpatentable as obvious.

We understand the Federal Circuit to have agreed with Petitioner’s argument that Solazzo’s “divider wall” embodiment teaches limitations 25e and 25g of claim 25. Op. *6–7. For claim 28, Petitioner argues that compartment 27 of Solazzo’s “divider wall” embodiment constitutes the lubrication chamber. Pet. 71–73. However, the Federal Circuit affirmed our conclusion that Solazzo’s compartment 27 was “too deep” to serve as the lubrication chamber recited in claim 9 of the ’596 patent. Op. *7–8. Claim 9 of the ’596 patent recites: “the first compartment is configured to

receive the lubricating jelly from the second syringe to lubricate a tip of the Foley catheter when the tip is placed into the first compartment.”

IPR2019-00223, Ex. 1001, 18:54–57.

Similarly, claim 28 at issue here recites: “the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a Foley catheter.” Ex. 1001, 29:56–58. We discern no material difference between the lubrication chamber introduced in claim 9 of the ’596 patent and the lubrication chamber introduced in claim 28 of the ’088 patent in this proceeding, and we conclude that the Federal Circuit’s analysis of claim 9 of the ’596 patent is dispositive of the issues presented for claim 28. Accordingly, we conclude that Petitioner fails to prove that the combined teachings of Solazzo’s “divider wall” embodiment and Serany render claim 28 unpatentable as obvious.

For all the reasons set forth above, we conclude that Petitioner has failed to prove that the combined teachings of Solazzo and Serany render claim 28 unpatentable as obvious.

E. DEPENDENT CLAIM 29

Claim 29 directly depends from claim 25 and further recites: “the first compartment defining one or more contours for accommodating flanges of one or more of the first syringe or the second syringe.” Ex. 1001, 29:59–62. We find the limitations introduced in claim 29 to be materially identical to those introduced in claim 6. Both parties cross-reference their arguments relating to claim 6 to support their competing arguments relating to the challenge to claim 29. Pet. 73; PO Resp. 42. For the reasons expressed in Part VI.C above, we find that Petitioner has proven by a preponderance of

evidence that the combined teachings of Solazzo and Serany render claim 29 unpatentable as obvious.

F. DEPENDENT CLAIMS 30 AND 31

Each of claims 30 and 31 depends directly from claim 25 and recites various ways in which the syringes be arranged at different heights in the tray. Claim 30 further recites: “the first compartment to support the first syringe at a shallower depth within the tray than the second syringe.”

Ex. 1001, 29:63–65. Claim 31 further recites: “wherein a higher of the first syringe or the second syringe is for use in the catheterization procedure before a lower of the first syringe or the second syringe.” *Id.* at 29:64–30:2.

Petitioner argues that its showing that Solazzo and Serany taught the limitations introduced in claims 8 and 10 and limitation 25g (along with the other limitations of claim 25) is sufficient to prove obviousness of claims 30 and 31. Pet. 53–54. The Federal Circuit expressly agreed with Petitioner regarding its showing for limitations 25e and 25g. Op. *6–7. Patent Owner does not separately argue that claims 30 and 31 remained patentable in view of Petitioner’s challenge. PO Resp. 38–49 (arguing expressly about only claims 25, 28, and 29). Based upon Petitioner’s argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that the combined teachings of Solazzo and Serany render claims 30 and 31 unpatentable as obvious.

G. DEPENDENT CLAIM 32

Claim 32 depends directly from claim 25 and further recites: “the at least two compartments further comprising a second compartment, further comprising a Foley catheter disposed within the second compartment.”

Ex. 1001, 30:3–6. Petitioner identifies Solazzo’s compartment 3 (of the

divider wall embodiment), which holds a Foley catheter, as meeting the limitations introduced in claim 32. Pet. 74–75 (citing Ex. 1005, Fig. 8; Ex. 1002 ¶¶ 326–328). Patent Owner relies on its arguments for claim 1 that Solazzo and Serany “teach away from a tray with multiple compartments, one compartment holding two syringes and the other compartment holding a catheter.” PO Resp. 43. The Federal Circuit has rejected Patent Owner’s argument in connection with both claim 1 and claim 25. Op. *6–7.

Based upon Petitioner’s argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 32 unpatentable as obvious.

H. DEPENDENT CLAIMS 33 AND 34

Claim 33 depends from dependent claim 32, which depends from claim 25, and further recites: “the Foley catheter coupled to a fluid bag.” Ex. 1001, 30:7–8. Claim 34 depends from claim 33 and further recites: “the fluid bag disposed within the second compartment.” *Id.* at 30:9–10.

For claim 33, Petitioner concedes that, although Solazzo discloses a Foley catheter in its kit, it does not expressly mention pre-connecting its Foley catheter to a drainage bag. Pet. 80. Petitioner argues that because an ordinarily skilled artisan understands a Foley catheter to be an “indwelling catheter” that remains in place within a patient for a period of time, leaving Solazzo’s catheter open-ended to drain into an open tray “is not a long-term solution.” *Id.* (citing Ex. 1005, 2:42–46, 4:26–33; Ex. 1003 ¶¶ 11, 30, 31, 36). Instead, an ordinarily skilled artisan would have understood that a “closed container (e.g., a drainage bag) is required for a long-term catheterization solution.” *Id.* (citing Ex. 1003 ¶ 36; Ex. 1002 ¶ 342).

Petitioner contends that the combined teachings of Serany and Disston suggest connecting a drainage bag to Solazzo's Foley catheter. *Id.* at 81–82 (citing Ex. 1006, 3:23–32; Ex. 1002 ¶¶ 343–345). Serany describes connecting its catheter to drainage bottle 46, and Petitioner argues that an ordinarily skilled artisan would have found it obvious to simply substitute Disston's drainage bag 10 for Serany's bottle 46 and would have found the substitution to produce predictable results. *Id.*

Petitioner argues that an ordinarily skilled artisan would have been motivated to include a Foley catheter pre-connected to a drainage bag from Serany and Disston into Solazzo's tray to (1) reduce the number of steps in a catheterization procedure and (2) reduce the risk of infection. *Id.* at 83 (citing Ex. 1002 ¶ 349; Ex. 1003 ¶ 35; Ex. 1006,¹¹ 1:31–32, 3:23–36; Ex. 1008, 2:72, 3:1). Petitioner also argues that using a closed-system Foley catheter in Solazzo would still permit Solazzo's tray to be used for irrigation procedures. *Id.* at 83–84 (citing Ex. 1002 ¶ 350; Ex. 1003 ¶¶ 38, 41, 42). Petitioner also argues that an ordinarily skilled artisan would have been motivated to use the closed-system Foley catheters taught by Serany and Disston in Solazzo's tray because doing so would have involved applying a known technique (closed-system catheter) to a known device (catheter kit) that was ready to be improved to reduce infection. *Id.* at 84 (citing Ex. 1002 ¶ 351).

Patent Owner responds that including a pre-connected bag to the Foley catheter in Solazzo's tray would have increased the size of Solazzo's

¹¹ Based on the context, we conclude that Petitioner intended to cite Exhibit 1006 (Serany) rather than Exhibit 1005 (Solazzo), which it inadvertently cited.

tray to the point that the tray would no longer fit between a patient's legs, "defeating the entire purpose of Solazzo's design." PO Resp. 43–46 (citing Ex. 2026 ¶¶ 125–126; Ex. 2027 ¶¶ 102, 167–169). Patent Owner proffers evidence of various actual trays made by Petitioner that Ms. Chiappetta concludes are too small to accommodate a catheter, tubing, and drainage bag. E.g., Ex. 2027 ¶ 169. However, on cross examination, Ms. Chiappetta conceded that the tray she analyzed would accommodate a Foley catheter, tubing, and drainage bag. Ex. 1073, 162:4–165:5; *see also* Ex. 1071 ¶ 28–39 (testimony from Dr. Yun examining the capacity of Petitioner's tray to hold a catheter, tubing, and drainage bag).

Based on our review of all the evidence, Petitioner persuades us by a preponderance of evidence that the combined teachings of Solazzo, Serany, and Disston render claims 33 and 34 unpatentable as obvious.

I. DEPENDENT CLAIM 35

Claim 35 depends from claim 32, which depends from claim 25. Claim 35 further recites "printed instructions instructing application of lubricating jelly to the Foley catheter using the first compartment." Ex. 1001, 30:12–13. Petitioner contends that the combined teachings of Solazzo, Serany, and Franks-Farah render claim 35 unpatentable as obvious. Pet. 85–86. Petitioner relies on Franks-Farah as including printed instructions in a catheter tray and instructing the user to lubricate the tip of the catheter. *Id.* at 86 (cross-referencing showing for claims 18 and 19 (*id.* at 54–59 (citing Ex. 1007, 2:5–14, 4:12–17, Figs. 1, 1A, 2A, 2B; Ex. 1002 ¶¶ 146–150, 258–271))). Petitioner argues that claim 35 does not affirmatively require a "lubrication chamber" but merely recites that the kit include printed instructions relating to the application of lubricating jelly

using the first compartment, which cannot serve as a “patentable distinction” over the prior art. Pet. 22–23 (citing *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004) (“[Ngai] is not, however, entitled to patent a known product by simply attaching a set of instructions to that product.”)); Pet. Remand Reply 19–20 (citing *Ngai*, 367 F.3d at 1338–39; *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1065 (Fed. Cir. 2011)).

Patent Owner responds that Petitioner’s argument rests upon the proposition that the “claimed kit is known” and the Federal Circuit found that Petitioner “failed to show the presence of the ‘lubrication channel’ limitation in the prior art.” PO Remand Br. 4. However, Patent Owner never addresses Petitioner’s argument that “printed instructions” are generally not entitled to patentable weight unless the instructions bear a functional relationship to the claimed subject matter. *See* PO Remand Reply. 7–8 (arguing that claim 35 remains patentable based upon limitations introduced in dependent claim 32).

We find Petitioner’s argument to be persuasive on this point because claim 35 merely introduces instructions for using the “first compartment” as a lubrication chamber without requiring that the “first compartment” be configured as a lubrication chamber. Ex. 1001, 30:12–13. Accordingly, we conclude that the limitations introduced in claim 35 do not serve as a patentable distinction, and we conclude that Petitioner has proven that the combined teachings of Solazzo, Serany, and Franks-Farah render claim 35 unpatentable as obvious.

J. DEPENDENT CLAIM 36

Claim 36 depends directly from claim 25 and further recites: “the tray comprising a single tray.” Ex. 1001, 30:14–15. Petitioner identifies

Solazzo's tray 1 as the "single tray" further required in claim 36. Pet. 75. Patent Owner does not argue in favor of the patentability of claim 36 based upon the limitations introduced in claim 36 alone, but relies instead upon its arguments relating to claim 25. PO Resp. 38–49 (arguing expressly about only claims 25, 28, and 29).

We consider and weigh objective evidence of nonobviousness relating to claim 36 in Part IX below. For all the reasons expressed above including weighing objective evidence of nonobviousness, Petitioner persuades us by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 36 unpatentable as obvious.

VIII. CLAIMS 37–44

A. INDEPENDENT CLAIM 37

Independent claim 37 recites:

37. A medical procedure kit, comprising:

- [a] a tray having a compartment for receiving a medical assembly;
- [b] a first syringe and a second syringe disposed within the tray;
- [c] at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material; and
- [d] an outer packaging disposed about both the tray and the at least one layer of wrap material, wherein:
 - [e] the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure; and
 - [f] the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe;

[g] wherein steps of the catheterization procedure use a higher of the first syringe or the second syringe before a lower of the first syringe or the second syringe.

Ex. 1001, 30:16–36 (with added letter designations a–g to ease discussion).

Limitations 37a–f of claim 37 are identical to limitations 25a–f of claim 25 respectively and limitations 1a–f of claim 1 respectively. *Compare id.* at 30:16–33 (limitations 37a–f), *with id.* at 29:29–45 (limitations 25a–f) and *id.* at 27:47–64 (limitations 1a–f). We find that the difference between limitations 37g and 25g are immaterial to our analysis.

Previously, we concluded that Petitioner had failed to prove by a preponderance of evidence that the combination of Solazzo and Serany described elements 37e and 37g and thus failed to establish that claim 37 was obvious. Dec. 27–28. The Federal Circuit found that: “Given the prior art disclosures and the finite number of predictable options, a skilled artisan would have been motivated to stack the syringes by height according to their order of use.” Op. *7. On this basis, the Federal Circuit found that we erred in our “determination that the prior art did not teach the claim limitation of a compartment that supports syringes at different heights according to order of use.” *Id.* Thus, the Federal Circuit has found in Petitioner’s favor that the combined teachings of Solazzo and Serany suggest limitations 25e and 25g and the similar limitations 37e and 37g. *Id.* at *6–7. The Federal Circuit vacated our decision that claim 37 remained patentable and remanded for further proceedings consistent with its opinion. *Id.* at *7, 10. On remand, we must (1) address whether the combination of Solazzo and Serany describes or suggests all other elements of claim 37 and (2) consider and weigh Patent Owner’s objective evidence of nonobviousness.

Petitioner argues that claim 37 is unpatentable for the same reasons and evidence offered in connection with its challenges to claims 1 and 25. Pet. 76–77 (cross-referencing showing for limitations 1a–e, 25f, 25g). For all the reasons expressed in Parts VI.A and VII.A above, we similarly conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 37 unpatentable as obvious.

B. DEPENDENT CLAIM 38

Claim 38 depends from independent claim 37 and further recites: “the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a catheter assembly.” Ex. 1001, 30:37–39. Petitioner argues that claim 38 is unpatentable for the same reasons proffered for claim 28. Pet. 77 (cross-referencing showing for claim 28).

For the reasons expressed in Part VII.D above, we conclude that Petitioner has failed to prove that the combined teachings of Solazzo and Serany render claim 38 unpatentable as obvious.

C. DEPENDENT CLAIM 39

Claim 39 depends from claim 37 and further recites: “the first compartment defining one or more contours for accommodating flanges of one or more of the first syringe or the second syringe.” Ex. 1001, 30:41–44. We find the limitations introduced in claim 39 to be materially identical to those introduced in claim 6. Petitioner cross-references its arguments relating to claim 6 to support its challenge to claim 39. Pet. 73. Patent Owner does not separately argue the patentability of claim 39. *See* PO Resp. 50 (separately addressing only claims 38 and 40 and arguing for claims 37–44 by cross-referencing arguments for independent claims 1

and 25). Even upon considering Patent Owner's arguments in support of claims 6 and 29, which introduce materially identical limitations as claim 39, we find such an argument unpersuasive. Accordingly, for the reasons expressed in Part VI.C above regarding claim 6, we find that Petitioner has proven by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 39 unpatentable as obvious.

D. DEPENDENT CLAIM 40

Claim 40 depends directly from claim 37 and further recites: "the tray comprising a single tray." Ex. 1001, 30:45–46. Petitioner identifies Solazzo's tray 1 as the "single tray" further required in claim 40. Pet. 75. Patent Owner concedes that Solazzo provides a single tray but contends that Serany does not. PO Resp. 50. However, Patent Owner argues, without citing legal authority or evidentiary support, that Petitioner "cannot choose some features it likes from among the disclosures of the prior art, but ignore other teachings it does not like, to arrive at a conclusion of obviousness." *Id.* Patent Owner proffers no other argument in support of claim 40. We find Patent Owner's argument both factually and legally unsupported.

We consider and weigh objective evidence of nonobviousness relating to claim 40 in Part IX below. For all the reasons expressed above including weighing objective evidence of nonobviousness, Petitioner persuades us by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 40 unpatentable as obvious.

E. DEPENDENT CLAIM 41

Claim 41 depends from claim 40 and further recites: "the tray comprising a surface defining a second compartment, further comprising a Foley catheter disposed within the second compartment." Ex. 1001,

30:47–50. Petitioner argues that claim 41 is unpatentable for the same reasons proffered for claim 28. Pet. 78 (cross-referencing showing for claim 32 (*id.* at 74–75 (citing Ex. 1005, Fig. 8; Ex. 1002 ¶¶ 326–328))). Patent Owner does not separately argue the patentability of claim 41. *See* PO Resp. 50 (separately addressing only claims 38 and 40 and arguing for claims 37–44 by cross-referencing arguments for independent claims 1 and 25).

We consider and weigh objective evidence of nonobviousness relating to claim 41 in Part IX below. Based upon Petitioner’s argument and reasoning, which we adopt as our own, and the evidence cited in the Petition, Petitioner persuades us by a preponderance of evidence that the combined teachings of Solazzo and Serany render claim 41 unpatentable as obvious.

F. DEPENDENT CLAIM 42

Claim 42 depends from claim 41 and further recites: “further comprising a fluid bag disposed within the second compartment.” Ex. 1001, 30:51–52. Dependent claim 34 introduces a substantively similar limitation. *Compare id.*, *with id.* at 30:9–10. Both parties address the patentability of claim 42 based on the same arguments and evidence that they proffer for claim 34. Pet. 85; PO Resp. 49.

We consider and weigh objective evidence of nonobviousness relating to claim 42 in Part IX below. For the reasons expressed in Part VII.H above in our analysis of the patentability of claims 33 and 34, Petitioner persuades us by a preponderance of evidence that the combined teachings of Solazzo, Serany, and Disston render claim 42 unpatentable as obvious.

G. DEPENDENT CLAIMS 43 AND 44

Claim 43 depends from claim 42, and claim 44 depends from claim 43. Claim 43 recites, in pertinent part: “further comprising printed instructions for using the tray,” Ex. 1001, 30:53–54, and claim 44 adds: “the printed instructions instructing application of lubricating jelly to the Foley catheter using the first compartment,” *id.* at 30:55–57.

Petitioner contends that the combined teachings of Solazzo, Serany, Disston, and Franks-Farah render claims 43 and 44 unpatentable as obvious. Pet. 86–87. Petitioner relies on Franks-Farah as including printed instructions in a catheter tray and instructing the user to lubricate the tip of the catheter. *Id.* Petitioner contends that the limitations introduced in claims 43 and 44 are not entitled to patentable weight for the reasons set forth in connection with claims 18 and 19. *Id.* at 87 (cross-referencing *id.* at 22–23 (citing *Ngai*, 367 F.3d at 1339 (“[Ngai] is not, however, entitled to patent a known product by simply attaching a set of instructions to that product.”))); Pet. Remand Reply 19–20 (citing *Ngai*, 367 F.3d at 1338–39; *AstraZeneca*, 633 F.3d at 1065). Petitioner therefore argues that claims 43 and 44 are unpatentable for the same reasons proffered in connection with claims 18 and 19. *Id.* at 87.

Petitioner persuades us that the printed instructions introduced in claims 43 and 44 do not serve as a patentable distinction because they bear no functional relationship to the structural elements recited in intervening claim 42. That notwithstanding, we find that Franks-Farah teaches providing such instructions in a catheter kit. As explained above, we have found that the combined teachings of Solazzo, Serany, and Disston render claim 42 unpatentable as obvious. Accordingly, we conclude that Petitioner

has proven that the combined teachings of Solazzo, Serany, Disston, and Franks-Farah render claims 43 and 44 unpatentable as obvious.

IX. OBJECTIVE INDICIA OF NONOBVIOUSNESS

A. COLLATERAL ESTOPPEL

We made findings on the probative value of Patent Owner’s objective evidence of nonobviousness in a related proceeding, IPR2019-00208, which involves a related patent, U.S. Patent No. 9,808,400 B2 (“the ’400 patent”). IPR2019-00208, Paper 57 (the “208 Decision”), 22–26. All challenged claims of the ’400 patent (i.e., claims 13, 14, 16, and 17) require a single layer tray, but none requires arranging two syringes in a single compartment according to their preferred order of use. IPR2019-00208, Ex. 1001, 11:47–12:28. We concluded that claims 13, 14, 16, and 17 of the ’400 patent were unpatentable. 208 Decision, 34–35. Patent Owner did not appeal the 208 Decision.

Petitioner argues that, because the 208 Decision is now final and involved an “identical issue,” Patent Owner is estopped from “relying on secondary considerations.” Pet. Remand Br. 21. We disagree.

IPR2019-00208 and this proceeding do not involve an “identical issue” despite Patent Owner relying on essentially the same body of objective evidence of nonobviousness in both proceedings. The challenged claims in this proceeding materially differ from those at issue in IPR2019-00208. *Compare* Ex. 1001, 27:47–30:57, *with* IPR2019-00208, Ex. 1001, 11:47–12:28; *see also* PO Remand Br. 23. The material differences in the claims, alone, and thus the issues previously decided, precludes a finding of collateral estoppel. Therefore, we conclude that Patent Owner is not collaterally estopped from relying upon its objective evidence of

nonobviousness. Rather, we consider and weigh that evidence as it applies to the claims at issue in this proceeding below.

B. LEGAL PRINCIPLES

We necessarily must evaluate and weigh objective evidence of nonobviousness (alternatively, “secondary considerations”) in determining whether any challenged claim is unpatentable as obvious. Op. *10.

In order to accord substantial weight to secondary considerations in an obviousness analysis, “the evidence of secondary considerations must have a ‘nexus’ to the claims, i.e., there must be ‘a legally and factually sufficient connection’ between the evidence and the patented invention.” *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (quoting *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988)). “The patentee bears the burden of showing that a nexus exists.” *WMS Gaming Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999). “To determine whether the patentee has met that burden, we consider the correspondence between the objective evidence and the claim scope.” *Henny Penny*, 938 F.3d at 1332.

Fox Factory, Inc. v. SRAM, LLC, 944 F.3d 1366, 1373 (Fed. Cir. 2019).

C. PRESUMED NEXUS

[P]resuming nexus is appropriate “when the patentee shows that the asserted objective evidence is tied to a specific product and that product ‘embodies the claimed features, and is coextensive with them.’” *Id.* (quoting *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) (quoting *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000))). “Whether a product is coextensive with the patented invention, and therefore whether a presumption of nexus is appropriate in a given case, is a question of fact.” *Id.*

[T]he degree of correspondence between a product and a patent claim falls along a spectrum. At one end of the spectrum lies

perfect or near perfect correspondence. At the other end lies no or very little correspondence, such as where “the patented invention is only a component of a commercially successful machine or process.” *Id.* Although we do not require the patentee to prove perfect correspondence to meet the coextensiveness requirement, what we do require is that the patentee demonstrate that the product is essentially the claimed invention. *See id.*

Fox Factory, 944 F.3d at 1374 (quoting and citing *Demaco*, 851 F.2d at 1392). Patent Owner bears the burden of proving that its objective evidence of nonobviousness is attributable to the combination of features that is claimed rather than “prior art features in isolation or unclaimed features.” *Id.* at 1378.

Petitioner argues that Patent Owner fails to carry this burden because: (1) the claims fail to recite a critical feature (that the tray have only one layer); (2) the claimed critical feature is taught by the prior art (arranging syringes according to their order of use); or (3) the claim was not compared against any commercial product. Pet. Remand Br. 4–9. Petitioner argues that Patent Owner, through testimony by its experts, identifies two critical features as the basis for its argument that a nexus exists between the claims and the objective evidence of nonobviousness, namely, a single layer tray and syringes being arranged in their order of use. *Id.* at 5 (citing Reply 18 (citing Ex. 2027 ¶ 125; Ex. 2026 ¶ 208; Ex. 2028 ¶¶ 8, 23)). Petitioner argues that Patent Owner fails to demonstrate a presumed nexus between the claimed subject matter and any of its objective evidence for all claims, but for different reasons. We find Petitioner’s arguments to be persuasive for the reasons expressed below in connection with groups of claims that we consider to be substantively similar.

1. Independent Claims 1, 25, and 37

Petitioner correctly points out that none of the challenged independent claims 1, 25, and 37 recites the first feature alleged to demonstrate nexus, a single layer tray. Pet. Remand Br. 5; *see also* Ex. 1001, 27:47–67 (claim 1), 29:29–48 (claim 25), 30:16–36 (claim 37). The second feature, the arrangement of syringes in the tray according to their order of use is required in each of claims 1, 25, and 37. Ex. 1001, 27:64–67 (claim 1 reciting mnemonic device), 29:46–48 (claim 25 reciting arranging syringes at different heights according to predetermined steps), 30:34–36 (claim 37 reciting using higher positioned syringe before lower positioned syringe).

Patent Owner identified the single layer feature of the tray as a critical feature that “very significantly” lowered the risk of contaminating the items in a catheter tray. For example, Ms. Chiappetta testified that:

The *single-layer tray design* discussed above for the indwelling catheterization kit *was very significant*. This single layer tray greatly decreases the risk of contamination of the catheter, lubricant, and other components of the catheterization system as compared to the dual-layer tray because the risks with having two trays and transferring elements between those trays is eliminated.

Ex. 2027 ¶ 125 (emphases added).

Patent Owner concedes that claims 1, 25, and 37 do not “explicitly recite ‘single layer,’” but argues nevertheless that they implicitly require a single layer. PO Remand Br. 12. More specifically, Patent Owner argues that, because the claims require medical components and “critical components” in “compartments of the tray,” a second tray “would serve no purpose.” *Id.*

We find Patent Owner's argument unpersuasive for at least three reasons. First, Patent Owner cites no other claim language or evidence from the Specification or prosecution history to support its argument. *Id.* Accordingly, we find the argument to be unsupported by persuasive evidence.

Second, Patent Owner identifies no paper submitted during the trial that includes this argument, and we find no such paper. We previously instructed Patent Owner that "any arguments for patentability not raised in the [Patent Owner Response] may be deemed waived." Paper 19, 7; *see also In re Nuvasive, Inc.*, 842 F.3d 1376, 1381 (Fed. Cir. 2016) (holding that patent owner's failure to proffer argument at trial as instructed in scheduling order constitutes waiver). Accordingly, we consider Patent Owner's argument to have been forfeited.

Third, we discern no requirement in claims 1, 25, and 37 that a "medical assembly" is actually disposed within any compartment of the claimed tray. Rather, each claim merely recites that the claimed tray includes a "compartment for receiving a medical assembly" without expressly requiring the presence of the medical assembly in that compartment or any other compartment. Ex. 1001, 27:48–49 (claim 1), 29:30–31 (claim 25), 30:17–18 (claim 37). We do not agree with Patent Owner's argument that such a second tray would necessarily "serve no purpose." For example, the medical assembly could be disposed in a second tray and then moved to the "compartment for receiving a medical assembly" when the tray is used during a procedure. Additionally, such a second tray could contain important components of the kit other than the syringes or

“medical assembly.” Finally, Patent Owner cites no evidence to support its contention that a second tray would serve no purpose. PO Remand Br. 12.

The failure of a claim to recite a materially significant feature, like the failure of each of claims 1, 25, and 37 to recite a single tray, weighs against finding a presumed nexus between the claim and objective evidence of nonobviousness. *Fox Factory*, 944 F.3d at 1375–77. Independent claim 45, which is at issue in IPR2019-00036, recites a “single layer tray” but does not recite the second allegedly critical feature of the invention, arranging syringes in their order of use. Ex. 1001, 30:58–31:5. Patent Owner proffers the same evidence in support of its showing of nexus for claim 45 as it does for its showing relating to claims 1, 25, and 37. *See* PO Remand Br. 12–22. We find the *Fox Factory* decision to be instructive in this proceeding when it found that the “same evidence of secondary considerations cannot be presumed to be attributable to two different combinations of features.” *Fox Factory*, 944 F.3d at 1378.

For all the reasons expressed above, we conclude that Patent Owner is not entitled to a presumed nexus between its objective evidence of nonobviousness and the subject matter of independent claims 1, 25, and 37.

2. Dependent Claims 36 and 40–44

Claim 36 depends from claim 25 and further recites: “the tray comprising a single tray.” Ex. 1001, 30:14–15. Claim 40 depends from claim 37 and also recites: “the tray comprising a single tray.” *Id.* at 30:45–46. Claims 41–44 ultimately depend from claim 40, which depends from claim 37. *Id.* at 30:47–57. The independent claims from which claims 36 and 40–44 depend, namely claims 25 and 37 respectively, also require that two syringes be placed in one compartment of the tray

according to their preferred order of use. *Id.* at 29:46–48 (claim 25 reciting arranging syringes at different heights according to predetermined steps), 30:34–36 (claim 37 reciting using higher positioned syringe before lower positioned syringe). Therefore, each of claims 36 and 40–44 is directed to a tray that includes both of the features that Patent Owner identified during the trial as justifying a presumption of nexus.

Petitioner argues that Patent Owner has failed to prove that any of claims 36 and 40–44 are entitled to a presumption of nexus for three reasons. Pet. Remand Br. 8–9.

First, Petitioner argues that Patent Owner failed to meet its burden of proof because it relied on claim charts comparing other claims, namely claims 1 and 7, to Petitioner’s and Patent Owner’s products. *Id.* (citing *Centripetal Networks, Inc. v. Cisco Sys., Inc.*, 847 F. App’x 869, 880 (Fed. Cir. 2021) (finding patent owner did not establish nexus when patent owner’s “expert did not even create a claim-construction chart to map the products to each limitation”)). Petitioner also contends that some of Patent Owner’s claim charts are deficient because one of the two versions of Petitioner’s products that Patent Owner charted do not meet the requirement in independent claims 25 and 37 of placing the syringes at different heights in one compartment of the tray. *Id.*

Patent Owner responds that it met its burden of proof by presenting claim charts, albeit for different claims, analyzing at least one of Petitioner’s products in connection with each one of the critical features. PO Remand Reply. 11. Patent Owner compared claim 45 (at issue in IPR2019-00036), which recites a single layer tray (but not syringes arranged according to their

order of use), with Petitioner’s “Tray C.” *Id.* (citing Ex. 2026 ¶ 166).¹² Patent Owner also compared claim 1 with Petitioner’s “Tray C,” which allegedly arranges syringes in the order in which they are used. *Id.* (citing Ex. 2026 ¶ 164). Patent Owner’s arguments prove that, in its attempt to establish a presumption of nexus, Patent Owner did not compare any single claim of the ’088 patent that recites the combination of both of its allegedly critical features to any product of its own or Petitioner’s. *See generally* Ex. 2026 (comparing four of Petitioner’s trays and one of Patent Owner’s trays to claims 1, 7, 45, 54, 61, 66, and 67, none of which recites the combination of both critical features). Based on this failure alone, we conclude that Patent Owner has failed to carry its burden of proving that it is entitled to a presumption of nexus for claims 36 and 40–44.

Second, Petitioner argues that Patent Owner’s objective evidence of nonobviousness was directed to “one prior art feature in isolation—a single layer tray,” and not the combination of the single layer tray and arranging syringes according to their order of use. Pet. Remand Br. 9. Petitioner contends that linking the objective evidence only to the “single layer tray” is legally insufficient under *Fox Factory*. *Id.* Patent Owner responds that it is not solely relying upon the single layer feature and argues that it is not legally required to prove nexus based upon claim limitations that are not taught by the prior art. PO Remand Reply. 10 (citing *Lectrosonics Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 33 (PTAB Jan. 24, 2020))

¹² Patent Owner asserts that it also charted claim 25, the claim from which claim 36 depends. Pet. Remand Reply. 11. However, Patent Owner cited no relevant evidence to support this assertion, and we can find no claim chart comparing claim 25 to any product. Patent Owner cited Ex. 2026 ¶ 166, which is a claim chart comparing claim 45 to one of Petitioner’s trays.

(precedential) (quoting *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016))). Patent Owner also argues that a showing of presumed nexus cannot be defeated by showing that different prior art references separately disclose the individual limitations of an inventive combination. *Id.* at 10–11 (citing *Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, 4 F.4th 1370, 1378 (Fed. Cir. 2021)).

Third, Petitioner responds that both of the two critical features are shown in the prior art by at least Solazzo. Pet. Remand Br. 9 (citing Reply 19; Ex. 1002 ¶¶ 44, 102–104); Reply 19 (citing Ex. 1005, 4:45–48, Figs. 1, 8; Ex. 1073, 180:2–18; Ex. 1074, 220:19–221:7); *see also* Op. *7 (holding that the prior art taught “support[ing] syringes at different heights according to order of use”). Patent Owner contends that the combination of a single layer tray and arranging syringes in a compartment according to their order of use is not “in the prior art” because the “Federal Circuit found that Solazzo could be *modified* to meet these requirements—not that they were in the prior art.” PO Remand Reply. 11 (citing Op. *6).

Patent Owner’s argument is unpersuasive. There is no dispute that Solazzo’s tray 1 is a single layer tray, and the Federal Circuit expressly concluded that Solazzo alone or in combination with Serany suggests arranging syringes based on their order of use. Op. *6 (“Given the prior art disclosures, a skilled artisan would have been motivated to design a compartment with a bottom portion that would elevate one syringe above another, without the aid of other items.”), *id.* at *7 (“Given the prior art disclosures and the finite number of predictable options, a skilled artisan would have been motivated to stack the syringes by height [in one compartment] according to their order of use.”). We find that Patent Owner

fails to prove that it is entitled to a presumption of nexus because Solazzo suggests the combination of features that Patent Owner relies upon in its attempt to demonstrate a presumption of nexus.

D. NEXUS IN FACT AND WEIGHT OF OBJECTIVE EVIDENCE

A finding that a presumption of nexus is inappropriate does not end the inquiry into secondary considerations. *See In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996). To the contrary, the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the “direct result of the unique characteristics of the claimed invention.” *Id.*

Fox Factory, 944 F.3d at 1373–74. Additionally, a presumption of nexus is rebuttable.

The presumption of nexus is rebuttable: a patent challenger may respond by presenting evidence that shows the proffered objective evidence was “due to extraneous factors other than the patented invention.” *Demaco*, 851 F.2d at 1393. Such extraneous factors include additional unclaimed features and external factors, such as improvements in marketing. *See, e.g., Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1378 (Fed. Cir. 2000) (applying presumption even though commercial embodiment had unclaimed mobility feature); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006) (holding that evidence that commercial success was due to unclaimed or non-novel features of device “clearly rebuts the presumption that [the commercial product’s] success was due to the claimed and novel features”). However, a patent challenger cannot successfully rebut the presumption with argument alone—it must present evidence. *Brown & Williamson*, 229 F.3d at 1130 (citing *Demaco*, 851 F.2d at 1393).

WBIP, 829 F.3d at 1329.

1. Long-felt Need

Patent Owner argues that its single-layer tray met a long-felt need to reduce catheter-associated urinary tract infections (“CAUTI”). PO

Resp. 46–49. The argument rests largely upon testimony from Ms. Chiappetta. *Id.* (citing Ex. 2027 ¶¶ 73, 85–91, 93–97, 105–124, 126–136, 197–205). Ms. Chiappetta testifies that the design of the tray “guides the user in applying proper aseptic technique” to reduce the incidence of CAUTI. Ex. 2027 ¶¶ 125, 128. To support her conclusion that single layer trays reduce the incidence of CAUTIs, Ms. Chiappetta cites anecdotal reports from three hospitals that used Patent Owner’s commercial ERASE CAUTI trays and reported reduced incidence of CAUTIs. *Id.* ¶¶ 131–135 (citing Ex. 2049; Ex. 2050; Exs. 2057–2059).

Petitioner persuasively points out that the underlying evidence from these three hospitals fails to support Patent Owner’s claims because: (1) the hospital did not report infection rates at all (Ex. 2057, 4); (2) Patent Owner cherry-picked data in a manner that distorted the outcome (Ex. 2058, 7; Ex. 1087, 2); and (3) the data reflected a reduction in infection rates that mostly occurred before the hospital bought trays from Patent Owner (Ex. 1085, 15). Reply 22–24. Petitioner also persuasively discredits Ms. Chiappetta’s testimony that CAUTI rates declined in 2015–2016 after single level trays “had time to gain traction in the market,” Ex. 2027 ¶ 73, because she was unaware that the apparent reduction in infection rates largely reflected a change in the definition of CAUTI in 2015 to exclude yeast infections, Ex. 1073, 209:9–22, 211:6–20; Ex. 1042. Reply 23–24. Finally, Petitioner persuasively demonstrates that CAUTI rates declined steadily before single level trays gained market share and thus decreased for reasons unrelated to the claimed tray. *Id.* at 24 (citing Ex. 1042, 5; Ex. 1073,

218:7–14; Ex. 1071 ¶¶ 60–72¹³). Based on the entire record, we conclude that Patent Owner fails to establish that single level trays reduced CAUTI rates rather than other factors identified by Petitioner. Accordingly, we consider Patent Owner’s argument that the claimed invention addressed a long-felt need to be unpersuasive.

2. Copying and Praise

“[P]raise from a competitor tends to indicate that the invention was not obvious.” *In re Cree, Inc.*, 818 F.3d 694, 702 (Fed. Cir. 2016).

“‘Copying may indeed be another form of flattering praise for inventive features,’ . . . and thus evidence of copying tends to show nonobviousness.” *WBIP*, 829 F.3d at 1331 (quoting *Crocs, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1311 (Fed. Cir. 2010)).

Not every competing product that arguably falls within the scope of a patent is evidence of copying; otherwise, “every infringement suit would automatically confirm the nonobviousness of the patent.” Our case law holds that copying requires evidence of efforts to replicate a specific product, which may be demonstrated through internal company documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a replica, or access to the patented product combined with substantial similarity to the patented product.

Wyers v. Master Lock Co., 616 F.3d 1231, 1246 (Fed. Cir. 2010) (quoting *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004)) (other citations omitted).

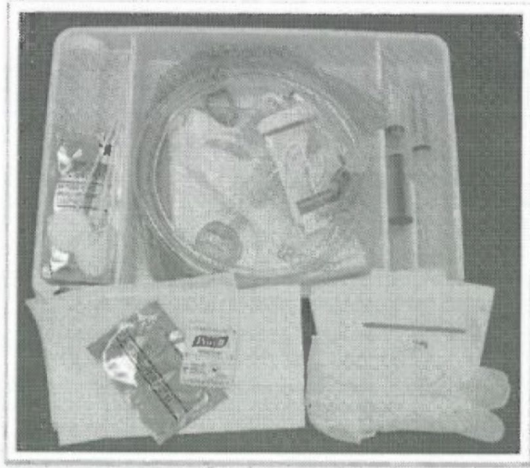
Petitioner and Patent Owner focus on dramatically different facts when addressing whether Petitioner copied Patent Owner’s ERASE CAUTI

¹³ It is apparent from the context and our review of the record that Petitioner mistakenly cited Exhibit 1070 rather than Exhibit 1071.

tray. Patent Owner focuses on Petitioner's actions earlier in the development process before it finalized and released the SureStep trays. For example, Petitioner commissioned a survey of a group of 17 users to understand the appeal of Patent Owner's ERASE CAUTI tray. *See* Ex. 2100. Patent Owner argues that the report concluded that participants "preferred [Patent Owner's] tray as having a '[m]ore intuitive insertion sequence due to order of components and single level tray,' and criticized [Petitioner's] tray as 'not intuitive.'" PO Remand Br. 14–15 (citing Ex. 2028 ¶ 32; Ex. 2100 at BARD 0227940; Ex. 2101 at BARD 0227984). Various employees of Petitioner identified the reasons underpinning Patent Owner's competitive threat as "1 level tray, more user friendly" (Ex. 2048, 4); "single layer tray, such as Medline's would be preferred" (Ex. 2081, 2); and "kit components and configuration." (Ex. 2082, 2). Patent Owner cites numerous examples of Petitioner expressing a need to develop a new product that includes a single layer tray and an intuitive layout. PO Remand Br. 15–16 (citing Ex. 2086, 2–3; Ex. 2110, 3; Ex. 2106 at BARD 0004235; Ex. 2107 at BARD 0333084; Ex. 2108; Ex. 2092, 1).

Petitioner also conducted an internal design contest to create a product to compete with the ERASE CAUTI tray, which ultimately resulted in a prototype. Ex. 2066. Below, we reproduce an image of the prototype tray made by Petitioner on the left and an image of ERASE CAUTI rotated 180 degrees to ease comparison on the right.

Tray Design
The following prototype was reviewed with respondents (Image 2).



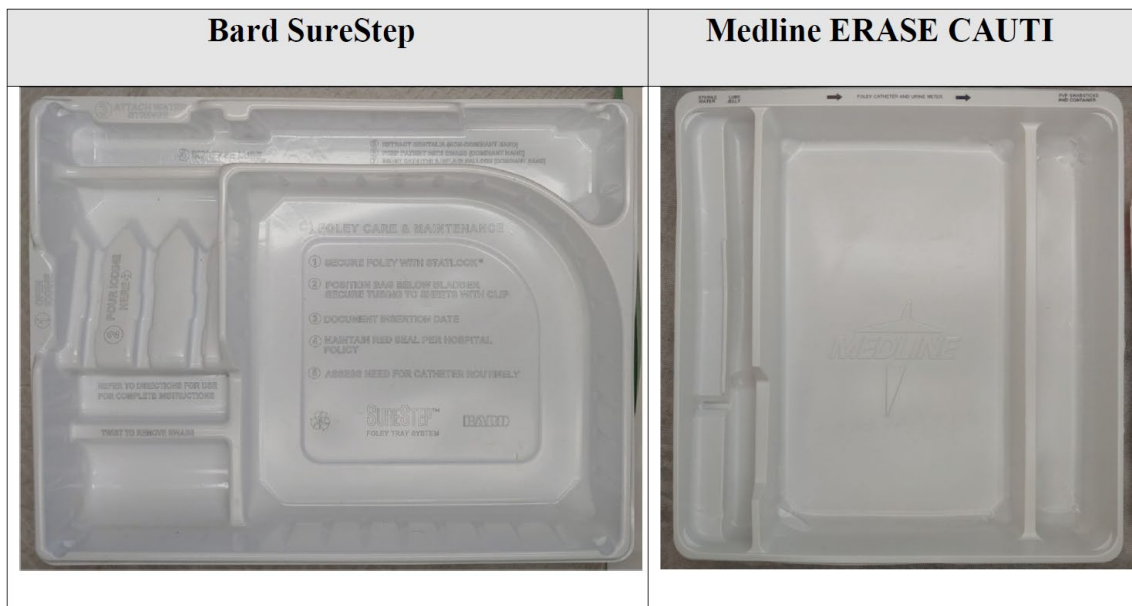
Petitioner's prototype tray



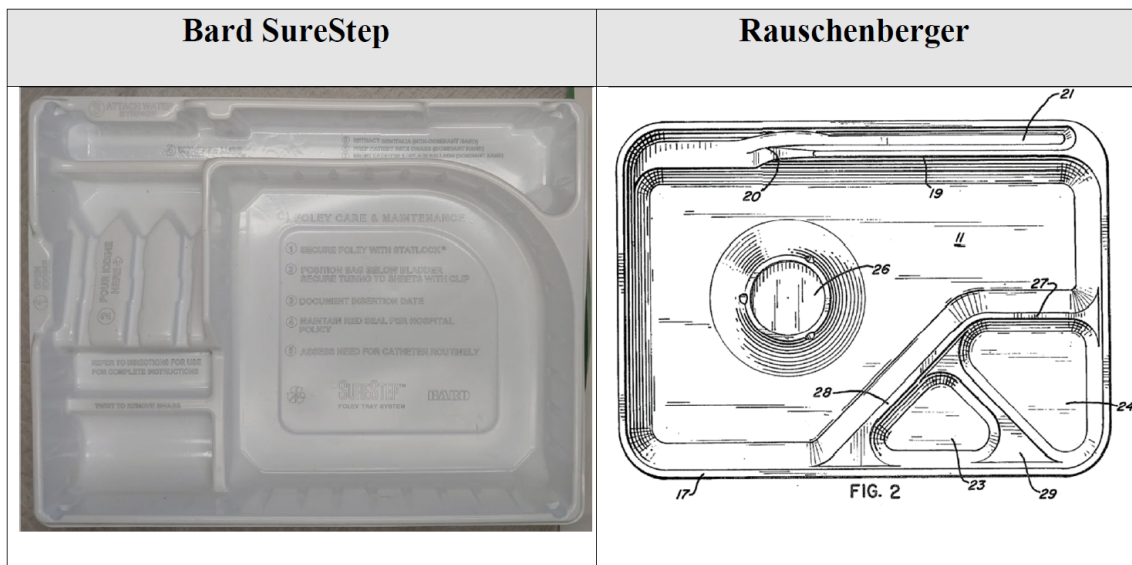
ERASE CAUTI tray

Petitioner's witness in related litigation admitted that the prototype and ERASE CAUTI trays had "essentially the same layout." Ex. 2068, 259:11–261:15; Ex. 1082, 4. But, Petitioner persuasively demonstrates that it never sold the prototype tray, which Petitioner persuasively argues "bears little resemblance to the SureStep tray." Reply 31 (citing Ex. 1070 ¶¶ 40–45).

Petitioner contends that its SureStep trays dramatically differed from Patent Owner's ERASE CAUTI tray and more closely resembled a prior art tray described in U.S. Patent No. 4,160,505 (Ex. 1013, "Rauschenberger"). Petitioner supports its contention with the exemplary images reproduced below.



The image above illustrates one of Petitioner's SureStep trays on the left and Patent Owner's ERASE CAUTI tray on the right. The second image (shown below) illustrates the same SureStep tray on the left and the prior art tray shown in Rauschenberger's Figure 2 on the right.



Petitioner argues, for example, that the SureStep trays do not store syringes in stepped compartment like the ERASE CAUTI tray, but rather hold syringes in a flat compartment. Pet. Remand Br. 14 (citing

Reply 31–32 (citing Ex. 1070 ¶¶ 52–54)). Petitioner’s SureStep trays do not position syringes in a manner to guide the user on how or when to use each syringe but rather are color coded for that purpose (green plunger for lubricant, white plunger for water). *Id.* (citing Ex. 1070 ¶ 52). Petitioner’s SureStep trays are also imprinted with numbered steps to direct the user through a catheterization procedure. *Id.* (citing Ex. 1073, 251:2–13.)

Based on the entirety of evidence, Patent Owner persuades us that Petitioner made a prototype that was a “copy” of the ERASE CAUTI tray and ultimately adopted the single layer feature in its SureStep trays. Petitioner’s initial reaction to the “competitive threat” posed by the ERASE CAUTI tray to incorporate a single layer tray does tend to weigh against a finding of obviousness. However, we agree with Petitioner that (1) it never sold the prototype tray, and (2) the commercial SureStep tray was not a copy of the ERASE CAUTI tray but more closely resembles the Rauschenberger tray. Petitioner’s SureStep trays included an altered single layer feature that was indisputably well known within the prior art, which diminishes the probative value of Patent Owner’s evidence of copying and praise. On balance, we find that the evidence of copying and praise slightly favors a finding of nonobviousness.

3. Failure of Others

Patent Owner argued during the trial that Petitioner’s design contest and the resulting prototype reflected a “failure of others” because (1) Petitioner “devoted great resources to this project,” Sur-reply 17–18 (citing Ex. 2068, 251:13–25, 117:21–120:5, 139:15–21, 143:1–15, 189:16–190:1, 234:11–237:24, 238:7–240:4, 265:20–266:4; Ex. 2070; Ex. 2097), and (2) Ms. Chiappetta testified that Petitioner “tried, but failed,

to solve the CAUTI problem,” Ex. 2027 ¶¶ 98–104. Petitioner responds that the design contest succeeded because important ideas were generated and the budget for each competing design team was only \$200. Pet. Remand Br. 14 (citing Reply 32–33); Reply 32–33 (citing Ex. 1070 ¶¶ 57–60; Ex. 2066, 1, 9; Ex. 2065, 89:24–90:12, 98:3–20). Patent Owner implies that its evidence of “failure of others” is weak at best, stating “regardless of the effort expended, [Petitioner] ultimately chose to copy [Patent Owner].” PO Remand Reply. 14. We agree with Patent Owner’s implication and discern no logical or evidentiary support for its argument that “failure of others” weighs against a finding of obviousness.

4. Commercial Success

Each party proffers its own expert, Dr. Rao for Patent Owner and Dr. Sheridan for Petitioner, to analyze the sales data and offer opinions on the relationship between sales, “commercial success,” and obviousness. Ex. 1072; Ex. 2028. Both experts analyze data for four products, Petitioner’s sales of Legacy, Advance, and SureStep trays, and Patent Owner’s sales of ERASE CAUTI kits. Ex. 1072; Ex. 2028. Of these, only the SureStep and ERASE CAUTI kits include a single layer tray. Both experts include spreadsheets alleged to be reporting the unit sales, revenues, profits, and average selling prices for 2006 through 2018. Ex. 2028, p. 65 (Tab 3); Ex. 1072, p. 102¹⁴ (Schedule 5.0). Based on our close examination of this data, we find that both witnesses materially agree on the numbers of

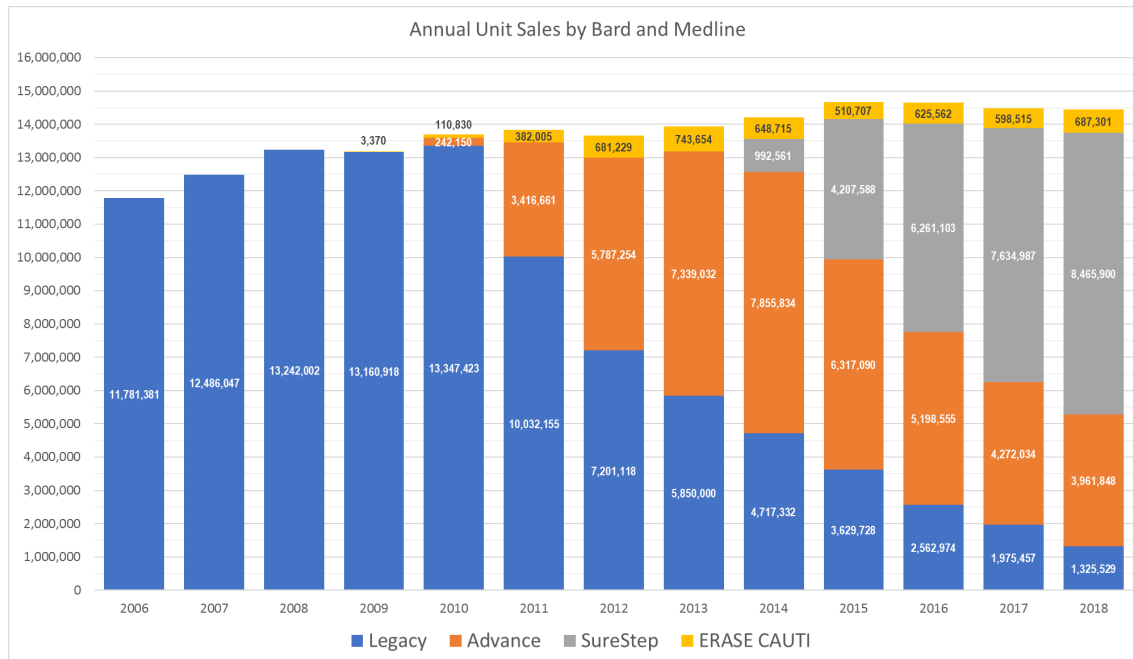
¹⁴ Dr. Sheridan’s report does not include page numbers, but, when necessary, we refer to the page number as revealed in the electronic version of the report. When available and helpful, we also refer to Dr. Sheridan’s own labels for the various schedules in his report (e.g., Schedule 5.0).

units sold and revenues for all but Petitioner's "Legacy" products. *Compare* Ex. 2028, p. 65 (Dr. Rao's data), *with* Ex. 1072, p. 102 (Schedule 5.0) (Dr. Sheridan's data showing 22.4% higher unit sales and 38.0% higher revenue for Legacy than Dr. Rao's data). Significant differences exist in the data for Legacy sales during 2007 through 2013, with especially large differences during 2008 through 2011. *Compare* Ex. 2028, p. 65 (Dr. Rao's data), *with* Ex. 1072, p. 102 (Schedule 5.0) (Dr. Sheridan's data showing 22.4% higher unit sales and 38.0% higher revenue for Legacy than Dr. Rao's data).

Based on our careful review of both reports, we find that Dr. Sheridan's data is more reliable because Dr. Sheridan cites and provides copies of the evidence upon which his numbers for the Legacy product are based. Ex. 1072 ¶ 99 (citing Schedule 5.0, which cites Schedules 6.0 (ERASE CAUTI), 7.0 (SureStep), 8.0 (Advance), and 9.0 (Legacy with Schedule 9.0 citing Schedule 9.6 for unit sales, which cites Bard_1086170 (Ex. 1098)). Dr. Rao cites "BARD_1087970_HIGHLY CONFIDENTIAL.xlsx" as the source of his Legacy information. We, however, cannot verify the accuracy of Dr. Rao's numbers because we cannot identify a copy of the cited evidence in the record of this proceeding. Ex. 2028, p. 65 (Tab 3).

Using the data from Dr. Sheridan's spreadsheet, we have generated the chart below to illustrate the annual unit sales of the Legacy, Advance, SureStep, and ERASE CAUTI products from 2006 through 2018.¹⁵

¹⁵ We copied and transposed relevant data from Dr. Sheridan's spreadsheet into a new spreadsheet, which we used to generate the chart. Ex. 3003.



The data reveals that Petitioner’s total unit sales of all its catheter trays remained comparatively stable throughout the entire reported period with year-over-year changes ranging from -3.4% to +6.1%. Ex. 3003. Petitioner argues that it “actively converted Advance and Legacy customers to SureStep” and “converted its customers to SureStep at the same rate it previously converted its customers to Advance” from Legacy. Reply 35 (citing Ex. 1072 ¶ 100). We find Petitioner’s argument persuasive based on the data reflected in the chart above.

The chart also reflects that Patent Owner’s annual unit sales grew relatively quickly but at a declining rate from 2010 to 2012 immediately after ERASE CAUTI was introduced in 2009. Ex. 1072 ¶ 88; Ex. 3003. Even with this fast growth, ERASE CAUTI sales did not meet Patent Owner’s expectations. Ex. 1072 ¶ 89 (citing Ex. 1093). ERASE CAUTI sales declined in 2014, the year that Petitioner’s SureStep was introduced, and declined again in 2015, but largely rebounded in 2016 through 2018. *Id.* Patent Owner argues that the decline in ERASE CAUTI sales during 2014

was caused by Petitioner entering the market with its single layer SureStep kit. Sur-reply 20. However, our review of Patent Owner's internal management report from 2014 identifies the more likely reason for the decline was the poor quality of the components in the ERASE CAUTI kit. The report states:

The ERASE CAUTI line has experienced several significant quality issues over the last two years. These issues, combined with a lack of key-connections at the higher levels at our accounts, have resulted in the loss of our largest customers thus affecting our reputation amongst the sales team. As a result, the past 12 months have been spent raising the bar on the quality of the Urological product line in an effort to make our product line surpass the expectations of our customers. We are now in a situation where we must prove to the sales force that this is a product they should want to sell.

Ex. 1065, 12–13. The report explained the precise reasons for losing a large portion of ERASE CAUTI sales as follows:

Approximately \$2.39M in Acute Care business has been lost over the past 12 months at 4 key healthcare systems; Providence Health & Services, Ohio Health, Wake Forrest, and University of Indiana. This business was lost due to a combination of quality and sales related issues; sample ports breaking off, drainage, Silvertouch [catheter] malfunctions, latex catheter balloon deflation and poor clinical relationships to name a few.

Id. at 2. Patent Owner's ERASE CAUTI sales declined by about \$944K.

Ex. 3003. If Patent Owner had retained the \$2.39M in business lost directly because of poor quality components, Patent Owner would have reported an increase in sales for 2014 of almost \$1.5M (or about 15% increase over 2013). We find that these quality issues and the dramatic effect that they had on sales of ERASE CAUTI trays demonstrate that the quality of the

items in the kits are a primary driver of sales success or failure, not the number of layers in the tray, or the layout of items in the tray.

We infer that the importance of the quality of items in a kit as a driver of sales is further demonstrated by how many customers continued to use kits with two trays rather than one during the relevant time period. Until 2017, eight years after Patent Owner introduced ERASE CAUTI and three years after Petitioner introduced SureStep, Petitioner sold more kits with two-layer trays than both companies sold kits with single layer trays. Even in 2018, Petitioner's two-layer Legacy and Advance kits accounted for about 43% of the parties' combined sales, and in 2019 they accounted for more than 36% of the parties' combined sales. Ex. 1072 ¶ 88; Ex. 3003.

Although not shown in the chart above, Patent Owner, acting as a distributor, also sold Petitioner's Legacy, Advance, and SureStep kits between 2014 and 2018 (after the introduction of SureStep in 2014). Ex. 1072 ¶ 90. Further demonstrating the market equivalence of two-layer and single layer trays, Patent Owner consistently sold about twice as many of Petitioner's Legacy and Advance two-layer kits as it sold its own ERASE CAUTI kits during 2014 and 2018. Ex. 1072 ¶ 91, Schedules 6.0, 10.1, 10.5. Patent Owner also sold about 1.5 times the number of Petitioner's Legacy and Advance two-layer kits as it sold Petitioner's single layer SureStep kits. *Id.*

Rather, Petitioner persuasively argues that its ability to retain existing customers was driven by factors other than a switch to a one-layer tray in the SureStep kit, namely: (1) brand loyalty; (2) the distributors and Group Purchasing Organizations involved; (3) price; and (4) quality. Reply 36 (citing Ex. 1071 ¶¶ 116–126; Ex. 1072 ¶ 83). To the extent that Patent

Owner penetrated the market with ERASE CAUTI, Petitioner persuasively argues that Patent Owner did so by competing on price. *Id.* 36–37 (citing Ex. 1072 ¶¶ 109–110).

Patent Owner contends that Petitioner sold SureStep for an average of \$1.10 more than Advance. PO Resp. 70 (citing Ex. 2028 ¶¶ 46–49); Ex. 2028 ¶ 46 (summarizing Dr. Rao’s analysis of price differences between SureStep and Advance). Dr. Rao notes that SureStep kits had a single layer tray with an “improved component layout” when compared to Advance. Ex. 2028 ¶ 47 (citing BARD_0004235–0004236 (Ex. 2106, 1–2)). Dr. Rao concludes that “the claimed features command a price premium when incorporated in catheterization kits.” Ex. 2028 ¶ 49.

After carefully reviewing Dr. Rao’s analysis of price differences, we identified a number of issues that diminish the weight we accord his conclusion. First, the evidence upon which Dr. Rao relies when comparing features of SureStep and Advance describes Petitioner’s prototype tray, not SureStep. *See* Ex. 2106, 1 (referring to “Bearcat1”). Even assuming that the improvements noted in Exhibit 2106 were also present in SureStep, Exhibit 2106 lists three improvements in the prototype tray other than “Single level tray” and “Improved component layout,” namely: “Improved labeling,” “New foam swabs,” and “Drainage system tubing design improvements.” Ex. 2106, 2. The prototype single layer kit was also to include an improved “Fidelis” catheter. *Id.* Dr. Rao does not comment upon or analyze the effect, if any, on how these other three improvements affected the price or performance of SureStep compared to Advance. Ex. 2028 ¶¶ 46–49.

Petitioner responds that the price of Patent Owner's ERASE CAUTI kits was comparable to Patent Owner's previous two-layer kit. Reply 36 (citing PO Resp. 58). Petitioner also responds that Patent Owner sold Petitioner's Advance kits at a higher average price than ERASE CAUTI kits. *Id.* (citing Ex. 1072 ¶ 109). Finally, Petitioner criticizes Dr. Rao's analysis of the alleged "price premium" that SureStep commanded over Advance as failing to account for the higher cost of goods for SureStep resulting, for example, from SureStep including peri-care products that were not included in the Advance kit. *Id.* (citing Ex. 1072 ¶¶ 113–125). We have reviewed the evidence upon which Petitioner bases its response and find it to persuasively rebut Patent Owner's argument that the inclusion of claimed features in the SureStep kits commanded a price premium over prior Advance kits.

After a thorough review of the evidence relating to commercial success, we find that the commercial success of the parties' products was not the direct result of the claimed features of a single layer tray or Patent Owner's arrangement of syringes in the tray. Accordingly, we find that Patent Owner has not shown that the "commercial success" of kits incorporating a single layer tray, an arrangement of syringes according to their order of use, or both weighs significantly against a conclusion of obviousness.

5. Conclusion

For the reasons expressed above, Patent Owner's objective evidence of nonobviousness does not weigh significantly against a conclusion of obviousness for any claim at issue on remand.

X. CONCLUSION

For all the reasons expressed above, Petitioner has demonstrated by a preponderance of the evidence that claims 1, 2, 6, 8–10, 16, 25–27, 29–37, and 39–44 are unpatentable for obviousness, but Petitioner fails to do so for claims 7, 17–19, 28, and 38.

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 2, 6–10, 16, 17, 25–32, 36–41	103	Solazzo, Serany	1, 2, 6, 8–10, 16, 25–27, 29–32, 36, 37, 39–41	7, 17, 28, 38
18, 19, 35	103	Solazzo, Serany, Franks-Farah	35	18, 19
33, 34, 42	103	Solazzo, Serany, Disston	33, 34, 42	
43, 44	103	Solazzo, Serany, Disston, Franks- Farah	43, 44	
Overall Outcome			1, 2, 6, 8–10, 16, 25–27, 29–37, 39–44	7, 17–19, 28, 38

XI. ORDER

For the reasons given, it is:

ORDERED that Petitioner has demonstrated by a preponderance of evidence that claims 1, 2, 6, 8–10, 16, 25–27, 29–37, and 39–44 of U.S. Patent No. 9,745,088 B2 are unpatentable as obvious under 35 U.S.C. § 103;

FURTHER ORDERED that Petitioner has failed to establish based on a preponderance of evidence that claims 7, 17–19, 28, and 38 of U.S. Patent No. 9,745,088 B2 are unpatentable as obvious under 35 U.S.C. § 103; and

FURTHER ORDERED that because this is a final written decision, the parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2019-00035
Patent 9,745,088 B2

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