

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C.R. BARD, INC.,
Petitioner,

v.

MEDLINE INDUSTRIES, INC.,
Patent Owner.

Case IPR2019-00036
Patent 9,745,088 B2

Before JOSIAH C. COCKS, MITCHELL G. WEATHERLY, and
TIMOTHY J. GOODSON, *Administrative Patent Judges*.

WEATHERLY, *Administrative Patent Judge*.

DECISION

Instituting *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. §§ 42.4, 42.108

I. INTRODUCTION

A. BACKGROUND

C.R. Bard, Inc. (“Petitioner”) filed a petition (Paper 2, “Pet.”) to institute an *inter partes* review of claims 45–58, 60–74, 76–90, and 92 (the “challenged claims”) of U.S. Patent No. 9,745,088 B2 (Ex. 1001, “the ’088 patent”). 35 U.S.C. § 311. Medline Industries, Inc. (“Patent Owner”)

timely filed a Preliminary Response. Paper 11 (“Prelim. Resp.”). Institution of an *inter partes* review is authorized by statute when “the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a); 37 C.F.R. § 42.108. Based on our review of the record, we conclude that Petitioner is reasonably likely to prevail with respect to at least one of the challenged claims.

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. § 103 based on the following grounds (Pet. 25–79):

References	Basis	Claims challenged
U.S. Patent No. 7,278,987 B2 (Ex. 1005, “Solazzo”) U.S. Patent No. 3,329,261 (Ex. 1006, “Serany”), and U.S. Patent No. 3,166,189 (Ex. 1008, “Disston”)	§ 103	45–48, 50–51, 55–58, 60–64, 66–67, 71–74, 76–80, 82–83, 87–90, and 92
Solazzo, Serany, Disston, and U.S. Patent No. 5,931,303 (Ex. 1009, “Salvadori”)	§ 103	49, 54, 65, 70, 81, and 86
Solazzo, Serany, Disston, and U.S. Patent No. 6,840,379 B2 (Ex. 1007, “Franks-Farah”)	§ 103	52–53, 68–69, 84, and 85
Solazzo, Serany, Disston, and U.S. Patent Publication No. 2008/0249476 A1 (Ex. 1020, “Bierman”)	§ 103	55, 71, and 87

Generally, Patent Owner contends that the Petition should be denied in its entirety. For the reasons described below, we institute an *inter partes* review of all challenged claims on all grounds.

B. 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.) (“*Medline III* Litigation”). Pet. 82; Paper 4, 2. The parties also identify a petition for *inter partes* review of claims 1, 2, 6–10, 16–19, and 25–44 of the ’088 patent (IPR2019-00035) as a related matter. Pet. 82; 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.* at 2–3.

C. 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, which we reproduce below.

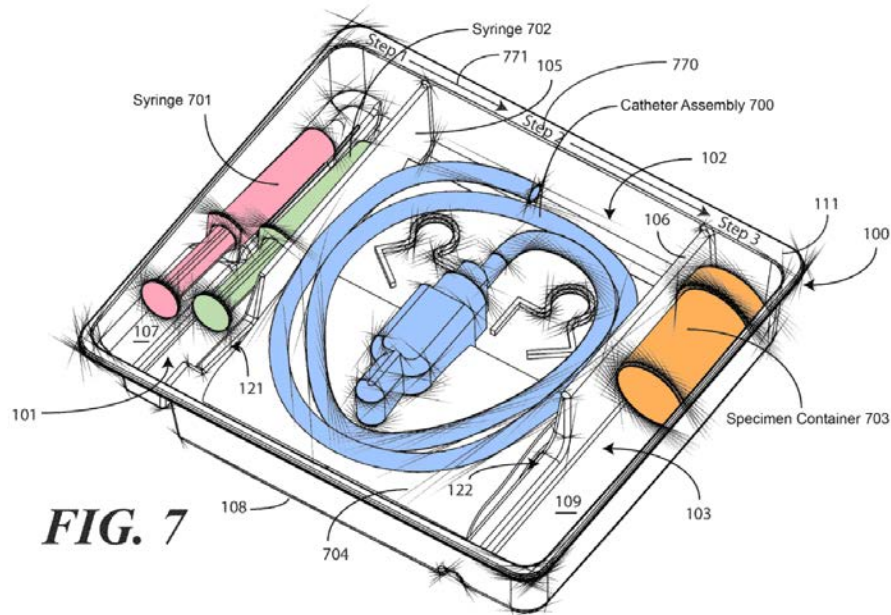


Figure 7 illustrates a catheter, two syringes, and a specimen bottle located within single-level tray 100. *Id.* at 2:45–49.

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 accept 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 fluid bag. *Id.* at 9:26–28. Third compartment 103 accommodates specimen container 703 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 45, 61, and 77 are the independent claims among the challenged claims. *Id.* at 30:58–32:49. Claim 45, which is illustrative, recites:

45. A medical procedure kit, comprising:
- [a] a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly;
 - [b] a first syringe and a second syringe disposed within the first compartment;
 - [c] the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter;
 - [d] at least one layer of wrap material enclosing the single layer tray within one or more folds of the at least one layer of wrap material; and
 - [e] an outer packaging disposed about both the single layer tray and the at least one layer of wrap material.

Id. at 30:58–31:5 (with added letter designations a–e to ease discussion).

II. PRELIMINARY MATTERS

As a preliminary matter, Patent Owner argues that we should exercise discretion under either 35 U.S.C. § 314(a) or § 325(d) and deny the Petition. For the reasons expressed below, we decline to deny the Petition as an exercise of discretion under either statute.

A. DISCRETIONARY DENIAL UNDER § 325(D)

Patent Owner argues that “the Board has more than good cause” to deny the Petition in its discretion under § 325(d) because the Petition “is yet another of the repeated administrative attacks on Medline’s patent portfolio . . . that includes the ’088 Patent (‘Medline Portfolio’).” Prelim. Resp. 2. Patent Owner admits that the Medline Portfolio is “complex.” *Id.* at 8.

Nevertheless, Patent Owner contends that “Solazzo adds nothing new that has not already been considered by the Office.” *Id.* at 3. Patent Owner argues at length why its analysis of the six factors set forth in *Becton Dickinson & Co. v. B. Braun Melsungen AG*, Case IPR2017-01586, slip op. 17–18 (PTAB Dec. 15, 2017) (Paper 8) (informative) weighs in favor of discretionarily denying the Petition under § 325(d). Prelim. Resp. 4–21.

Patent Owner’s argument is weakened substantially by its failure to address whether the Office has meaningfully evaluated Solazzo against a claim that is substantively the same as a claim challenged in this proceeding. For example, when discussing *Becton* factor 1, Patent Owner notes that the Examiner described a version of Solazzo¹ as the “closest” prior art in the Notice of Allowance for U.S. Patent No. 9,795,761, the claims of which include a limitation to a “patient aid” that is not recited in any claim of the ’088 patent. *Id.* at 8 (citing Ex. 1019).

Factor 1 relates to “similarities and material differences between the asserted art and the prior art involved *during examination.*” *Becton*, slip op. at 17 (emphasis added). This factor relates to a comparison of Solazzo (the asserted art) to prior art applied *during examination* of the claims of the ’088 patent. The factor does not relate to how Solazzo was considered by the Examiner during examination of the claims of the ’761 patent, which Patent Owner admits differ from the claims of the ’088 patent. The Examiner of the ’761 patent simply did not apply Solazzo against the claims

¹ The version of Solazzo considered by the Examiner is the published patent application (Ex. 1018) rather than the patent that issued from that application (Ex. 1005).

of the '088 patent. Patent Owner's argument based on these facts does not support a discretionary denial of the Petition in this proceeding.

Patent Owner's discussion of similarities between Solazzo and Rauschenberger (Ex. 1013), Misra (Ex. 2006), and Busch (Ex. 2007) while addressing *Becton* factor 1 suffers from a similar logical flaw. Prelim. Resp. 9–14. The Office considered those three prior art references against claims that differed from the challenged claims of the '088 patent. *See id.* (describing Office's analysis of Rauschenberger, Misra, and Busch against claims of U.S. Patent Nos. 8,631,935 (Ex. 2003); 9,283,352 (Ex. 2004); or 9,522,753 (Ex. 2005) without sufficiently analyzing any differences among claims in those patents and the challenged claims). Patent Owner's analysis of *Becton* factors 2–6 is similarly weakened by Patent Owner's failure to demonstrate that the Office considered Solazzo (or a materially similar prior art reference) when determining whether the claims of the '088 patent were patentable. Prelim. Resp. 15–21 (analyzing the Office's review of prior art as it related to “other patents in the Medline Portfolio” including U.S. Patent Nos. 9,522,753; 9,795,761; 8,631,935; 9,283,352; 8,448,786; and 8,678,190).

We also determine that *Becton* factor 3 weighs against exercising discretion to deny the Petition. Under *Becton* factor 3, we consider “the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection.” *Becton*, slip op. 17. Patent Owner submitted an information disclosure statement (“IDS”) during examination of the '088 patent that identified Solazzo as one of about 375 prior art references. Pet. 80; *see also* Ex. 1004, 151–71 (listing Solazzo among prior art references in an IDS spanning 21 pages). Patent Owner's

argument relating to *Becton* factor 3, Prelim. Resp. 16–18, is unpersuasive because it fails to recognize that, although Solazzo was before the Examiner during examination of the '088 patent, the Examiner did not discuss or apply Solazzo as a basis for rejection when examining the claims of the '088 patent.

Based on our review of the parties' arguments, we are not persuaded that exercising discretion under § 325(d) to deny the Petition is warranted. Accordingly, we decline to do so.

B. DISCRETIONARY DENIAL UNDER § 314(A)

Patent Owner argues that “the Board should further exercise its discretion to deny instituting *inter partes* review because Petitioner failed to address evidence of *known* secondary considerations produced during the concurrent district court litigations involving the '088 patent and other related patents with common claim limitations.” Prelim. Resp. 21. Patent Owner informs us that:

[O]n October 1, 2018, in *Medline III*, PO produced and served upon Petitioner Bard (1) a response to its interrogatories addressing secondary considerations for the '088 patent (e.g., industry praise, long-felt need and copying), and (2) thousands of pages of documents, including deposition testimony and exhibits, which evidence secondary considerations for the '088 patent.

Id. at 21–22 (citing Ex. 2012, 9–14). The cited Exhibit is the responses to interrogatories that Patent Owner served in the *Medline III* Litigation three days before the Petition was filed. The version of the interrogatory responses in Exhibit 2012 is signed only by counsel and is not verified. *See Villareal v. El Chile, Inc.*, 266 F.R.D. 207, 211 (N.D. Ill. 2010) (“Under Rule 33 [of the Federal Rules of Civil Procedure], answers to interrogatories

must be verified and must be signed by the person answering the interrogatory, not only by the party's attorney.”). Unverified interrogatory responses like Exhibit 2012 are not testimonial evidence of objective indicia of non-obviousness. *See* 37 C.F.R. § 42.53(a) (specifying that direct testimony must be submitted in the form of an affidavit). None of the “thousands of pages of documents” referenced in Patent Owner's interrogatory response is of record in this proceeding. Nor does Patent Owner otherwise make any admissible evidence of objective indicia of non-obviousness of record in this proceeding. *See* Prelim. Resp. 21–24 (citing only interrogatory responses (Exs. 2012, 2013, 2014)). Essentially, Patent Owner asks us to exercise discretion and deny the Petition because Petitioner failed to address in the Petition alleged evidence of objective indicia of non-obviousness even though Patent Owner has not made any such evidence of record in this proceeding. We decline to do so.

Whether we exercise discretion under § 314(a) to deny a petition is guided by the Board's decision in *General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha*, Case IPR2016-01357, slip op. at 15–16 (PTAB Sept. 6, 2017) (Paper 19) (precedential) (articulating a non-exhaustive list of factors to be considered in determining whether to exercise discretion under § 314(a) to deny a petition). Patent Owner neither cites the *General Plastic* decision nor analyzes any factor set forth in that decision as a basis for denying the Petition in our discretion under § 314(a). Instead, Patent Owner quotes language out of context from three Board decisions attempting to support its argument that “Petitioner had the burden of setting forth secondary consideration arguments and evidence in the Petition.” Prelim. Resp. 23–24 (quoting *Omron Oilfield & Marine, Inc. v. MD/Totco*, Case

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IPR2013-00265, slip op. at 3–4 (PTAB Feb. 13, 2014) (Paper 14);
Semiconductor Component Indus., LLC v. Power Integrations, Inc.,
IPR2016-01588, slip op. at 28–29 (PTAB Feb. 17, 2017) (Paper 15);
Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd., IPR2016-00777,
slip op. at 9–10 (PTAB Sept. 22, 2016) (Paper 10)).

All three cited Board decisions are inapposite because each involves a petitioner’s failure to rebut evidence of objective indicia that was of record and that the Office had previously evaluated for its effect on an obviousness determination. *Omron*, slip op. 4; *Semiconductor Component*, slip op. 28–29; *Praxair*, slip op. 9. We also note that two of the cited Board decisions involve the Board weighing evidence and determining whether the petitioner had met its burden to warrant institution of *inter partes* review. *Omron*, slip op. 4; *Semiconductor Component*, slip op. 29. The third decision involves the Board determining whether to discretionarily deny a petition under § 325(d) because the petitioner relied upon an identical argument that had been previously presented, considered, and ruled upon by the Board. *Praxair*, slip op. 9–10. The circumstances before us here differ dramatically.

With no evidence of objective indicia of non-obviousness currently before us in this proceeding and no indication that the Office or the Board has previously weighed any such evidence in connection with a challenged claim, we discern no basis for denying the Petition in our discretion under § 314(a). When, if at all, Patent Owner proffers admissible evidence relating to objective indicia of non-obviousness, we will evaluate the effect of that evidence on Petitioner’s challenges to claims. At this stage, we reject Patent

Owner’s argument that we should discretionarily deny the Petition under § 314(a).

III. ANALYSIS

A. 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)²; *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 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).

² Our recently changed version of this Rule, which requires that we interpret claims in the same manner used in a civil action under 35 U.S.C. § 282(b), does not apply here 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).

Petitioner proposes interpretations of two phrases recited within various dependent claims, namely, “barrier” and “lubricating jelly application . . . compartment.” Pet. 23. Patent Owner does not address Petitioner’s proposed interpretations of these two phrases. We do not express an opinion about the meaning of these phrases at this stage of the proceeding because we determine that *inter partes* review is warranted based upon Petitioner’s showing regarding claim 45.

B. LEGAL STANDARDS

Petitioner challenges the patentability of claims 45–58, 60–74, 76–90, and 92 on the grounds that the claims would have been obvious in view of various references including: Solazzo, Serany, Disston, Salvadori, Franks-Farah, and Bierman. Pet. 25–79. 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 reasonably likely to be 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.

With these standards in mind, we address each challenge below.

C. CLAIMS 45–48, 50–51, 55–58, 60–64, 66–67, 71–74, 76–80, 82–83, 87–90, AND 92: OBVIOUSNESS IN VIEW OF SOLAZZO, SERANY, AND DISSTON

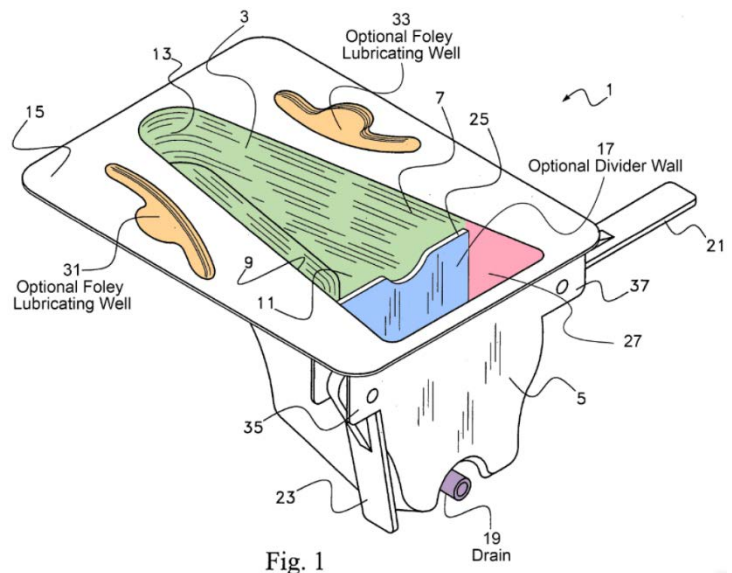
Petitioner argues that claims 45–48, 50–51, 55–58, 60–64, 66–67, 71–74, 76–80, 82–83, 87–90, and 92 are unpatentable as obvious in view of

the combined teachings of Solazzo, Serany, and Disston. Pet. 27–64. Claims 45, 61, and 77 are the independent claims among this group of challenged claims. Ex. 1001, 30:58–33:22. Patent Owner argues that the combination of Solazzo, Serany, and Disston fails to render independent claims 45, 61, and 77 unpatentable as obvious. Prelim. Resp. 25–42. For the reasons expressed below, we determine that Petitioner has demonstrated a reasonable likelihood of establishing that at least claim 45 is unpatentable as obvious.

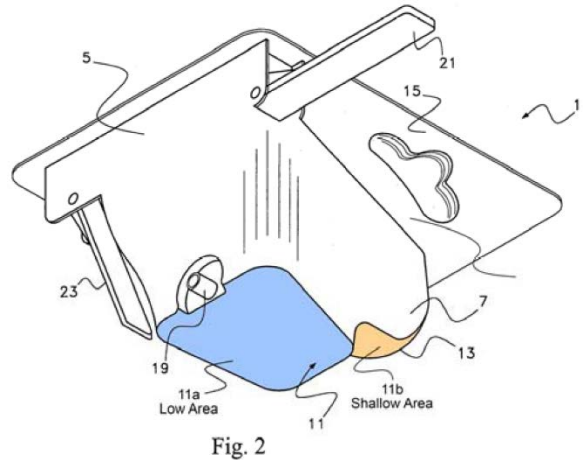
1. *Overview of Solazzo*

Solazzo is directed to an ergonomic, single layer catheterization/irrigation tray 1 having multiple compartments, including recessed area 3 (green), compartment 27 (pink), and wells 31, 33 (orange) as shown in Petitioner’s annotated Figure 1, which we reproduce below.

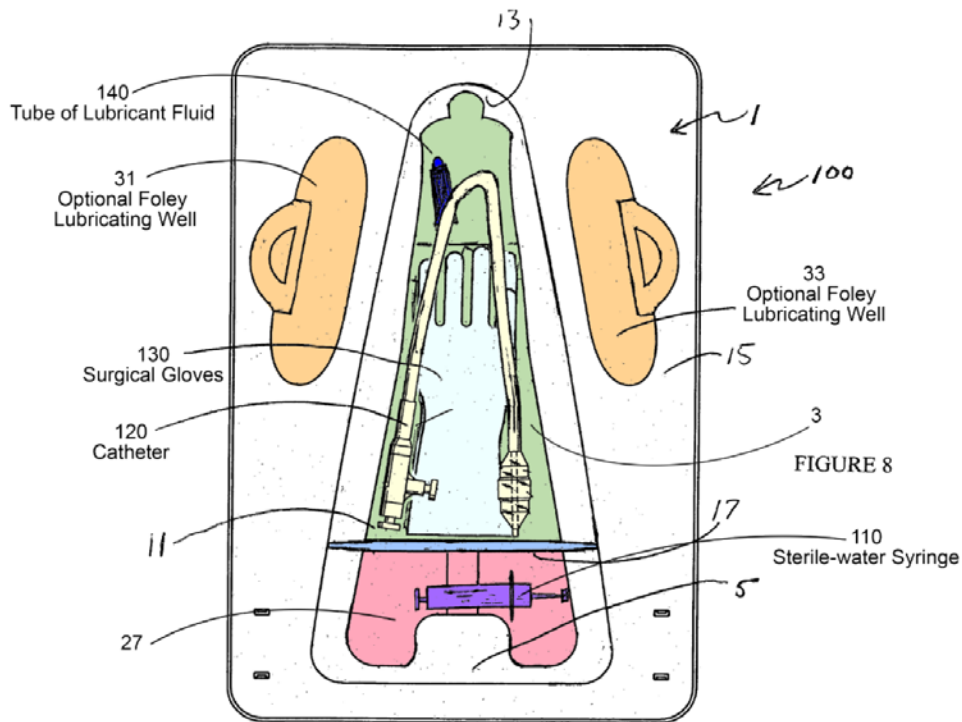
Ex. 1005, 4:15–25; Fig.1. Solazzo’s Figure 1 is a perspective view of the catheterization and irrigation tray illustrating its major features. *Id.* at 3:31–33. Divider wall 17 is optional and, when present, divides recessed area 3 into two compartments, with compartment 27 being configured to receive fluid passing over top 25 of wall 17. *Id.* at 4:15–20.



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



Id. 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 Petitioner’s annotated version of 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.



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.

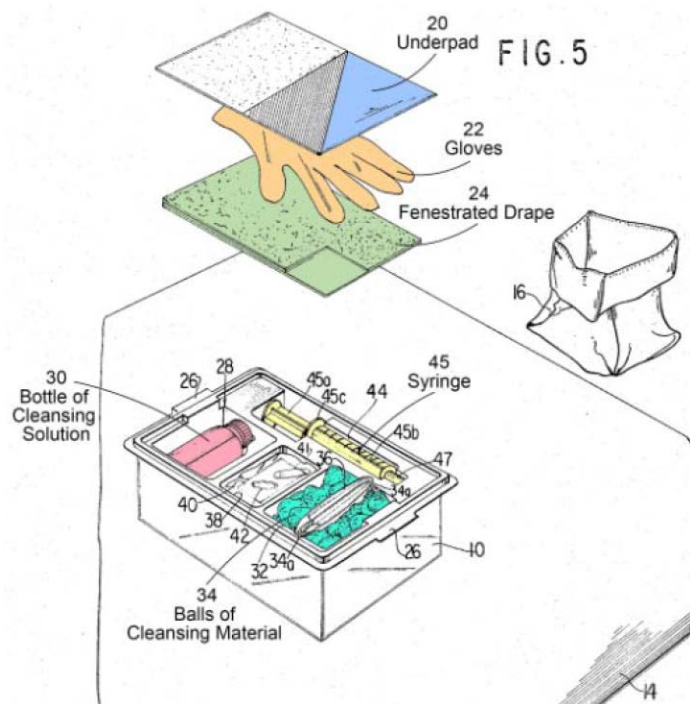
Inflation syringe 110 (purple) is stored at low area 11A (pink), and lubricant 140 is stored at shallow area 11B (green). *Id.* at 4:41–45; Fig. 8.

In use, the 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.

2. Overview of Serany

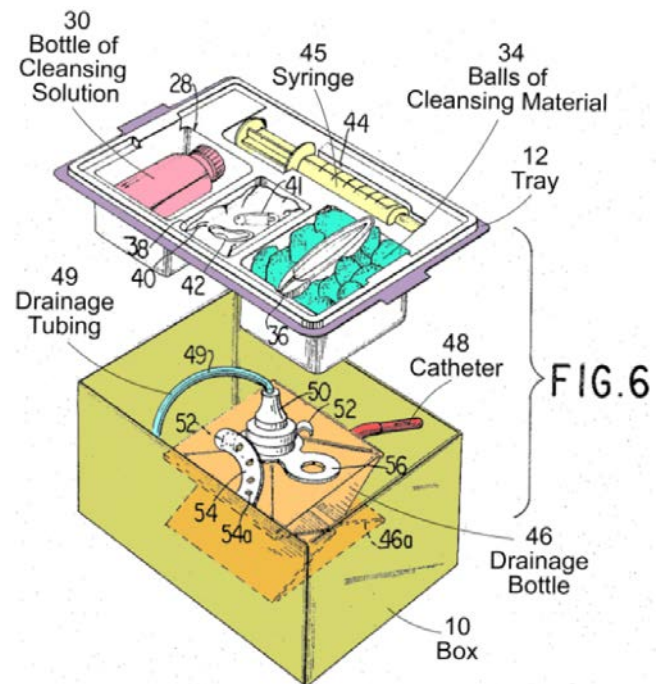
Serany is directed to a double-wrapped, sterile package providing catheterization components ready for use in the order needed. Ex. 1006, 1:8–16, 1:60–63, 3:63–4:2; Figs. 1–3, 5. The package includes multi-compartment single-layer tray 12 mounted on box 10 and enclosed with sealed outer envelope 16 and inner wrap 14 that unfolds to provide a sterile field work area.

Id. at 1:60–72, 2:17–20; Figs. 1–5. Petitioner’s annotated version of 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.



For example, prefilled syringe 45 (yellow) of sterile water 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 a waterproof underpad 20 (blue), gloves 22 (orange), fenestrated drape 24 (green), cleansing solution bottle 30 (red), rayon balls 34 (turquoise), 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 (red) that is preconnected to a collapsible drainage bottle 46 (orange) via tube 49 (light blue) and "ready for use" as shown in Petitioner's annotated version of 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. The collapsible drainage "bottle 46 [orange] 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 (red) and tubing 49 (light blue) are coiled in the box about bottle 46 (orange) as shown in annotated Figure 6. *Id.* at 3:33–35.



3. *Overview of 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.

4. *Independent Claim 45*

a) *Petitioner’s Argument and Evidence*

Petitioner argues that the combined teachings of Solazzo, Serany, and Disston render claim 45 unpatentable as obvious. Pet. 36–53. Petitioner contends that Solazzo describes the tray and its two compartments (elements 45a, 45b), *id.* at 36–41 (citing Ex. 1005, 2:61–63, 3:15–24, Figures 1, 5, 8, 10; Ex. 1002 ¶¶ 366–376) and the medical assembly disposed in the second

compartment (element 45c), *id.* at 42–45 (citing Ex. 1005, 2:42–46, 4:26–33; Ex. 1002 ¶ 385; Ex. 1003 ¶¶ 11, 30, 31, 36). Petitioner contends that Serany describes the “wrap material” and “outer packaging” (elements 45d and 45e), *id.* at 47–52 (citing Ex. 1006, 1:13–16, 1:60–72, 2:1–20, Figures 1, 2, 2a, 3; Ex. 1002 ¶¶ 396–402, 404–08), and aspects of the tray and medical assembly (elements 45a, 45c), *id.* at 43–45 (citing Ex. 1006, 1:31–32, 3:23–36, Figure 6; Ex. 1002 ¶¶ 386–388). Petitioner also contends that Disston describes aspects of the medical assembly (element 45c). *Id.* at 44–45 (citing Ex. 1008, 2:15–23, 2:72–3:1, Figure 1; Ex. 1002 ¶ 385).

Petitioner recognizes that Solazzo does not describe how its catheterization tray is packaged but argues that an ordinarily skilled artisan would have been motivated to use Serany’s wrap and outer packaging on Solazzo’s catheterization tray because doing so was a well-known way to keep the components of a catheterization tray in place and sterile before use. *Id.* at 47–52 (citing Ex. 1005, 3:15–24 (recognizing need to keep items in tray sterile); Ex. 1006, 1:13–16, 1:60–72 (describing the purpose of Serany’s outer wrap), Ex. 1002 ¶¶ 396–412). Petitioner also argues that Serany and Disston further suggest that Solazzo’s tray could be used “for receiving a medical device” in the form of a closed-system Foley catheter because an ordinarily skilled artisan would have been motivated to do so to reduce the risk of infection. *Id.* at 45–46 (citing Ex. 1006,³ 1:31–32, 3:23–36; Ex. 1008, 2:72–3:1; Ex. 1002 ¶¶ 349, 390; Ex. 1003 ¶ 35; Ex. 1010, 51–52).

³ At this location in the Petition, Petitioner mistakenly refers to Exhibit 1005 in its citation to evidence supporting its contentions about Serany.

b) Analysis of Patent Owner's Counterarguments

Patent Owner argues that Petitioner's challenge to claim 45 fails for three reasons, none of which is persuasive at this stage of the proceeding. We address each argument below.

(1) Element 45a

Element 45a refers to the following portion of claim 45: "a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly." Petitioner contends that catheter 120 within recessed area 3 as shown in Solazzo's Figure 8, constitutes the claimed "medical assembly." Pet. 37–38 (citing Ex. 1005, Figure 8; Ex. 1002 ¶¶ 366–371). Petitioner further contends that Solazzo's compartment 27 is structured to receive multiple syringes. *Id.*

Patent Owner contends that Solazzo fails to describe a "medical assembly" as recited in claim 45. Prelim. Resp. 26. Patent Owner argues that Solazzo's catheter 120 is not "multiple components as required in an 'assembly'." *Id.* at 26–27 (citing Ex. 1001, 4:6–7 (allegedly differentiating a catheter from a catheter assembly)). Patent Owner also argues that the District Court has interpreted "catheter assembly" as referring to "a medical device that includes a catheter connected via coiled tubing to a drainage receptacle." *Id.* (citing Ex. 2011).

Patent Owner's argument is unpersuasive for two reasons. First, Solazzo's Figure 8 clearly depicts its catheter 120 as an assembly of more than one component. Ex. 1005, Figure 8 (depicting tubing and a fixture coupled to at least one end of the tubing). Second, claim 45 does not recite a "catheter assembly," which diminishes if not eliminates the probative value of the District Court's interpretation of that term.

However, claim 45 later specifies (element 45c) that the “medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter.” Ex. 1001, 30:65–67. Petitioner relies upon a combination of teachings from Solazzo, Serany, and Disston, not just Solazzo, to establish that it would have been obvious to modify Solazzo’s open-system catheter to a closed-system catheter. Pet. 42–46.

On the record currently before us, we determine that Petitioner has demonstrated a reasonable likelihood of establishing that Solazzo describes element 45a, which is directed solely to the first and second compartments of the tray and their respective functional capabilities to receive two syringes and a medical assembly.

(2) Element 45b

Element 45b refers to the following portion of claim 45: “a first syringe and a second syringe disposed within the first compartment.” Petitioner contends that Solazzo expressly describes that its catheterization/irrigation tray kit includes two syringes, inflation syringe 110 and an irrigation syringe. Pet. 39 (citing Ex. 1005, 3:15–24). Although Solazzo does not expressly describe where the irrigation syringe is located within recessed area 3, Petitioner contends that compartment 27 is the “natural place to store the irrigation syringe because it already holds the inflation syringe.” *Id.* (citing Ex. 1002 ¶¶ 372–376). Petitioner also argues that Solazzo and Serany together suggest substituting Solazzo’s lubricant tube 140, which is shown in Solazzo’s recessed area 3, with a syringe filled with lubricant placed in the compartment 27 with Solazzo’s other syringes. *Id.* at 40–41 (citing Ex. 1006, 1:31–35, 2:57–61; Ex. 1011; Ex. 1012; Ex. 1002 ¶¶ 372–382 and cross-referencing argument relating to claim 46).

Petitioner further argues that Serany and other prior art suggest that an ordinarily skilled artisan would have been motivated to group at least two syringes in the same compartment so that the syringes were arranged in “logical order” and to avoid damaging the catheter stored in the other compartment. *Id.* at 40–41 (citing Ex. 1006, 1:31–35, 2:57–61; Ex. 1011; Ex. 1012; Ex. 1002 ¶¶ 377–382).

Patent Owner responds that Solazzo fails to describe or suggest two syringes disposed within the first compartment of the tray. Prelim. Resp. 28–34. Patent Owner provides no persuasive evidence, however, that an ordinarily skilled artisan would not have considered Solazzo’s compartment 27, which Solazzo’s Figure 8 illustrates as the storage location for Solazzo’s inflation syringe 110, to be the natural place to store Solazzo’s irrigation syringe. Mr. Plishka testifies that “there are very limited locations where [the irrigation syringe] would likely be held, e.g., compartment 3 or compartment 27. Compartment 27 is a natural place to store the irrigation syringe because it already holds the inflation syringe.” Ex. 1002 ¶ 375.

Claim 45 requires nothing more than two syringes disposed within the first compartment. Solazzo expressly describes two syringes in its kit. Ex. 1005, 3:15–24. Only two locations are available for storing syringes, the portions of recessed area 3 on opposite sides of the optional divider wall 17. Mr. Plishka testifies on behalf of an ordinarily skilled artisan that compartment 27 is the “natural” place for the irrigation syringe and explains why. Patent Owner provides no persuasive evidence that we should not accept Mr. Plishka’s opinion on this issue. Prelim. Resp. 28–34.⁴ Based on

⁴ Most of Patent Owner’s argument in this portion of the Preliminary Response relates to whether an ordinarily skilled artisan would have found it

the record before us, we are persuaded by Petitioner’s argument that the combination of Solazzo and Serany describes or suggests element 45b.

(3) *Element 45c*

Element 45c refers to the requirement that “the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter.” Petitioner contends that an ordinarily skilled artisan would have found it obvious to place a closed-catheter as described by Serany and Disston for Solazzo’s open-catheter 120 in recessed area 3. Pet. 42–46. Petitioner contends that an ordinarily skilled artisan would have been motivated to do so because modifying Solazzo to incorporate a “ready for use” closed-catheter system would simplify Solazzo’s catheterization procedure and reduce the risk of infection for patients. *Id.* at 45–46 (citing Ex. 1002 ¶ 349; Ex. 1003 ¶ 35; Ex. 1010, 51). Petitioner also contends that including a closed-catheter assembly in Solazzo’s kit would render Solazzo’s kit more versatile because the modified kit could be used for both permanent catheterization and irrigation procedures. *Id.* at 46 (citing Ex. 1002 ¶ 393; Ex. 1003 ¶¶ 38, 41, 42).

Patent Owner argues that an ordinarily skilled artisan would not modify Solazzo’s kit as proposed by Petitioner for two reasons. Prelim. Resp. 34–40. Patent Owner argues that, because Solazzo’s recessed area is too small to accommodate a closed-catheter assembly, modifying Solazzo to enlarge its recessed area would (1) render Solazzo unsatisfactory for its

obvious to put Solazzo’s lubricant in a syringe rather than the tube 140. We express no opinion on the strength or weakness of this argument in this Decision.

intended purpose, *id.* at 36–37, and (2) change its principle of operation, *id.* at 38–40. Based on the record currently before us, neither of Patent Owner’s arguments is persuasive.

Patent Owner’s first argument rests upon the factual premise that Solazzo’s recessed area 3, which is designed to be positioned between a patient’s legs, Ex. 1005, 1:7–13, 3:9–11, 3:58–63, 3:66–4:3, 4:26–33, is too small to accommodate a closed catheter like Serany’s. Patent Owner contends that Serany’s bottle 46, which is attached to Foley catheter 48, “consumes nearly all of the space in the box 10.” Prelim. Resp. 36 (citing Ex. 1006, 3:22–44, Figure 6). However, Serany contradicts Patent Owner’s contention by explaining that Figure 6 illustrates bottle 46 in a “partially expanded” state but “may be folded flat for storage.” Ex. 1006, 3:26–31.

Serany also contradicts Patent Owner’s contention that Serany suggests “removing [bottle 46] from the box only when catheterization is completed,” which implies that bottle 46 would be expanded within its storage compartment during use, making it even harder to fit within Solazzo’s recessed area 3. Serany explains that “drainage bottle 46 is removed from the box 10 and suspended from a bed rail . . . by the strap 54 The drainage tubing 49 is attached to a bed sheet . . . to thereby complete the catheterization procedure.” *Id.* at 3:51–57. Thus, Serany suggests removing the collapsed bottle 46 from its storage compartment and hanging the bottle on the patient’s bedside before use. The current record does not support Patent Owner’s contention that Serany’s flat, collapsed bottle 46 would not fit within Solazzo’s recessed area 3, which is illustrated as being large enough to accommodate an unfolded set of gloves 130 and a mostly uncoiled catheter 120. Ex. 1005, Figure 8.

Based on Patent Owner's unsupported contentions about the size and use of Serany's bottle 46, Patent Owner argues, based solely upon testimony of Richard Meyst, that modifying as suggested by Petitioner would render Solazzo's tray too large to fit between the patient's legs and therefore unsatisfactory for its intended purpose. Prelim. Resp. 37 (citing Ex. 2001 ¶¶ 43–47). Mr. Meyst cites no objective evidence to support the conclusions that he reaches in the cited testimony. Based on the current record, Patent Owner's argument that Solazzo as modified would be unsuitable for its intended purpose is not persuasive.

Patent Owner's second argument is that modifying Solazzo to use a closed-catheter changes the principle of operation of the tray because it renders Solazzo's drain 19 for emptying fluid from tray 1 "useless." Prelim. Resp. 38–39. First, we observe that the proposed modified version of Solazzo's tray still functions as a container for a catheterization kit, one of its primary functions. Ex. 1005, 4:41–48, Figure 8. Petitioner also argues that drain 19 would still be of use because Solazzo's tray 1 could still be used for irrigation procedures. Pet. 46 (citing Ex. 1002 ¶¶ 393, 394; Ex. 1003 ¶¶ 38, 41, 42). Patent Owner contests Petitioner's evidence by providing testimony from Ms. Weintraub. Prelim. Resp. 40 (citing Ex. 2002 ¶¶ 15–17). At this stage of the proceeding, we view expert testimony that creates a genuine issue of material fact in the light most favorable to Petitioner. 37 C.F.R. § 42.108(c). Based on the record before us as we consider that record under our Rules, we are sufficiently persuaded by Petitioner's argument and evidence that the proposed modification of Solazzo would not change Solazzo's principle of operation.

For these reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood that it will prove that the combination of Solazzo, Serany, and Disston suggests element 45c.

(4) Objective Indicia of Non-obviousness

As explained in Part II.B above, although Patent Owner has indicated that it contends in the *Medline III* Litigation that objective indicia of non-obviousness weigh against a finding that the claims of the '088 patent are obvious, Patent Owner has not proffered admissible evidence of those objective indicia in this proceeding. Accordingly, we do not address or weigh objective indicia of nonobviousness in this Decision.

c) Conclusion

For the reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood of proving that the combination of Solazzo, Serany, and Disston renders claim 45 unpatentable as obvious.

5. Dependent Claims 46–48, 50, 51, 55–58, and 60

Petitioner identifies the portions of Solazzo, Serany, and Disston that support its argument that dependent claims 46–48, 50, 51, 55–58, and 60 are also obvious in view of Solazzo, Serany, and Disston. Pet. 53–62 (citing Ex. 1005, 1:15–21, 1:38–42, 3:15–24, 4:21–25, 4:41–58, Figures 1, 3, 8; Ex. 1006, 2:21–33, 3:1–5, 3:23–26, 3:50–51, 3:55–58, Figure 5). Petitioner also supports its argument with testimony from Mr. Plishka and Dr. Yun. *Id.* (citing Ex. 1002 ¶¶ 417–419, 422, 423, 427–30, 434–436, 439–441, 446, 450, 451; Ex. 1003 ¶ 22).

Patent Owner does not separately argue that limitations introduced in dependent claims 46–48, 50, 51, 55–58, and 60 are a basis for finding that any of these claims remain patentable over Solazzo and Serany. Prelim.

Resp. 40. At this stage of the proceeding, we are persuaded that Petitioner has demonstrated a reasonable likelihood of proving that these claims are obvious. However, the burden remains on Petitioner to prove unpatentability of each challenged claim. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

6. *Independent Claims 61 and 77 and Their Respective Dependent Claims 62–64, 66–67, 71–74, 76, 78–80, 82–83, 87–90, and 92*

Patent Owner presents the same arguments for the patentability of independent claims 61 and 77 that it presents in support of the patentability of independent claim 45. *Compare* Prelim. Resp. 26–40 (addressing claim 45) *with* 41 (addressing claim 61) *and* 41–42 (addressing claim 77). At this stage of the proceeding, we disagree with Patent Owner's arguments relating to claims 61 and 77 for the reasons given above in our analysis of claim 45 and we are persuaded that Petitioner has demonstrated a reasonable likelihood of proving that these claims would have been obvious. Patent Owner does not separately argue that limitations introduced in claims 62–64, 66–67, 71–74, 76 (depending from claim 61) or claims 78–80, 82–83, 87–90, and 92 (depending from claim 77) are a basis for finding that any of these dependent claims remain patentable over Solazzo, Serany, and Disston. Prelim. Resp. 41. Accordingly, we also institute *inter partes* review of claims 61 and 77 and their respective dependent claims 62–64, 66–67, 71–74, 76, 78–80, 82–83, 87–90, and 92. However, the burden remains on Petitioner to prove unpatentability of each challenged claim. *Dynamic Drinkware*, 800 F.3d at 1378.

D. DEPENDENT CLAIMS 49, 52–55, 65, 68–71, 81, AND 84–87:
OBVIOUSNESS IN VIEW OF VARIOUS COMBINATIONS OF SOLAZZO,
SERANY, DISSTON, FRANKS-FARAH, AND BIERMAN

Petitioner also challenges claims 49, 54, 65, 70, 81, and 86 as being unpatentable over Solazzo, Serany, Disston, and Salvadori. Pet. 65–70. Petitioner challenges claims 52, 53, 68, 69, 84, and 85 as being unpatentable over Solazzo, Serany, Disston, and Franks-Farah. *Id.* at 70–75. Petitioner challenges claims 55, 71, and 87 as unpatentable over Solazzo, Serany, Disston, and Bierman. *Id.* at 76–79. Patent Owner currently presents no argument relating to any of these claims other than those relating to the independent claims from which they depend. *See* Prelim. Resp. 25–42 (addressing merits of patentability only for independent claims 45, 61, and 77). Because we have determined that *inter partes* review is warranted in connection with numerous claims in view of Solazzo, Serany, and Disston, we also institute *inter partes* review of claims 49, 52–55, 65, 68–71, 81, and 84–87, on the challenges presented by Petitioner. However, the burden remains on Petitioner to prove unpatentability of each challenged claim. *Dynamic Drinkware*, 800 F.3d at 1378.

IV. CONCLUSION

For the reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood of showing that claim 45 of the '088 patent is unpatentable as obvious in view of the combination of Solazzo and Serany. In accordance with the Court's decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018) and Office guidance,⁵ we institute

⁵ “Guidance on the impact of SAS on AIA trial proceedings” (Apr. 26, 2018), accessible at <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial> (last

an *inter partes* review of all challenged claims of the '088 patent on all grounds alleged by Petitioner. Nevertheless, this Decision does not reflect a final determination on the patentability of any claim. We further note that the burden remains on Petitioner to prove unpatentability of each challenged claim. *Dynamic Drinkware*, 800 F.3d at 1378.

V. ORDER

For the reasons given, it is:

ORDERED that *inter partes* review of claims 45–58, 60–74, 76–90, and 92 of the '088 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '088 patent is instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is given of the institution of a trial.

accessed Oct. 2, 2018) (“At this time, if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition,” and “for pending trials . . . the panel may issue an order supplementing the institution decision to institute on all challenges raised in the petition.”).

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