

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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C.R. BARD, INC.,  
Petitioner,

v.

MEDLINE INDUSTRIES, INC.,  
Patent Owner.

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Case IPR2019-00035  
Patent 9,745,088 B2

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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 1, 2, 6–10, 16–19, and 25–44 (the “challenged claims”) of U.S. Patent No. 9,745,088 B2 (Ex. 1001, “the ’088 patent”). 35 U.S.C. § 311. Medline Industries, Inc. (“Patent Owner”)

timely filed a Preliminary Response. Paper 12 (“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. 23–87):

<b>References</b>	<b>Basis</b>	<b>Claims challenged</b>
U.S. Patent No. 7,278,987 B2 (Ex. 1005, “Solazzo”) and U.S. Patent No. 3,329,261 (Ex. 1006, “Serany”)	§ 103	1, 2, 6–10, 16, 17, 25–32, and 36–41
Solazzo, Serany, and U.S. Patent No. 6,840,379 B2 (Ex. 1007, “Franks-Farah”)	§ 103	18, 19, and 35
Solazzo, Serany, and U.S. Patent No. 3,166,189 (Ex. 1008, “Disston”)	§ 103	33, 34, and 42
Solazzo, Serany, Disston, and Franks-Farah	§ 103	43 and 44

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. 90; Paper

4, 2. The parties also identify a petition for *inter partes* review of claims 45–58, 60–74, 76–90 and 92 of the '088 patent as a related matter. 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.*

### 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 colored version of Figure 7, which we reproduce below.

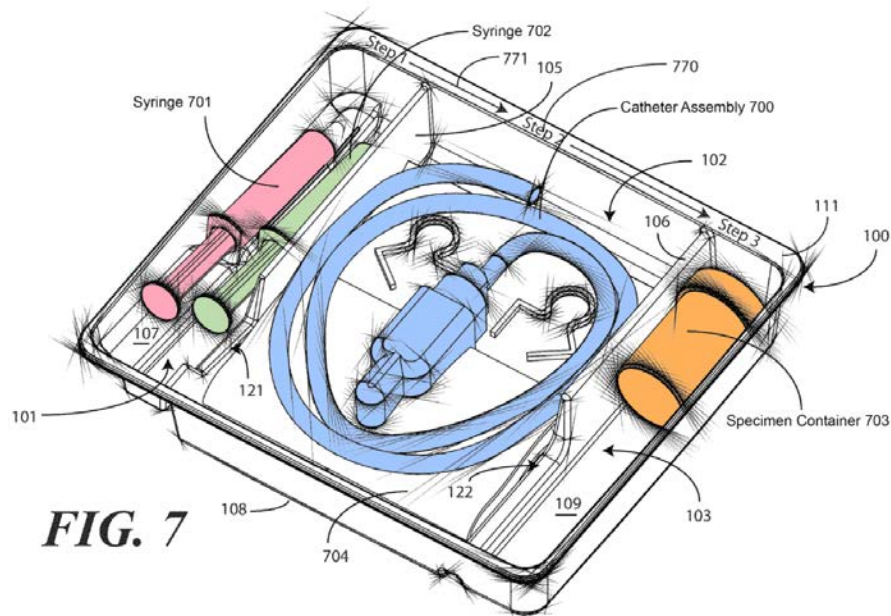


Figure 7 illustrates a catheter, two syringes, and a specimen bottle located within single-level tray 100. *Id.* at 2:45–49.

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 1, 25, and 37 are the independent claims among the challenged claims. *Id.* at 27:47–30:57. Claim 1, which is illustrative, recites:

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

[f] the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe; and

[g] the first compartment comprising a base member that defines a mnemonic device indicating which of the first syringe or the second syringe should be used first in the catheterization procedure.

*Id.* at 27:47–67 (with added letter designations a–g 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. 9. Patent Owner admits that the Medline Portfolio is “complex.” *Id.* at 16. Nevertheless, Patent Owner contends that “Solazzo adds nothing new that has not already been considered by the Office.” *Id.* at 10. 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. at 17–18 (PTAB Dec. 15, 2017) (Paper 8) (informative) weighs in favor of discretionarily denying the Petition under § 325(d). Prelim. Resp. 11–29.

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 Solazzo<sup>1</sup> 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 16 (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 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. 16–21. 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

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<sup>1</sup> 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).

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. 21–29 (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. 88; *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. 22–24, 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. 29. 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 30 (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. 29–32 (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 nonobviousness 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. 31–32 (quoting *Omron Oilfield & Marine, Inc. v. MD/Totco*, Case IPR2013-00265, slip op. at 3–4 (PTAB Feb. 13, 2014) (Paper 14); *Semiconductor Component Indus., LLC v. Power Integrations, Inc.*, Case IPR2016-01588, slip op. at 28–29 (PTAB Feb. 17, 2017) (Paper 15); *Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, Case 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)<sup>2</sup>; *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).

The parties present slightly differing interpretations of “mnemonic device” as recited in claim 1 with Patent Owner proposing that we apply the broader of those interpretations that “mnemonic device” means “a feature intended to assist the memory.” Pet. 20; Prelim. Resp. 33–34. The District Court in the related *Medline III* Litigation has issued a *Markman* Order agreeing with Patent Owner’s proposed broader definition of “mnemonic device,” and we agree with and apply that definition when analyzing claim 1 below. Ex. 3001, 7–8.

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<sup>2</sup> 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 also proposes interpretations of two phrases recited within various dependent claims, namely, “catheter assembly” and “lubricating jelly application chamber.” Pet. 20. 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 1.

#### B. LEGAL STANDARDS

Petitioner challenges the patentability of claims 1, 2, 6–10, 16–19, and 25–44 on the grounds that the claims would have been obvious in view of various references including: Solazzo, Serany, Disston, and Franks-Farah. Pet. 24–87. 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 1, 2, 6–10, 16, 17, 25–32, AND 36–41: OBVIOUSNESS IN VIEW OF SOLAZZO AND SERANY

Petitioner argues that claims 1, 2, 6–10, 16, 17, 25–32, and 36–41 are unpatentable as obvious in view of the combined teachings of Solazzo and Serany. Pet. 31–54, 59–78. Claims 1, 25, and 37 are the independent claims

among this group of challenged claims. Ex. 1001, 27:47–30:57. These three claims differ only in the language used in elements 1g, 25g, and 37g.

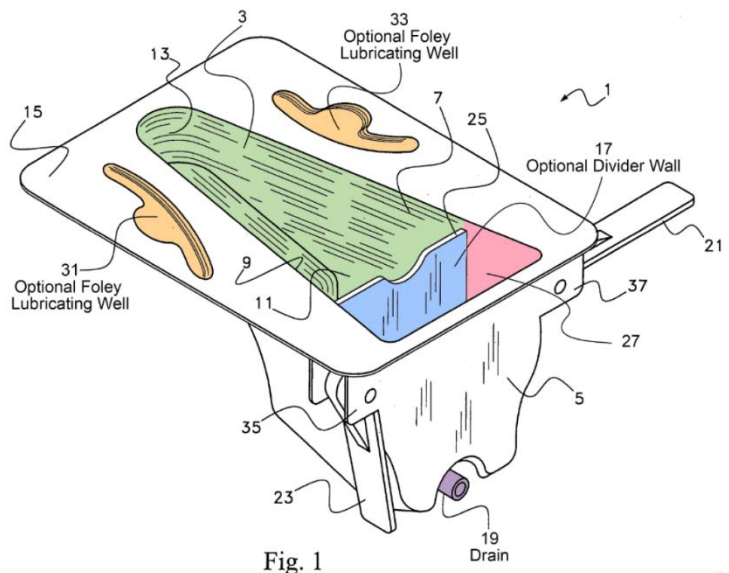
Pet. 18; *see also* Ex. 1001, 27:47–30:57 (listing claims). Patent Owner argues that the combination of Solazzo and Serany fails to render independent claims 1, 25, and 37 unpatentable as obvious. Prelim.

Resp. 35–60. For the reasons expressed below, we determine that Petitioner has demonstrated a reasonable likelihood of establishing that at least claim 1 is unpatentable as obvious.

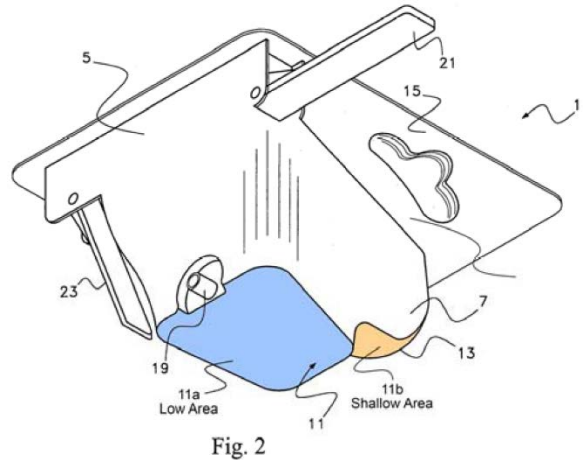
### 1. Overview of Solazzo

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.

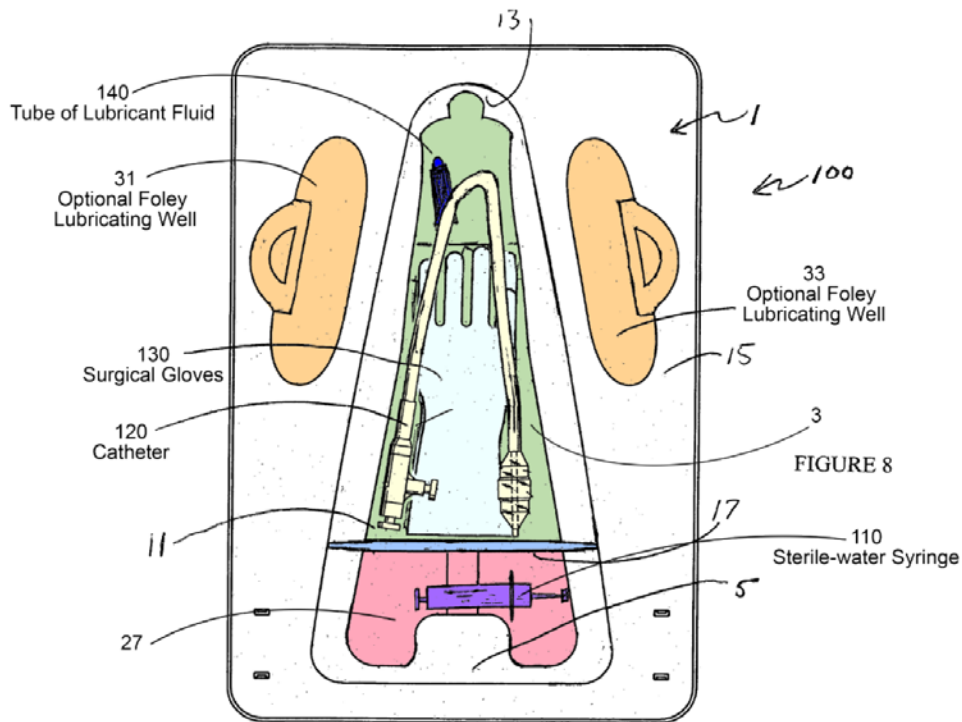
Ex. 1005, 4:15–25; Fig.1. Solazzo’s Figure 1 is a perspective view of the catheterization and irrigation tray illustrating its major features. *Id.* at 3:31–33. Divider wall 17 is optional and, when present, divides recessed area 3 into two compartments, with compartment 27 being configured to receive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



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.

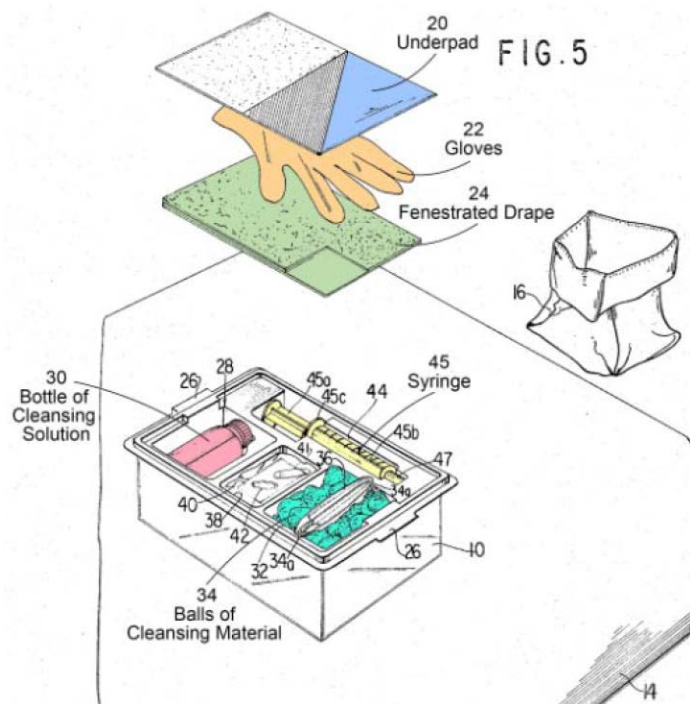
Inflation syringe 110 (purple) is stored at low area 11A (pink), and lubricant 140 is stored at shallow area 11B (green). *Id.* at 4:41–45; Fig. 8.

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

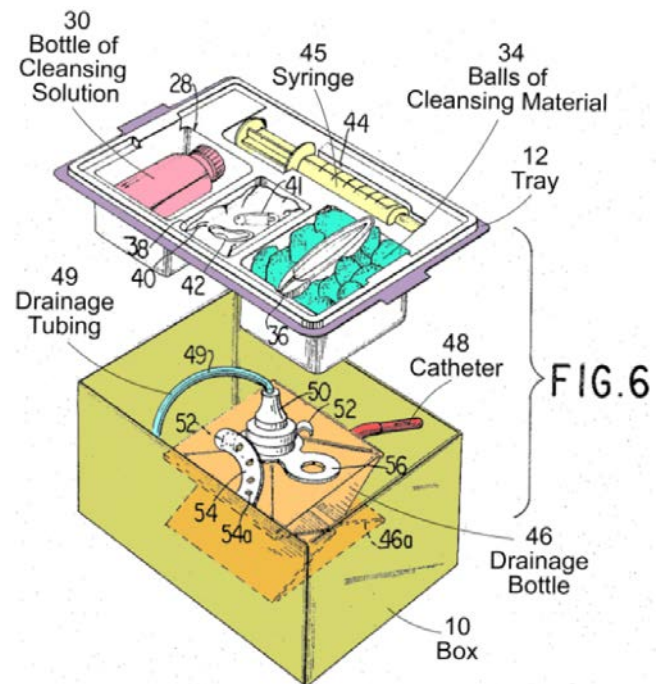
Serany is directed to a double-wrapped, sterile package providing catheterization components ready for use in the order needed. Ex. 1006, 1:8–16, 1:60–63, 3:63–4:2; Figs. 1–3, 5. The package includes multi-compartment single-layer tray 12 mounted on box 10 and enclosed with sealed outer envelope 16 and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

a) *Petitioner's Argument and Evidence*

Petitioner argues that the combined teachings of Solazzo and Serany render claim 1 unpatentable as obvious. Pet. 31–49. Petitioner contends that Solazzo describes the tray and its compartments (elements 1a, 1b), *id.* at 31–35 (citing Ex. 1005, 2:48–51, 3:15–24, 3:52–57, 4:41–46, Figures 1, 8; Ex. 1002 ¶¶ 157–61, 167–73; Ex. 1003 ¶ 22), the first and second syringes and the manner in which they are ordered within the tray (elements 1e, 1f), *id.* at 40–45 (citing Ex. 1005, 3:63–66, 4:21–25, Figures 1, 2, 8; Ex. 1002 ¶¶ 195–200, 204–09), and the mnemonic device within the tray (element 1g), *id.* at 45–48 (citing Ex. 1005, 3:12–13, 3:63–66, 4:24–31, Figures 1, 8; Ex. 1002 ¶¶ 210–16; Ex. 1016). Petitioner contends that Serany describes the “wrap material” and “outer packaging” recited in elements 1c and 1d. *Id.* at 35–40.

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 37–39 (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 ¶¶ 174–94). Petitioner also argues that Serany further suggests that Solazzo’s tray could be used “for receiving a medical assembly” 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 33 (citing Ex. 1006,<sup>3</sup> 1:31–32, 3:23–36; Ex. 1002 ¶¶ 162–66; Ex. 1003 ¶ 15; Ex. 1010, 52). Petitioner also relies upon Serany as further suggesting that the syringes described by Solazzo should be ordered according to their use during a catheterization procedure or serve as a mnemonic device (aspects of element 1e and element 1g). *Id.* at 42, 48 (citing Ex. 1006, 1:9–12, 1:23–25, 1:34–35; Ex. 1002 ¶¶ 201–202, 210–218).

*b) Analysis of Patent Owner’s Counterarguments*

Patent Owner argues that Petitioner’s challenge to claim 1 fails for four reasons, none of which is persuasive at this stage of the proceeding. We address each argument below.

*(1) Element 1a*

Element 1a refers to the following portion of claim 1: “a tray having a 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 device.” Pet. 32 (citing Ex. 1005, 2:48–51, 3:17, 3:52–57, 4:41–46, Figures 1, 8).

Patent Owner contends that Solazzo fails to describe a “medical assembly” as recited in claim 1. Prelim. Resp. 35. Patent Owner argues that Solazzo’s catheter 120 is not “multiple components as required in an ‘assembly.’” *Id.* (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

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

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 1 does not recite a “catheter assembly,” which diminishes if not eliminates the probative value of the District Court’s interpretation of that term. The Specification never uses the term “medical assembly” and none of the claims recites that the medical assembly comprises a “catheter assembly” or vice versa. Some claims in the ’088 patent not at issue in this proceeding specify that the “medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter.” *E.g.*, Ex. 1001, 30:65–67 (claim 45). By contrast, claim 1 merely recites “a tray having a compartment for receiving a medical assembly.” Not only does the claim language leave “medical assembly” reasonably open to broad interpretation, element 1a may not even affirmatively require that a medical assembly be part of the recited “medical procedure kit.” Instead, element 1a merely recites a “tray having a compartment” with the compartment having the functional capability of “receiving a medical assembly.” The parties should address this aspect of element 1a during the trial.

On the record currently before us, we determine that Petitioner has demonstrated a reasonable likelihood of establishing that Solazzo describes element 1a.

(2) *Element 1b*

Element 1b refers to the following portion of claim 1: “a first syringe and a second syringe disposed within the tray.” Petitioner contends that Solazzo expressly describes that its catheterization/irrigation tray kit includes two syringes, an inflation syringe and an irrigation syringe, and a tube containing lubricant. Pet. 34 (citing Ex. 1005, 3:15–24, 4:41–46). Petitioner argues that it would have been obvious to substitute a syringe of lubricant for the tube 140 of lubricant that is illustrated in Solazzo’s Figure 8 because an ordinarily skilled artisan would consider doing so to be a “simple substitution of one container (a tube as taught by Solazzo) for another known type of container (a syringe as also taught by Solazzo) to produce predictable results.” *Id.* at 35 (citing Ex. 1002 ¶¶ 167–73).

Patent Owner responds that Solazzo fails to describe or suggest two syringes disposed within the tray. Prelim. Resp. 42. Patent Owner contends that Solazzo’s use of a tube for lubricant is sufficient due to the size of its wells 31, 33 and that including two syringes within the same compartment as Solazzo’s catheter 120 would have “potentially damaging [side] effects” among other problems. *Id.* at 43. None of Patent Owner’s contentions is sufficiently supported by citations to evidence. Instead, we consider those contentions at this stage to be unpersuasive attorney argument not supported by evidence. On the record currently before us, we determine that Petitioner has demonstrated a reasonable likelihood that it will prove that Solazzo describes or suggests element 1b.

(3) *Element 1e*

Element 1e refers to the requirement that “the first syringe and the second syringe are ordered within the tray in accordance with their use

during a catheterization procedure.” Petitioner contends that Solazzo in view of Serany suggests placing two syringes in one compartment with an inflation syringe positioned in low area 11a of the embodiment of recessed area 3 without the optional divider wall 17 and a syringe filled with lubricant positioned in shallow area 11b of recessed area 3 where Solazzo indicates tube 140 is positioned. Pet. 40–41 (citing Ex. 1005, 3:63–66, Figure 2). Petitioner contends that Solazzo’s placing of these two syringes at different depths constitutes the claimed limitation of the syringes being “ordered within the tray in accordance with their use during a catheterization procedure” because an ordinarily skilled artisan would reach for the higher positioned syringe of lubricant before the lower positioned inflation syringe, which corresponds to the order of operations in a catheterization procedure. *Id.* at 42 (citing Ex. 1002 ¶¶ 195–200). The ’088 patent describes placing syringes at different elevations within a compartment as one type of mnemonic device to indicate the order in which the syringes should be used during a procedure. Ex. 1001, 4:24–31. Petitioner also contends that an ordinarily skilled artisan would understand the placement of the lubricant syringe near the lubricating wells 31, 33 to be an indicator that the lubricant syringe should be used first. Pet. 42 (citing Ex. 1005, Figures 1, 8; Ex. 1002 ¶¶ 195–200). Petitioner also relies upon Serany’s suggestion that items in a tray of medical components should be “arranged in logical step-by-step order to facilitate the nurse’s or physician’s task” as evidence of how an ordinarily skilled artisan would interpret the placement of syringes in Solazzo’s tray. *Id.* (citing Ex. 1006, 1:34–35; Ex. 1002 ¶¶ 201–202).

Patent Owner argues that because Solazzo fails to expressly indicate why its two syringes are located at two different elevations or why its

lubricating fluid is located near lubricating wells 31, 33, Solazzo alone does not suggest the order in which a user should select its lubricant and inflation syringes. Prelim. Resp. 46–51. Despite the arrangement of Solazzo’s two syringes at different heights, which the ’088 patent claims to be a mnemonic device, Patent Owner argues that “the syringes in Solazzo appear to be haphazardly placed within the tray without regard to their order of use.”<sup>4</sup> *Id.* at 47. Patent Owner cites no evidence for this contention. *Id.* In view of Petitioner’s testimonial evidence to the contrary, we are not persuaded by Patent Owner’s argument at this stage of the proceeding.

Patent Owner also argues that the combination of Solazzo and Serany fails to suggest arranging the syringes according to the order in which they are used during catheterization. Patent Owner contends that, despite Serany’s express statement that it arranges items in its kit in the order in which they should be used, the “contents of [Serany’s] tray 12 itself, however, are not arranged by order of use.” *Id.* at 51–52 (citing Ex. 1006, 2:62–72, 3:1–5, 3:45–62). Patent Owner admits, however, that Serany does arrange at least underpad 20, gloves 22, and drape 24 in their order of use. *Id.* at 51 (citing Ex. 1006, 2:21–39, Figures 5, 6). This aspect of Serany is all that Petitioner relies upon for its contention that Serany suggests placing items in a catheterization kit in a manner consistent with the order in which the items are used. Pet. 42. For these reasons, we are not persuaded by Patent Owner’s argument at this stage of the proceeding.

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<sup>4</sup> Patent Owner attempts to bolster this argument by contending that Solazzo arranges components other than the syringes in the wrong order. Prelim. Resp. 50–51. This argument is unpersuasive because claim 1 only addresses the arrangement of the syringes in the order of use, not the arrangement of other components in the claimed kit.

For all the reasons stated immediately above, we determine that Petitioner has demonstrated a reasonable likelihood that it will prove that Solazzo alone or in combination with Serany suggests element 1e.

*(4) Element 1g*

Element 1g refers to the limitation in claim 1 that “the first compartment comprising a base member that defines a mnemonic device indicating which of the first syringe or the second syringe should be used first in the catheterization procedure.” Petitioner contends that Solazzo’s “terraced bottom” 11 of recessed area 3 constitutes precisely the same type of mnemonic device described in the Specification, a “stair-stepped bottom” of compartment 101. Pet. 46 (citing Ex. 1005, 3:12–13, 3:63–66, Figure 2; Ex. 1001, 4:24–31). Petitioner explains how the two syringes of Solazzo are arranged on its terraced bottom 11 to serve as the claimed mnemonic device. *Id.* at 47–48 (citing Ex. 1005, 3:63–66, Figures 1, 8; Ex. 1002 ¶¶ 210–16).

Patent Owner repeats its argument that the arrangement of Solazzo’s syringes at different heights fails to serve as an indicator of the order in which the syringes are used and fails to aid memory about the order of using the syringes. Prelim. Resp. 53–55 (cross-referencing argument relating to element 1e). For the reasons expressed in Part III.C.3.b)(3) above, we are not persuaded by Patent Owner’s argument.

*(5) 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 and Serany renders claim 1 unpatentable as obvious.

*4. Dependent Claims 2, 6–10, 16, and 17*

Petitioner identifies the portions of Solazzo and Serany that support its argument that dependent claims 2, 6–10, 16 and 17 are also obvious in view of Solazzo and Serany. Pet. 49–54 (citing Ex. 1005, 3:63–66, 4:21–25, Figures 1, 2, 8). Petitioner also supports its argument with testimony from Mr. Plishka and Dr. Yun. *Id.* (citing Ex. 1002 ¶¶ 222–225, 227–251; Ex. 1003 ¶¶ 20, 21).

Patent Owner does not separately argue that limitations introduced in dependent claims 2, 6–10, 16, and 17 are a basis for finding that any of these claims remain patentable over Solazzo and Serany. Prelim. Resp. 55. At this stage of the proceeding, we are persuaded that Petitioner has demonstrated a reasonable likelihood of proving that these claims would have been 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).

*5. Independent Claims 25 and 37 and Their Respective Dependent Claims 26–32 and 38–42*

Patent Owner presents arguments for the patentability of independent claims 25 and 37 that largely follow the arguments presented in support of the patentability of independent claim 1. *Compare* Prelim. Resp. 35–55



(addressing claim 1), *with* 55–59 (addressing claim 25), *and* 60 (addressing claim 37). We discern no meaningful differences between the arguments that Patent Owner presents relating to independent claims 25 and 37 when compared to its arguments relating to independent claim 1. At this stage of the proceeding, we disagree with Patent Owner’s arguments for the reasons given above in our analysis of claim 1 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 26–32 (depending from claim 25) or claims 38–44 (depending from claim 37) are a basis for finding that any of these dependent claims remain patentable over Solazzo and Serany. Prelim. Resp. 60. Accordingly, we also institute *inter partes* review of claims 25 and 37 and their respective dependent claims 26–32 and 38–42. However, the burden remains on Petitioner to prove unpatentability of each challenged claim. *Dynamic Drinkware*, 800 F.3d at 1378.

D. DEPENDENT CLAIMS 18, 19, 33–35, 43, AND 44:  
OBVIOUSNESS IN VIEW OF VARIOUS COMBINATIONS OF SOLAZZO,  
SERANY, DISSTON, AND FRANKS-FARAH

Petitioner also challenges claims 18, 19, and 35 as being unpatentable over Solazzo, Serany, and Franks-Farah. Pet. 54–55 (claims 18, 19), 85–86 (claim 35). Petitioner challenges claims 33, 34, and 42 as being unpatentable over Solazzo, Serany, and Disston. *Id.* at 78–85. Petitioner challenges claims 43 and 44 as unpatentable over Solazzo, Serany, Disston, and Franks-Farah. *Id.* at 86–87. 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. 34–60 (addressing merits of patentability only for independent claims 1, 25, and

37). Because we have determined that *inter partes* review is warranted in connection with numerous claims in view of Solazzo and Serany, we also institute *inter partes* review of claims 18, 19, 33–35, 43, and 44 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 at least one claim of the '088 patent is unpatentable as obvious. In accordance with the Court's decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018) and Office guidance,<sup>5</sup> we institute 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.

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<sup>5</sup> “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 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.”).

V. ORDER

For the reasons given, it is:

ORDERED that *inter partes* review of claims 1, 2, 6–10, 16–19, and 25–44 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.

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