

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C.R. BARD, INC.,
Petitioner,

v.

MEDLINE INDUSTRIES, LP,¹
Patent Owner.

IPR2019-00223
Patent 9,808,596 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 All 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 66, 2. As of the same date, Medline Industries, LP was also the record owner of the '596 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 7–16, 21, and 22 (the “challenged claims”) of U.S. Patent No. 9,808,596 B2 (Ex. 1001, “the ’596 patent”). 35 U.S.C. § 311. Medline Industries, LP (“Patent Owner”) timely filed a Preliminary Response. Paper 12. On June 6, 2019, based on the record before us at the time, we instituted an *inter partes* review of all challenged claims and all grounds advanced by Petitioner. Paper 21.

Petitioner originally contended that the challenged claims are unpatentable under 35 U.S.C. § 103 based on the following grounds (Pet. 25–82):

Claims challenged	35 U.S.C. §	References
7, 9–16, 21, 22	103	Solazzo ² , Serany ³
8	103	Solazzo, Serany, Boedecker ⁴
7, 9, 11–16, 22	103	Solazzo, Disston ⁵
8	103	Solazzo, Disston, Boedecker
10, 21	103	Solazzo, Disston, Serany

After we instituted this review, Patent Owner filed a Patent Owner Response in opposition to the Petition. Paper 32 (“PO Resp.”). Petitioner

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. 3,965,900 (Ex. 1034, “Boedecker”).

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

filed a Reply in support of the Petition. Paper 43 (“Reply”). Patent Owner filed a Sur-reply. Paper 49 (“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 52, 53. Patent Owner did not move to amend any claim of the ’596 patent.

We heard oral argument on March 5, 2020, a transcript of which appears in the record (Paper 57, “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 7–16, 21, and 22 were unpatentable. Paper 58, 5–35. Our Decision was based upon our determinations that Petitioner had failed to demonstrate that the prior art described or suggested all limitations of each independent claim. *Id.* at 12–20, 28–35. We also found that Petitioner had failed to demonstrate that the prior art described or suggested the limitations introduced in claim 9. *Id.* at 20–25. We also found that Petitioner had failed to demonstrate that the prior art described or suggested the limitations introduced in claim 11. *Id.* at 25–28. We did not weigh the objective evidence of nonobviousness adduced by Patent Owner. *See generally, id.* in its entirety.

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 claim 7. *Id.* at *7–8. More specifically, the Federal Circuit vacated our Decision that claims 7, 8, and 11–13 of the ’596 patent were not

unpatentable. *Id.* at *9. However, the Federal Circuit affirmed our conclusion that Petitioner had failed to demonstrate that claims 9, 10, 14–16, 21, and 22 were unpatentable. Op. *8–9. 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 IPR2019-00208,⁶ 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 on remand, 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.

C. REMAND BACKGROUND

The challenges to claims 7, 8, and 11–13, which remain at issue on remand are shown in the table below.

Claims challenged	35 U.S.C. §	References
7, 11–13	103	Solazzo, Serany
8	103	Solazzo, Serany, Boedecker
7, 11–13	103	Solazzo, Disston
8	103	Solazzo, Disston, Boedecker

⁶ IPR2019-00208 involves U.S. Patent No. 9,808,400 B2, which is owned by Patent Owner, “share[s] similar disclosures with” the ’596 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.

On remand, we authorized the parties to concurrently file an opening brief on the merits and concurrently file a responsive reply brief. Paper 68, 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 the issues on remand based on the record that was submitted during the original trial.

Petitioner filed an opening brief (Paper 72, “Pet. Remand Br.”). Patent Owner filed an opening brief (Paper 74, “PO Remand Br.”). Petitioner filed a Reply responding to Patent Owner’s opening brief (Paper 80, “Pet. Remand Reply”). Patent Owner filed a Reply responding to the Remand Reply (Paper 77, “PO Remand Reply”).

Patent Owner, but not Petitioner, requested an oral hearing, and we denied Patent Owner’s request. Paper 81. 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 all challenged claims remaining on remand are unpatentable as obvious.

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. 93; Paper 3, 2. The parties collectively also identify as related matters petitions for *inter partes* review of claims of: U.S. Patent No. 9,745,088 B2 (IPR2019-00035 and IPR2019-00036); U.S. Patent No. 9,795,761 B2 (IPR2019-00109); and U.S. Patent No. 9,808,400 B2 (IPR2019-00208). Pet. 93–94; Paper 3, 2–3. Patent Owner further identifies as a related matter U.S. Patent Application No.

15/804,520, which is a continuation-in-part of the application that issued as the '400 patent. Paper 3, 2. Patent Owner further identifies U.S. Patent Application Nos. 15/703,514; 14/265,920; 15/684,787; 15/803,383; 13/374,509; 15/640,224; and 15/051,964 as related matters because these applications “share similar disclosures and claim language” with the '596 patent. *Id.* Patent Owner further identified U.S. Patent Application No. 16/986,803 as a “continuation application” claiming priority to the '596 patent and U.S. Patent Application Nos. 16/258,231; 16/688,185; 16/833,575; 16/944,667; 17/180,680; 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 '596 patent. Paper 66, 2–3.

E. THE '596 PATENT

The '596 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, 1:32–35. The Specification describes tray 100 shown in Petitioner’s annotated and colorized version of Figure 7, which we reproduce below.

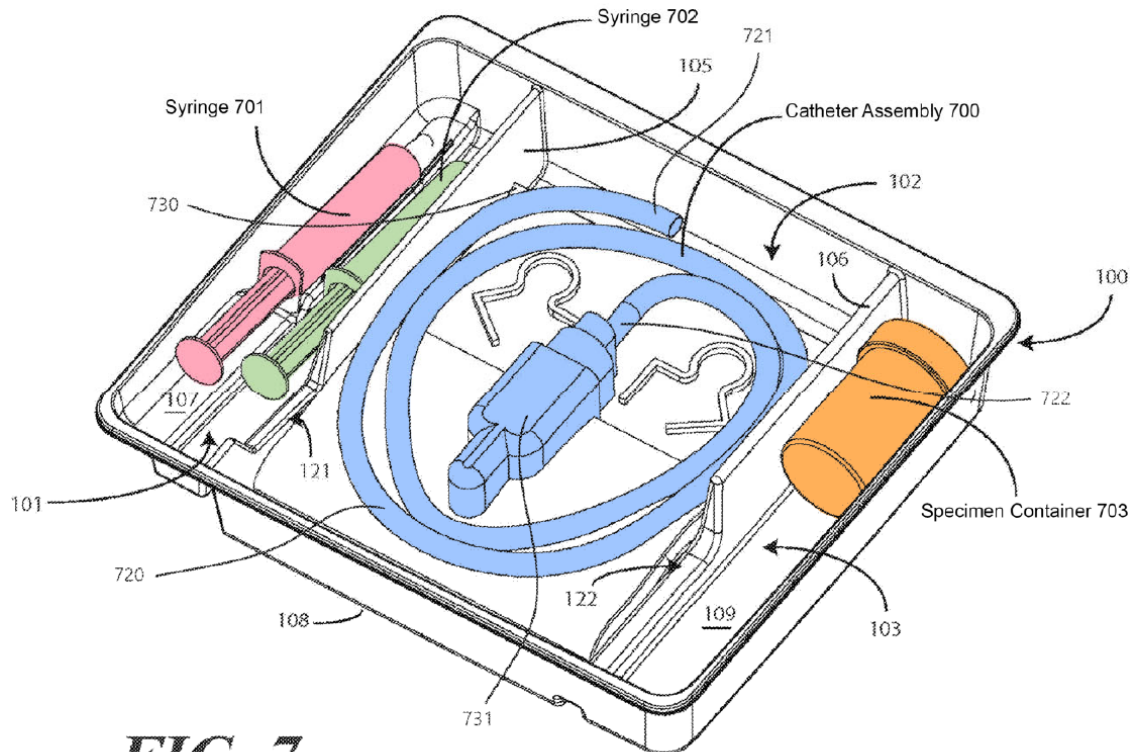


FIG. 7

Figure 7 illustrates a catheter, two syringes, and a specimen bottle located within single-level tray 100. *Id.* at 10:53–55.

Before use, tray 100 is optionally 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 11:49–59, Fig. 10. Tray 100 includes three compartments 101, 102, 103 adapted to accept various items used in a catheterization procedure. *Id.* at 8:48–54. First compartment 101 accommodates syringes 701, 702 (red, green) containing sterile water or lubricants. *Id.* at 8:50–52. Second compartment 102 accommodates catheter assembly 700 (blue) comprising indwelling (or Foley) catheter coupled to fluid bag 730 by tube 720. *Id.* at 8:52–54. First end portion 721 of tube 720 is coupled to the indwelling catheter and second end portion 722 of tube 720 is coupled to fluid bag 730 via anti-reflux device 731. *Id.* at 8:56–59. Third compartment 103

accommodates specimen container 703 for capturing samples taken from the patient via catheter 700. *Id.* at 8:59–61. Additional objects can be included with the tray, including one or more towels, a drape to cover the patient, rubber gloves, hand sanitizing materials, printed instructions, and so forth. *Id.* at 5:10–15.

Claim 7 is the only independent claim among the challenged claims that we address on remand. *Id.* at 18:30–19:9. The text of claim 7 is reproduced below in Part VI.A below.

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);⁷ *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

⁷ 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).

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 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. We discern no reason to expressly address the meaning of any claim term to resolve the dispute between the parties. Accordingly, 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 remaining on remand 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. 18–19 (citing Ex. 1002 ¶ 14); PO Resp. 13 (citing Ex. 2040 ¶ 37). 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); PO Resp. 13 (citing Ex. 2040 ¶ 37). 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. 18–19; PO Resp. 14 (citing Ex. 2041 ¶ 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. 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.

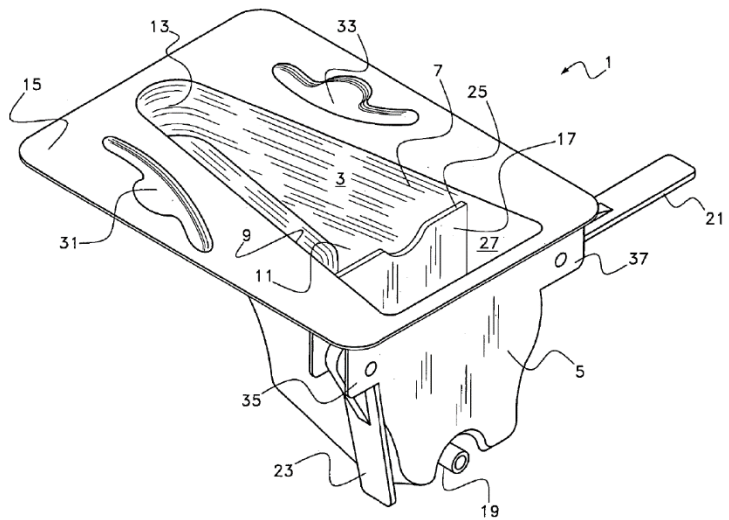


Fig. 1

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.*

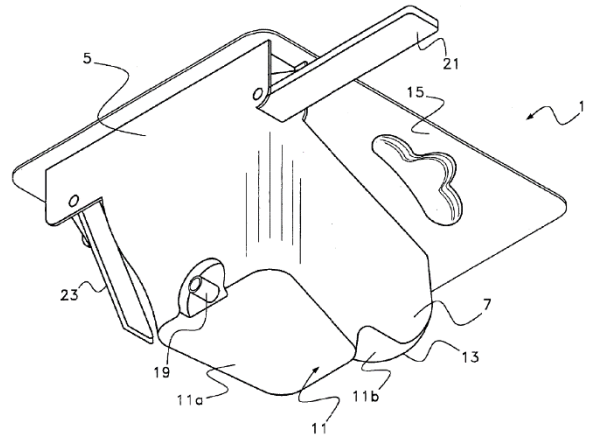


Fig. 2

at 3:61–66, Fig. 5. 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.

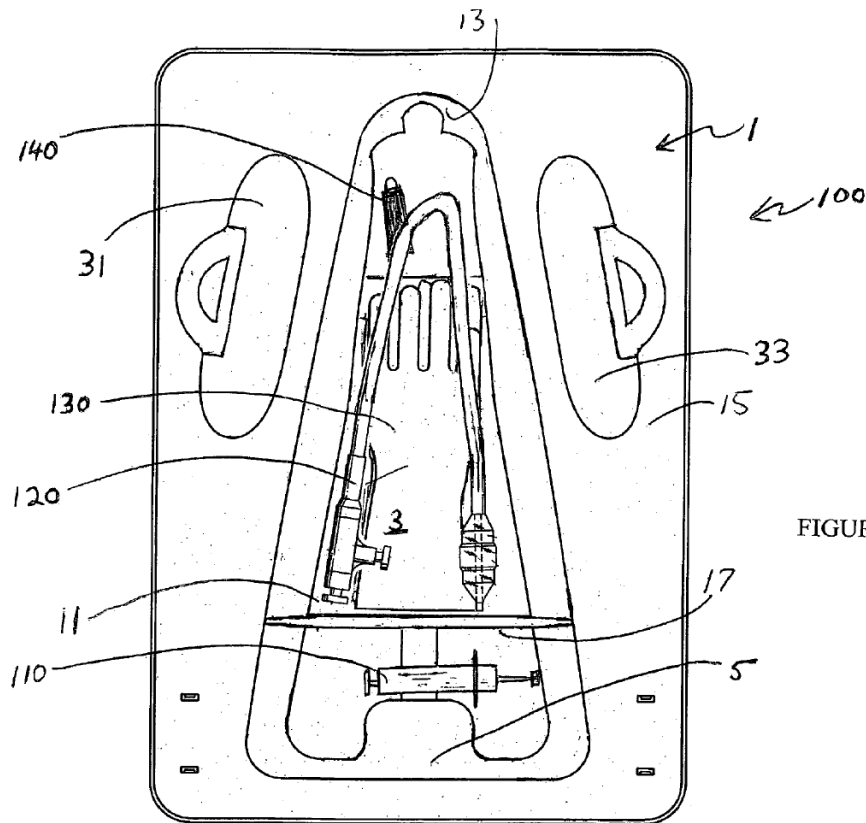


FIGURE 8

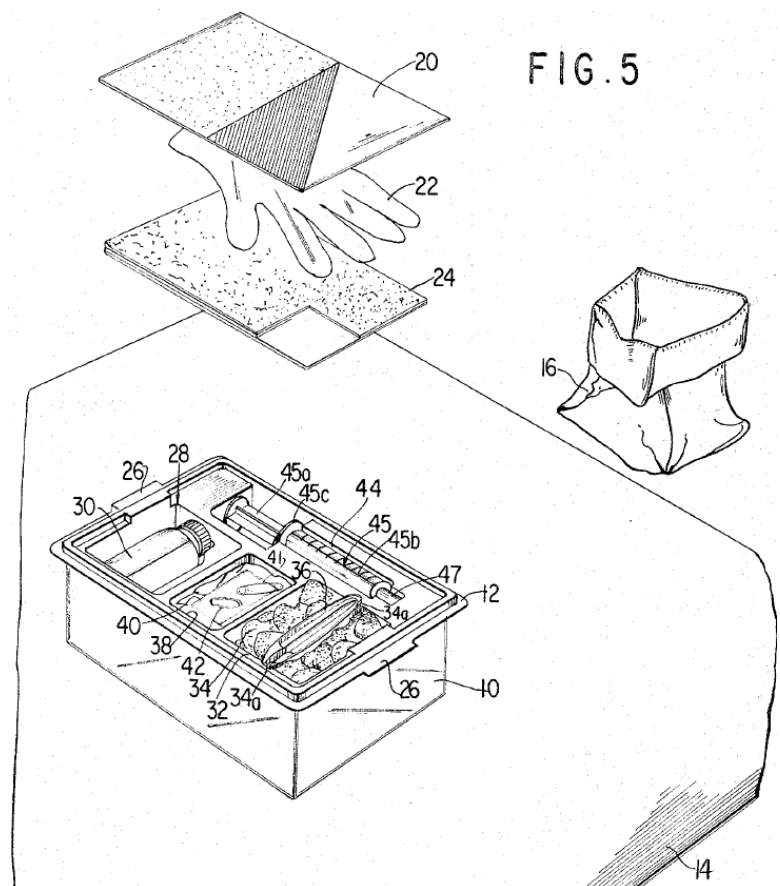
Solazzo’s Figure 8 is a top view of kit 100 illustrating various components stored in compartments of tray 1. *Id.* at 4:41–48.

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

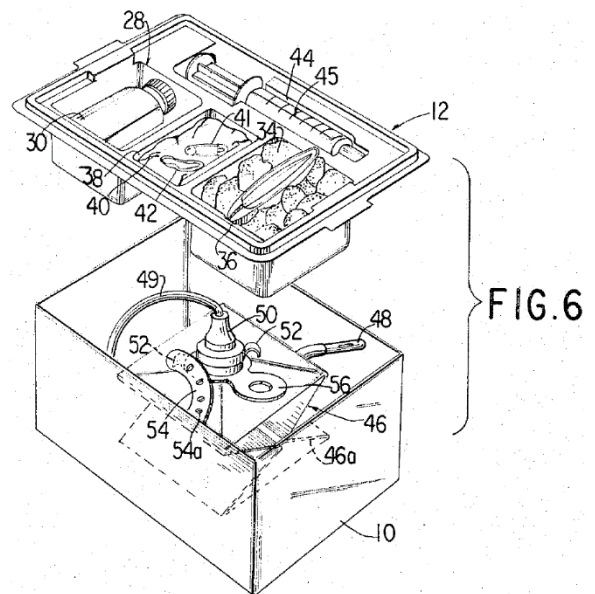
Serany is directed to a double-wrapped, sterile package providing catheterization components ready for use in the order needed. Ex. 1006, 1:8–16, 1:60–63, 3:63–4:2; Figs. 1–3, 5. Serany’s Figure 5 (reproduced at right in pertinent part) is an exploded view illustrating how various compartments are positioned 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.



C. DISSTON

Disston is directed to a double-wrapped catheterization tray package that “provide[s] for the first time a complete, properly organized, conveniently arranged, sterile set of equipment for catheterization, the entire drainage system being pre-assembled.” Ex. 1008, 1:59–67, 2:60–63, Figs. 2–3. The single-level tray 2 contains catheterization devices “arranged in such order and position as to be most conveniently available when the container is opened.” *Id.* at 2:15–23. The tray is slidably received in an open-ended sleeve 1 having a flap 3 folded downwardly over an edge of the tray, and further wrapped in a plastic outer envelope. *Id.* at 1:59–67, 2:23–26, Figs. 2–3.

When opened, the tray presents contents including gloves, cleansing solution, protective pad or sheet, lubricant, sterile water packet, syringe, “and most importantly, a pre-assembled catheter-drainage tube-drip chamber-drainage bag and hanger, assembly, sterile and ready for use immediately.” *Id.* at 1:26–35, 2:41–52, Fig. 1. This assembly “not only saves time and trouble but practically eliminates the danger of faulty connections and loss of sterility, inherent in the former system.” *Id.* at 1:42–46.

VI. CLAIMS 7, 8 AND 11–13

A. INDEPENDENT CLAIM 7 AND DEPENDENT CLAIMS 11 AND 12

7. A catheterization kit comprising:

- [a] a single level container defining a first compartment bounded by a first compartment base member and at least a first portion of a perimeter wall, the single level container defining a second compartment bounded, at least in part, by a second compartment base member and at least a second portion of the perimeter wall;

[b] a first syringe disposed within the first compartment of the single level container, the first syringe containing an inflation fluid;

[c][i] a second syringe disposed within the first compartment of the single level container,

[ii] the second syringe containing a lubricating jelly; and

[d][i] a coiled medical device disposed within the second compartment of the single level container, the coiled medical device including a Foley catheter, a fluid receptacle, and a tube coupling the Foley catheter to the fluid receptacle,

[ii] the Foley catheter and the fluid receptacle positioned within the second compartment such that the fluid receptacle is between the second compartment base member and the Foley catheter.

Id. at 18:30–51 (with added letter designations a–d 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 a tray with two syringes in one compartment and the medical assembly in a different compartment as collectively required of limitations 7a, 7b, 7c, and 7d.i. Dec. 12–16. We drew the same conclusion in connection with Petitioner’s challenge based on Solazzo and Disston. *Id.* at 31–32. We also found both combinations of prior art to fail to describe or suggest the remaining limitation 7d.ii. *See id.* at 17–20 (analyzing Solazzo and Serany), 32–34 (analyzing Solazzo and Disston).

The Federal Circuit focused its analysis on limitation 7d.ii and found: “That Serany does not ‘expressly’ describe a fluid receptacle in the claimed

arrangement does not defeat [Petitioner's] argument on obviousness.”

Op. *7. Later, the Federal Circuit found:

We therefore disagree with the Board's determination that the prior art did not teach the limitation of storing a fluid receptacle between the compartment bottom and the catheter, as recited in claims 7–8 and 11–13 of the '596 patent. These claims also recite two syringes in one compartment and claims 11–12 further recite two syringes positioned at different heights. For the reasons explained above, we also disagree with the Board's determination that the prior art did not teach those limitations.

Id. at *9. Claims 8 and 13 introduce limitations that the Federal Circuit did not expressly address. However, the Federal Circuit further concluded that: “we vacate the portion of the Board's decision concluding that claims 7–8 and 11–13, all of which are resolved by the above treatment of claim 7, are not unpatentable as obvious.” *Id.* Therefore, we understand the Federal Circuit to have found in Petitioner's favor that the prior art teaches all limitations recited in at least claims 7, 11, and 12 and likely also all limitations recited in claims 8 and 13. Regardless, however, the Federal Circuit has instructed us to consider and weigh Patent Owner's objective evidence of nonobviousness on remand. *Id.* at *10.

1. Objective Evidence of Nonobviousness

For the reasons expressed *infra* in Part VII, 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 claims 7, 11, and 12.

2. 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 either Solazzo

and Serany or Solazzo and Disston render claims 7, 11, and 12 unpatentable as obvious.

B. DEPENDENT CLAIM 8

Claim 8 depends from claim 7 and further recites: “wherein the tube is attached to the fluid receptacle via an anti-reflux device.” Ex. 1001, 18:52–53. Petitioner argues that the combined teachings of either Solazzo, Serany, and Boedecker or Solazzo, Disston, and Boedecker render claim 8 unpatentable as obvious. Pet. 65–70 (Solazzo, Serany, Boedecker), 87–90 (Solazzo, Disston, Boedecker). Petitioner relies upon Boedecker’s “anti-reflux device for a collection bag” that connects to “drainage tube 22” as meeting the limitations introduced in claim 8 for both combinations of prior art. *Id.* at 68–69 (citing Ex. 1034, 1:19–35, 1:45–47, 2:48–52, Fig. 1; Ex. 1002 ¶¶ 180–182, 287), 88–89 (citing Ex. 1034, 1:7–9, 2:49–60, 2:63–3:3, 3:20–30, Fig. 1; Ex. 1002 ¶¶ 387, 390).

Petitioner argues that it would have been obvious to replace Serany’s flexible drainage receptacle 46 with Boedecker’s liquid connection bag 24 such that Serany’s drainage tubing 49 would be connected to Boedecker’s connector 26 of its bag 24. *Id.* at 69–70 (citing Ex. 1034, 1:13–17, 1:19–35, 2:48–52; Ex. 1002 ¶¶ 289–292). Petitioner argues that an ordinarily skilled artisan would have been motivated to do so to prevent reflux of urine from Serany’s drainage receptacle into the patient’s bladder. *Id.* at 70 (citing Ex. 1002 ¶ 291). Petitioner also argues that substituting Boedecker’s anti-reflux device into a catheter kit would have merely involved making a simple substitution of one container for another known container to produce predictable results. *Id.* (citing Ex. 1002 ¶ 291). Petitioner makes similar arguments in connection with the combination of Solazzo, Disston, and

Boedecker and claim 8. *Id.* at 87–90 (citing Ex. 1008, 1:35–46, Fig. 1; Ex. 1034, 1:7–9, 1:19–35, 2:49–60, 2:63–3:3, 3:20–30, Fig. 1; Ex. 1002 ¶¶ 387, 390, 394–398).

Patent Owner does not respond to Petitioner’s showing for claim 8. *See generally* PO Resp. (not addressing claim 8 or discussing Boedecker).

For the reasons expressed *infra* in Part VII, 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 8. 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 either Solazzo, Serany, and Boedecker or Solazzo, Disston, and Boedecker render claim 8 unpatentable as obvious.

C. DEPENDENT CLAIM 13

Claim 13 depends from claim 7 and further recites: “wherein a length of the first compartment extends along a side length of the single level container.” Ex. 1001, 19:7–9. Petitioner contends that the combined teachings of Solazzo and Serany render claim 13 unpatentable as obvious. Pet. 58. Petitioner identifies Solazzo’s opposing sidewalls 7 and 9 of compartment 27 as meeting the limitations introduced in claim 13. *Id.* (citing Ex. 1005, 3:56–61, Figs. 2, 5; Ex. 1002 ¶¶ 245–249). Petitioner relies upon the same showing in connection with the challenge based on Solazzo and Disston. *Id.* at 84.

Patent Owner does not separately respond to Petitioner’s showing for claim 13 as distinct from its arguments relating to independent claim 7. *See generally* PO Resp. (not separately addressing claim 13).

For the reasons expressed *infra* in Part VII, 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 13. 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 either Solazzo and Serany or Solazzo and Disston render claim 13 unpatentable as obvious.

VII. 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. 20–27. 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 remaining on remand materially differ from those at issue in IPR2019-00208. *Compare* Ex. 1001, 18:30–19:9, *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 syringes be arranged in the tray according to their order of use); (2) the claimed critical feature is taught by the prior art (a single layer tray); or (3) Patent Owner’s showing is outweighed by the strong prima facie case of obviousness. Pet. Remand Br. 4–10, 19–23. 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 6 (citing Reply 23 (citing Ex. 2041 ¶ 125; Ex. 2040 ¶ 208; Ex. 2042 ¶¶ 8, 23)); *see also* Tr. 84:10–17 (Judge Goodson: “the specific combination that you’re relying on to establish nexus is a single-level tray with syringes arranged according to their order of use” . . .

Mr. Hoover: “I think that’s basically right.”). 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 Claim 7 and Dependent Claims 8 and 13

Petitioner correctly points out that claim 7 fails to recite the second feature alleged to demonstrate nexus, syringes arranged according to their order of use. Pet. Remand Br. 4; *see also* Ex. 1001, 18:30–51. Claims 11 and 12, which we discuss below, introduce this feature. Dependent claims 8 and 13 also fail to recite this feature. Ex. 1001, 18:52–53 (claim 8), 19:7–9 (claim 13). The first feature, the tray being a single layer, is required in claim 7 and thus all challenged claims on remand. Ex. 1001, 18:31.

However, the claimed feature, a single layer tray, was well known in the prior art, for example, as shown by Solazzo. Ex. 1005, Figs. 1, 8. Patent Owner cannot establish nexus by linking objective evidence of non-obviousness to “prior art features in isolation or unclaimed features.” *Fox Factory*, 944 F.3 at 1378. For these reasons, we find that Patent Owner has not proven that a presumption of nexus exists for independent claim 7 or dependent claims 8 and 13.

2. Dependent Claims 11 and 12

Claim 11 depends from claim 7 and further recites: “wherein the first syringe and the second syringe are positioned at different elevations within the first compartment, the different elevations being associated with an order of use of the first syringe and the second syringe during a catheterization procedure.” Ex. 1001, 18:65–19:3. Claim 12 depends from claim 11 and further recites: “wherein the first syringe is positioned within the first compartment at a higher elevation than the second syringe.” *Id.* at 19:4–6. Therefore, claims 11 and 12 are 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 11 and 12 are entitled to a presumption of nexus for three reasons. Pet. Remand Br. 7–10.

First, Petitioner argues that Patent Owner failed to meet its burden of proof because it relied on claim charts comparing other claims, namely claims 7 and 8, to Petitioner’s and Patent Owner’s products. *Id.* at 7–8 (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 11 and 12 of placing the syringes at different heights in one compartment of the tray. *Id.*

Petitioner is correct that Patent Owner did not compare any single claim of the '596 patent that recites the combination of both of its allegedly critical features to any product of its own or Petitioner's. *See* Ex. 2040 ¶¶152–168 (comparing four of Petitioner's trays and one of Patent Owner's trays to claims 7 and 8, 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 11 and 12.

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.* 8–9. 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*. 2 (citing *Lectrosonics Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 33 (PTAB Jan. 24, 2020) (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 2–3 (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.* 9–10 (citing

Reply 24 (citing Ex. 1002 ¶¶ 101–106, 195–200; Ex. 1071 ¶¶ 40–46);
Reply 24 (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 does not respond to Petitioner’s argument.

When specifically addressing all challenged claims remaining on
remand, the Federal Circuit stated:

We therefore disagree with the Board’s determination that
the prior art did not teach the limitation of storing a fluid
receptacle between the compartment bottom and the catheter, as
recited in claims 7–8 and 11–13 of the ’596 patent. These claims
also recite two syringes in one compartment and claims 11–12
further recite two syringes positioned at different heights. For
the reasons explained above, we also disagree with the Board’s
determination that the prior art did not teach those limitations.

Id. at *9.

We find that Patent Owner fails to prove that it is entitled to a
presumption of nexus because Solazzo alone 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. 57–61. The argument rests largely upon testimony from Ms. Chiappetta. *Id.* (citing Ex. 2041 ¶¶ 73, 85–91, 93–97, 105–124, 126–136, 196–207). Ms. Chiappetta testifies that the single layer tray “reduced the likelihood of accidental contamination” to reduce the incidence of CAUTI. Ex. 2041 ¶ 127. 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 23–26. 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. 2041 ¶ 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 28–29. 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 29 (citing Ex. 1122, 5; Ex. 1073, 218:7–14; Ex. 1071 ¶¶ 60–72⁸). 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.”

⁸ It is apparent from the context and our review of the record that Petitioner mistakenly cited Exhibit 1070 rather than Exhibit 1071.

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.

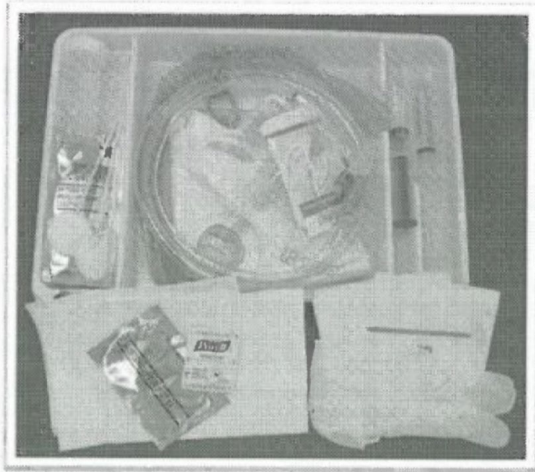
Wyers v. Master Lock Co., 616 F.3d 1231, 1246 (Fed. Cir. 2010) (quoting *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004)) (other citations omitted).

Petitioner and Patent Owner focus on dramatically different facts when addressing whether Petitioner copied Patent Owner’s ERASE CAUTI 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. 15 (citing Ex. 2042 ¶ 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). PO Remand Br. 15. 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

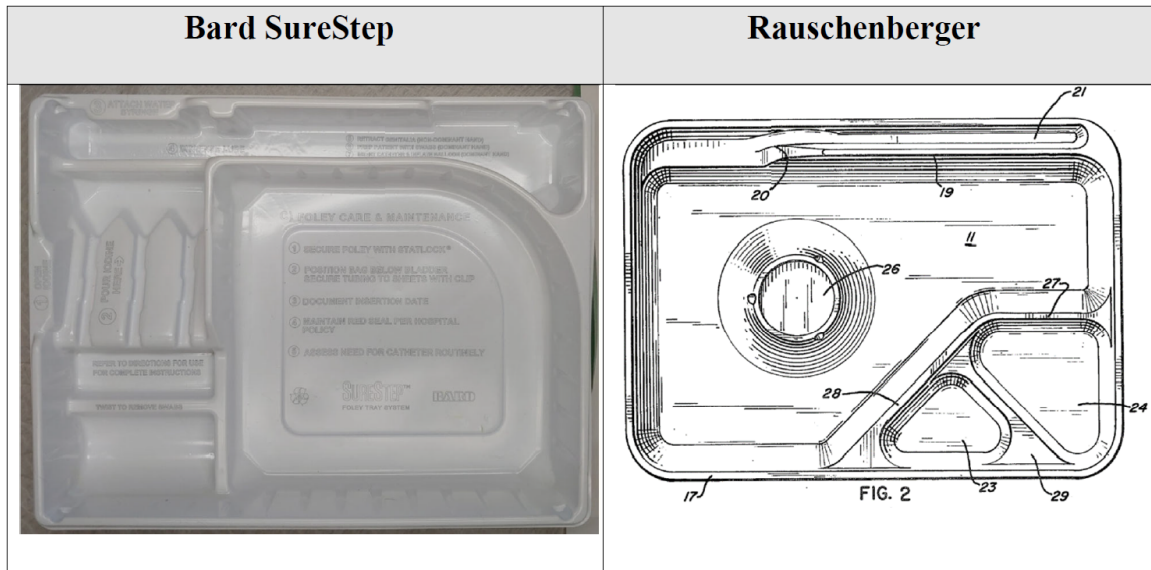
Petitioner's witness in related litigation admitted that the prototype and ERASE CAUTI trays had “essentially the same layout.” Ex. 2068, 259:11–261:15; Ex. 1082, 4. But, Petitioner persuasively demonstrates that it never sold the prototype tray. Reply 36 (citing Ex. 1070 ¶¶ 40–45).

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 bear numbered steps printed on the tray rather than being designed to be used in a “left-to-right configuration” as like Patent Owner’s ERASE CAUTI tray. Pet. Remand Br. 15 (citing Reply 36–37 (citing Ex. 1073, 251:2–13)). The printed steps on the SureStep tray advise the user to move from bottom-to-top, left-to-right, and right-to-left. *Id.* (citing Ex. 1070 ¶¶ 48–49).

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 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. 2041 ¶¶ 98–104. Petitioner responds that the design contest succeeded because important ideas were generated that ultimately were incorporated into the SureStep product. Pet. Remand Br. 16 (citing Reply 37); Reply 37 (citing Ex. 1070 ¶¶ 57–60; Ex. 2066, 1, 9; Ex. 2065, 89:24–90:12, 98:3–20). Patent Owner, by recognizing that Petitioner did not expend great effort, 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. 6. 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. 2042. 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. 2042. 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. 2042, p. 65 (Tab 3); Ex. 1072, p. 98⁹ (Schedule 5.0). Based on our close examination of this data, we find that both witnesses materially agree on the numbers of

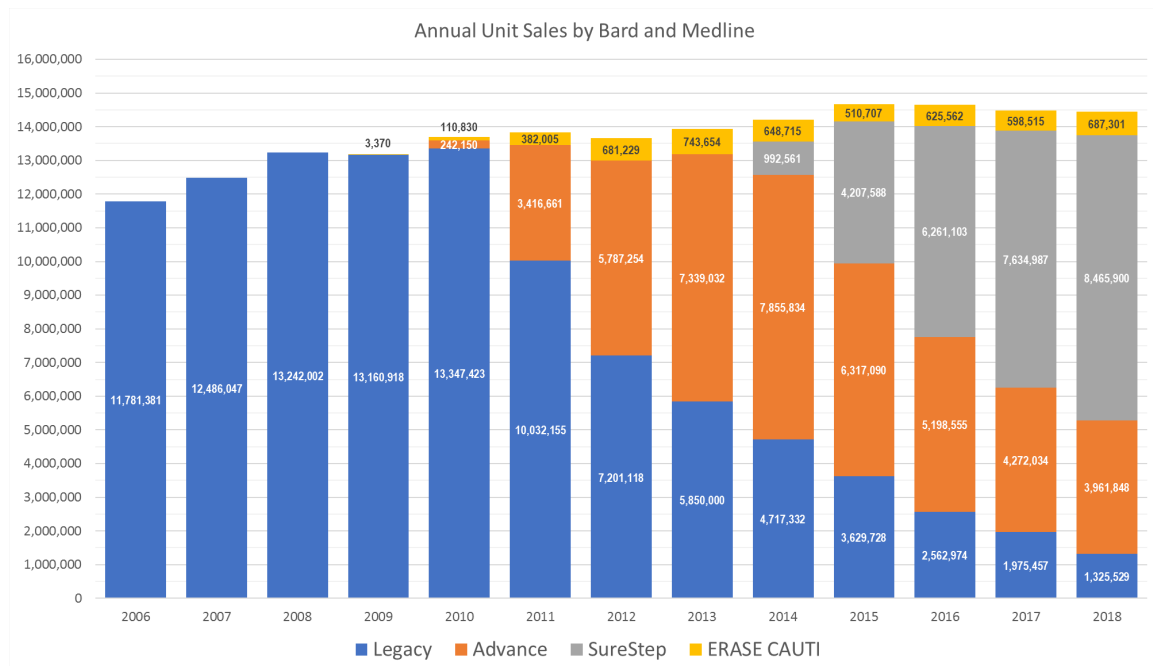
⁹ Dr. Sheridan’s report does not include page numbers, but, when necessary, we refer to the page number as revealed in the electronic version of the report. When available and helpful, we also refer to Dr. Sheridan’s own labels for the various schedules in his report (e.g., Schedule 5.0).

units sold and revenues for all but Petitioner's "Legacy" products. *Compare* Ex. 2042, p. 65 (Dr. Rao's data), *with* Ex. 1072, p. 98 (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. 2042, p. 65 (Dr. Rao's data), *with* Ex. 1072, p. 98 (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 ¶ 93 (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. 2042, 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 2018.¹⁰

¹⁰ 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 40 (citing Ex. 1072 ¶ 95). 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 ¶ 82; Ex. 3003. Even with this fast growth, ERASE CAUTI sales did not meet Patent Owner’s expectations. Ex. 1072 ¶ 83 (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.

Our inference that the importance of the quality of items in a kit as a driver of sales is further supported 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 ¶ 83; 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 ¶ 85. 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 ¶ 86, 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 41 (citing Ex. 1071 ¶¶ 116–126; Ex. 1072 ¶ 78). 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.* (citing Ex. 1072 ¶¶ 102, 109).

Patent Owner contends that Petitioner sold SureStep for an average of \$1.10 more than Advance. PO Resp. 71 (citing Ex. 2042 ¶¶ 46–49); Ex. 2042 ¶ 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. 2042 ¶ 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. 2042 ¶ 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. 2042 ¶¶ 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 40 (citing PO Resp. 59). Petitioner also responds that Patent Owner sold Petitioner's Advance kits at a higher average price than ERASE CAUTI kits. *Id.* at 40–41 (citing Ex. 1072 ¶ 103). 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 ¶¶ 108–111). 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.

VIII. CONCLUSION

For all the reasons expressed above, Petitioner has demonstrated by a preponderance of the evidence that claims 7, 8, 11–13 are unpatentable as obvious.

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
7, 11–13	103	Solazzo, Serany	7, 11–13	
8	103	Solazzo, Serany, Boedecker	8	
7, 11–13	103	Solazzo, Disston	7, 11–13	
8	103	Solazzo, Disston, Boedecker	8	
Overall Outcome			7, 8, 11–13	

IX. ORDER

For the reasons given, it is:

ORDERED that Petitioner has demonstrated by a preponderance of evidence that claims 7, 8, and 11–13 of U.S. Patent No. 9,808,596 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.

IPR2019-00223
Patent 9,808,596 B2

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