

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 IPR2019-00109  
Patent 9,795,761 B2

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

COCKS, *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 1–9, 10–19, and 22–25 (the “challenged claims”) of U.S. Patent No. 9,795,761 B2 (Ex. 1001, “the ’761 patent”). 35 U.S.C. § 311. Medline Industries, Inc. (“Patent Owner”) timely filed a Preliminary Response. Paper 15 (“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.

### *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. 88; Paper 4, 2. The parties also identify petitions for *inter partes* review of claims of the U.S. Patent No. 9,745,088 patent (IPR2019-00035 and IPR2019-00036) as related matters. Pet. 88; Paper 4, 3. Patent Owner further identifies as related matters U.S. Patent Application Nos. 15/703,514; 15/684,787; 15/803,383; 13/374,509; and 15/640,224, which are continuations or continuations-in-part of the application leading to issuance of the ’761 patent. Paper 4, 2. Patent Owner further identifies U.S. Patent Application Nos. 14/265,920; 15/804,520; and 15/051,964 as related matters

because those applications “share similar disclosures and claim language” with the claims of the ’761 patent. *Id.* at 3.

*C. Prior Art Relied Upon*

Petitioner relies on the following references in asserting that the challenged claims are unpatentable:

Reference	Exhibit No.
U.S. Patent No. 7,278,987 B2 issued Oct. 9, 2007 (“Solazzo”)	1005
U.S. Patent No. 3,329,261 issued July 4, 1967 (“Serany”)	1006
U.S. Patent No. 6,840,379 B2 issued Jan. 11, 2005 (“Franks-Farah”)	1007
U.S. Patent No. 3,166,189 issued Jan. 19, 1965 (“Disston”)	1008

*D. Asserted Grounds of Unpatentability*

Petitioner contends that the challenged claims are unpatentable based on the following grounds:

References	Basis	Claims challenged
Solazzo, Serany, and Franks-Farah	§ 103	“1–9, 10–19, 23–25” (Pet. 31) <sup>1</sup>
Solazzo, Serany, Franks-Farah, and Disston	§ 103	3, 12, 22, and 24

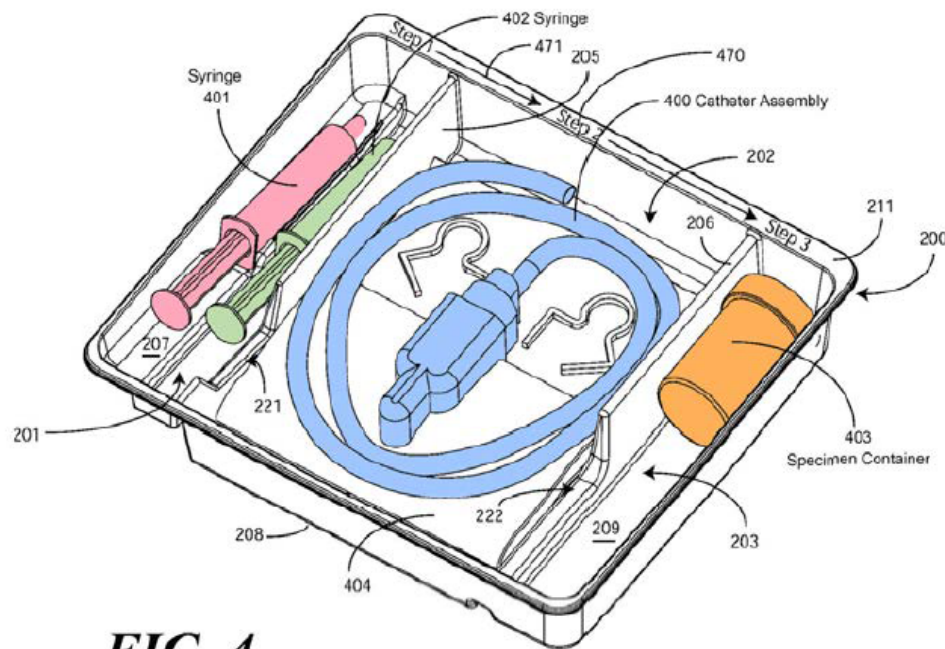
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<sup>1</sup> Although the Petition indicates that the ground of unpatentability based on Solazzo, Serany, and Franks-Farah is applied to claims “1–9, 10–19, 23–25,” review of the Petition reveals that claims 3, 12, and 24 are not discussed as a part of this ground.

In support of the above-noted grounds, Petitioner also relies on the Declaration testimony of Michael Plishka (Ex. 1002) and Dr. Edward Yun (Ex. 1003).

*E. The '761 Patent*

The '761 patent is titled “Medical Kit, Packaging System, Instruction Insert, and Associated Methods.” Ex. 1001, (54). The Specification describes tray 200 shown in Petitioner’s annotated and colorized version of Figure 4 (Pet. 17), which we reproduce below.

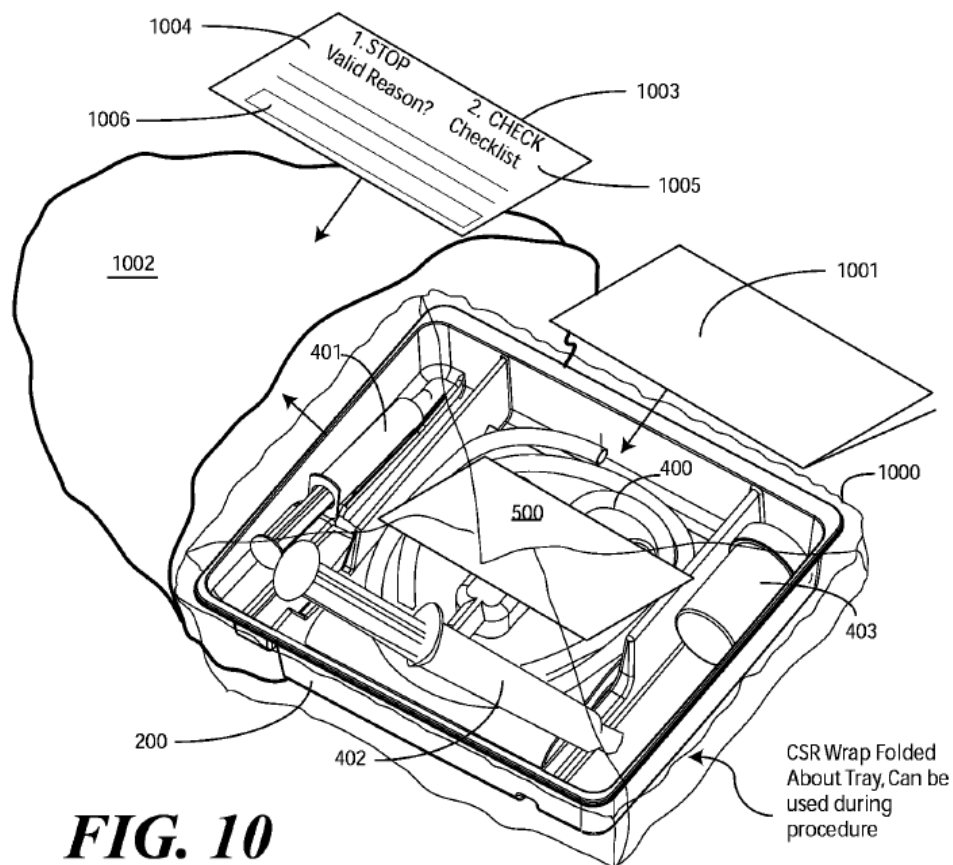


**FIG. 4**

Figure 4 “illustrates a medical procedure kit configured for a catheterization procedure in accordance with one or more illustrative embodiments of the invention.” Ex. 1001, 2:14–16. Tray 100 includes three compartments 201, 202, 203 adapted to accept various items used in a catheterization procedure. *Id.* at 7:54–64. First compartment 201 accommodates syringes 401, 402 (red, green) containing sterile water or

lubricants. *Id.* at 11:21–23. Second compartment 202 accommodates catheter assembly 400 (blue). *Id.* at 11:23–25. Third compartment 203 accommodates specimen container 403. *Id.* at 11:25–26. 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 11:26–45.

Figure 10 of the '761 patent is reproduced below.



**FIG. 10**

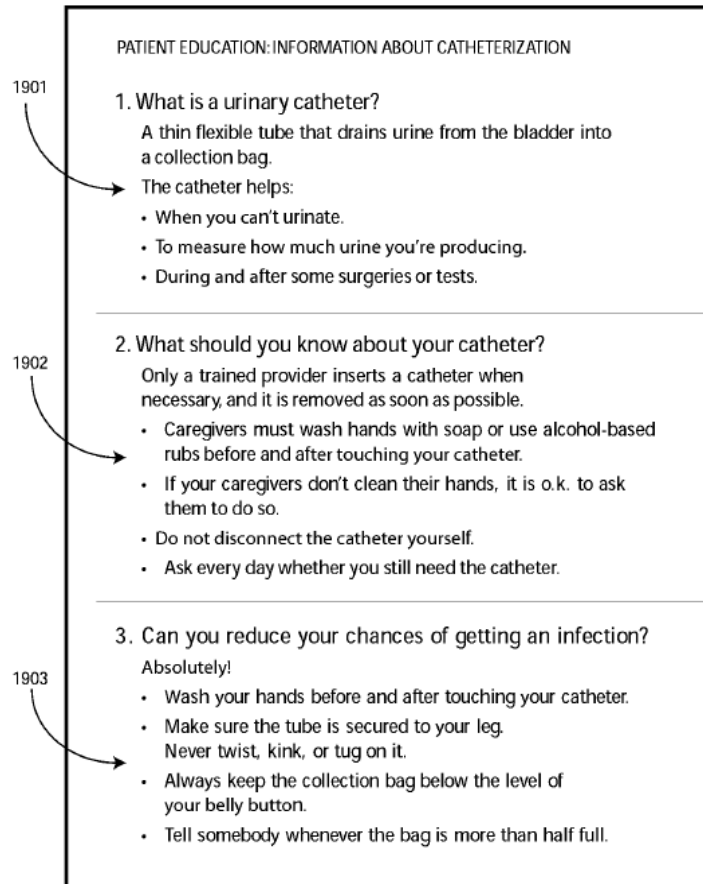
Figure 10 shows an “illustrative packaging arrangement for a medical procedure kit” including tray 200. *Id.* at 15:29–32. A Central Sterile Reprocessing (CSR) wrap 1000 may be folded around tray 200, and may be unfolded for use in to providing a sterile field in which tray 200 may sit during its use. *Id.* at 16:25–33. Figure 10 also shows that “patient aid” 500

may be contained within tray 200. *Id.* The content of patient aid 500 may include the following:

educational information corresponding to a medical procedure, patient care information corresponding to a medical procedure, information relating to a medical device, such as a urinary catheter, peripherally inserted central catheter, or wound dressing, that is applied to the patient, an illustrated guide depicting patient care for medical device, or combinations thereof.

*Id.* at 12:22–29.

Figure 19 of the '761 patent is reproduced below.



**FIG. 19**

Figure 19 illustrates an example of patient information that may be provided as a part of a patient aid. *Id.* at 23:8–10. The content of that patient information can include the following:

[I]nformation 1903 regarding how the patient can reduce the chances of getting an infection. This information 1903 can include a statement that the patient should wash their hands prior to touching the catheter assembly. The information 1903 may also include a statement that the drainage bag should always be kept at a level beneath the patient's navel, and that the patient should inform a helper when the bag is more than half full.

*Id.* at 23:25–33.

Claims 1, 10, 15, and 19 are the independent claims among the challenged claims. *Id.* at 27:47–30:57. Claim 1, which is illustrative, recites:

1. A tray configured to accommodate a Foley catheter, the tray comprising:

[a] a surface defining a single layer tray comprising at least two compartments separated by a barrier, the at least two compartments comprising:

[b] a first compartment supporting a first syringe and a second syringe at different heights based upon order of use in a Foley catheterization procedure;

[c] a second compartment to accommodate the Foley catheter; and

[d] the barrier separating the first compartment from the second compartment;

[e] the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter;

[f] further comprising a patient aid comprising post-procedure information, disposed on a first portion of the patient aid, for caring for the Foley catheter when applied to a patient.

*Id.* at 28:12–29 (with added letter designations a–f 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)*

Pursuant to 35 U.S.C. § 325(d), on behalf of the Director, we “may take into account whether, and reject the petition . . . because, the same or substantially the same prior art or arguments previously were presented to the Office.” Thus, § 325(d) permits us to exercise our discretion and reject or deny a petitioner in certain circumstances. The Board in its Trial Practice Guide Update (August 2018) emphasized that “[w]hether to deny institution of trial on the basis of 35 U.S.C. § 325(d) is a fact-dependent decision, in which the Board balances the petitioner’s desire to be heard against the interest of the patent owner in avoiding duplicative challenges to its patent.” See Trial Practice Guide Update, 11–12 (August 2018), available at <https://go.usa.gov/xU7GP>; see also Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989 (Aug. 13, 2018) (notice). The Board also pointed to certain non-exclusive factors that are evaluated in assessing whether denial of a petition under § 325(d) is warranted. *Id.* at 12 (citing *Becton Dickinson & Co. v. B. Braun Melsungen AG*, Case IPR2017-01586, slip op. at 17–18 (PTAB Dec. 15, 2017) (Paper 8) (informative)).

Those factors (“the *Becton* factors”) include the following:

1. the similarities and material differences between the asserted art and the prior art involved during examination;
2. the cumulative nature of the asserted art and the prior art evaluated during examination;



3. the extent to which the asserted art was evaluated during examination;
4. the extent of the overlap between the arguments made during examination and the manner in which a petitioner relies on the prior art or a patent owner distinguishes the prior art;
5. whether a petitioner pointed out sufficiently how the Office erred in evaluating the asserted prior art; and
6. the extent to which the additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.

*Id.* at 12.

In assessing those factors, we first consider the relevant prosecution history of the '761 patent.

*1. Prosecution History of the '761 Patent*

Patent Application No. 13/153,265 (“the '265 application”) matured into the '761 patent. The '265 application was filed on June 3, 2011 and initially included 47 claims. Ex. 1004, 516–521.<sup>2</sup> After the examiner issued a “Restriction Requirement,” the applicants elected claims 1–8 for examination and cancelled claims 9–47. *Id.* at 395–396. Claim 1, as it initially appeared, read as follows:

1. A pediatric patient aid, comprising:  
a set of patient information disposed on a first portion of the pediatric patient aid, the set of patient information comprising post-procedure information for caring for a medical device applied to a patient; and  
an activity card disposed on a second portion of the pediatric patient aid.

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<sup>2</sup> The page numbers referenced for Exhibit 1004 are those appearing on the bottom right hand side of each page.

*Id.* at 516.

During the course of prosecution, the applicants amended claim 1 to include the limitation “the pediatric patient aid comprising a request that a recipient be like a character depicted on the activity card.” *Id.* at 349. After a final rejection of the claims of the ’265 application was issued, the applicants appealed to the Patent Trial and Appeal Board (“Board”). *Id.* at 274–295. The Board ultimately issued a Decision affirming the examiner’s rejection of the claims. *Id.* at 217–224. In so affirming, the Board reasoned in part that “the specific type of request constitutes non-functional descriptive [material] that may not be relied upon for patentability. *Id.* at 221 (citing *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004)).

In response to the Board’s Decision, Applicants filed a “Request for Continued Examination” (“RCE”) adding new claims, such as claim 48. Ex. 1004, 103–113. Evidently, a new examiner was designated to handle the RCE. After a telephonic interview (*id.* at 68), the new examiner generated an “Examiner’s Amendment” adding to claim 48 the limitation “further comprising a patient aid comprising post-procedure information, disposed on a first portion of the patient aid, for caring for the Foley catheter when applied to a patient.” (*id.* at 74–75). The examiner then allowed the pending claims of the ’265 application, including claim 48, which became claim 1 of the ’761 patent. *Id.* at 79. The examiner provided a statement of the reasons for allowance, which included the following:

The closest prior art (previously cited Ehrenpreis and Stump, in addition to Stoller, US Patent Application Publication No. 2006/0271019 and Solazzo, US Patent Application Publication No. 2006/0009742) discloses a tray for a Foley catheter, syringes, and lubricant. The prior art also discloses an instructional patient aid. However, the prior art does not teach

or fairly suggest the particular combination and arrangement of the claimed compartment with the particular compartments, barriers, and items in combination with the claimed patient aid.

*Id.* at 79–80.

## 2. Discussion

Patent Owner argues at length why its analysis of the six factors set forth in *Becton* weighs in favor of discretionarily denying the Petition under § 325(d). Prelim. Resp. 11–29. On this record, however, it is difficult to reconcile the examiner’s assessment of the reason for the allowance of the claims of the ’761 patent in light of the record before us in this proceeding.

We focus first on *Becton* factor 5. That factor is directed to “whether a petitioner has pointed out sufficiently how the Office erred in evaluating the asserted prior art.” *Becton*, slip op. at 17. Petitioner contends that the “patient aid” feature that formed the underlying basis for the allowance of claim 1 of the ’761 patent is not entitled to patentable weight.<sup>3</sup> Pet. 28. Intrinsic to that contention is the assertion that the examiner erred in affording that feature patentable weight. Petitioner analogizes the “patient aid” to “printed instructions” that were at issue in *In re Ngai*. *Id.* at 29. In that case, the Federal Circuit determined that an applicant was not entitled “to patent a known product by simply attaching a set of instructions to that product.” *In re Ngai* 367 F.3d at 1339. On this record, we find the analogy credible. As this stage of the proceeding, and in the context of the ’761 patent, we understand a “patient aid” as amounting simply to a sheet of paper or card on which information, such as “post procedure information”

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<sup>3</sup> Petitioner also makes the same contention for similar features added to each of claims 10, 15, and 19. Pet. 28.

(claim 1), resides. That does not lend itself readily to a conclusion that the “patient aid” feature is anything more than “non-functional descriptive” material akin to the Board’s prior finding during prosecution of the ’265 application. *See* Ex. 1004, 221. In our view, such circumstance, in which a petitioner has pointed out sufficiently how the Office erred in evaluating the asserted prior art, weighs against a discretionary denial of a trial.

Factors 1–4 relate generally to the extent an examiner considered prior art and arguments during the course of examination. It is clear that, in allowing the claims of the ’761 patent, the examiner considered the teachings of Solazzo, which is a reference that underscores Petitioner’s asserted grounds of unpatentability. Indeed, the examiner characterized Solazzo as the “closest prior art.” *Id.* at 79. Petitioner, however, also now points to Frank-Farah as accounting for the “patient aid” feature (and other similar features) of the claims, in the event that such feature should be afforded patentable weight. Although Franks-Farah is one of the numerous references cited on the face of the ’761 patent, there is no indication in the record at hand that the examiner ever meaningfully evaluated the content of Franks-Farah when assessing the patentability of the claims of the ’761 patent. As discussed in more detail in Section III below, we are satisfied at this time that Petitioner has credibly set forth how Franks-Farah teaches the “patient aid” recited in the claims, and Petitioner reasonably explains why and how a person of ordinary skill in the art would have combined Franks-Farah’s teachings with those of Solazzo.<sup>4</sup>

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<sup>4</sup> We note that Patent Owner in its Preliminary Response has not advanced any arguments that the prior art, including Franks-Farah, does not disclose the claimed “patient aid” or that the “patient aid” feature distinguishes any claim over the prior art. Although Patent Owner was not required to file a

Factor 6 pertains to “the extent to which the additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.” In support of the Petitioner’s assessment of the disclosure of Franks-Farah, Petitioner also relies on new testimonial evidence from Michael Plishka (Ex. 1002) and Dr. Edward Yun (Ex. 1003). The examiner did not have the benefit of that testimonial evidence during the examination phase. We conclude that factor 6 also does not weigh in favor of a discretionary denial of a trial.

Based on our review of the record before us, including 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 [’761] patent and other related patents with common claim limitations.” Prelim. Resp. 30. 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 ’761 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.

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Preliminary Response, that it did so but opted not to argue patentability of the claims on the basis of the recited “patient aid” does not favor Patent Owner’s § 325(d) position.

*Id.* at 30–31 (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. 30–33 (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. 31–33 (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 significantly.

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 Construction

“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>5</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

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<sup>5</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).



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).

Petitioner contends that “no term or phrase requires specific construction to find that the challenged claims are invalid.” Pet. 25.

Petitioner, however, contends that Patent Owner, in the related district court proceeding, advanced constructions for three claims terms. In that regard, Petitioner provides the following table:

Claim Term	Patent Owner Construction
Barrier	structure that separates one compartment from another and prevents or blocks movement between the two
Mnemonic device	feature intended to assist in the memory, such as ordering items left to right or top to bottom
Lubricating jelly application chamber/ compartment	a compartment or channel where lubrication is applied

Pet. 26. There is no apparent disagreement between the parties that the above-noted terms should take on the above-noted meanings in this proceeding. We determine that it is not necessary to express an opinion about the meaning of any claim term or phrase at this stage of the proceeding.

*B. Obviousness in View of Solazzo, Serany, and Franks-Farah*

Petitioner contends that claims “1–9, 10–19, 23–25” (Pet. 31) are unpatentable over Solazzo, Serany, and Franks-Farah. Claims 1, 10, 15, and 19 are independent claims. Claim 1 is drawn to a “tray configured to

accommodate a Foley catheter.” Claims 10, 15, and 19, are similar directed to, respectively, a “Foley catheter container,” a “tray for a Foley catheter,” and a “single-layer tray.” The recited content of those trays/container generally are similar as between each claim. The Patent Owner argues that the combination of Solazzo, Serany, and Frank-Farah fails to render any claim unpatentable based on obviousness. Prelim. Resp. 35–60. For the reasons expressed below, we determine that Petitioner has demonstrated a reasonable likelihood of establishing that at least one claim of the ’761 patent is unpatentable.

### *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.

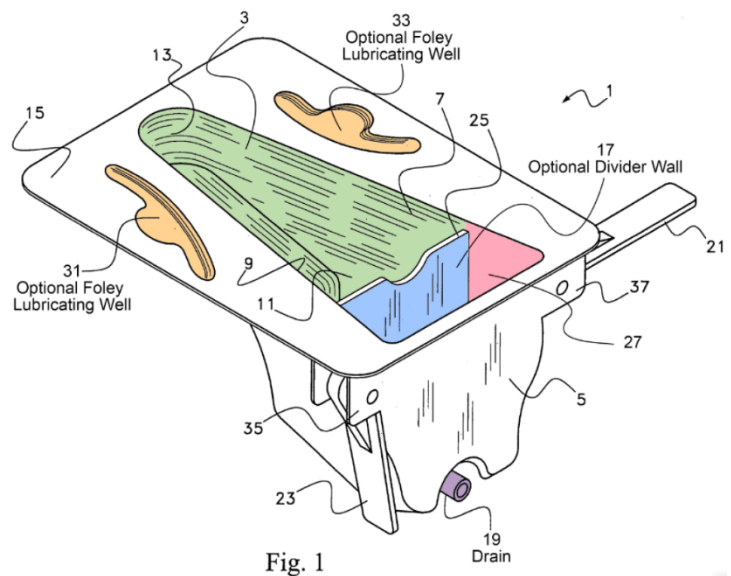
Pet. 32; *See* Ex. 1005, 4:15–25; Fig.1. Petitioner’s annotated version of

Solazzo’s Figure 1 is a

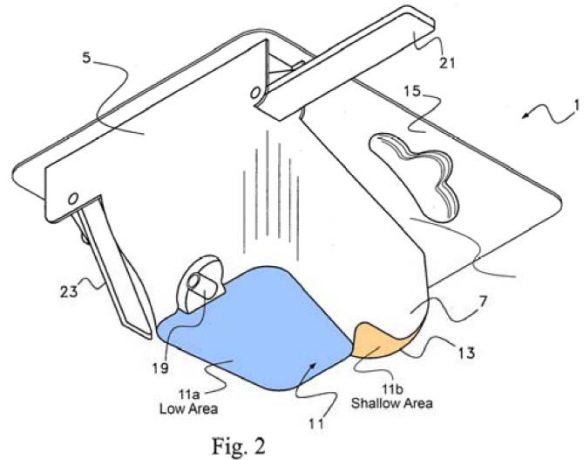
perspective view of the catheterization and irrigation tray illustrating its major features.

Ex. 1005 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

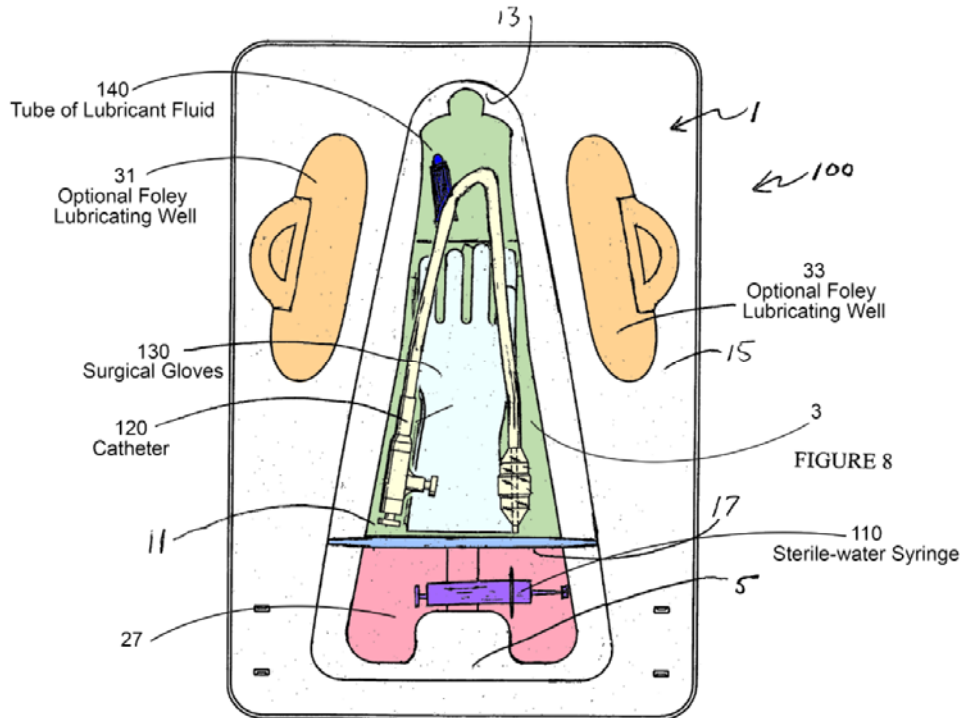
passing over top 25 of wall 17. *Id.* at 4:15–20.



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. Pet. 34; Ex. 1005, 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. Pet. 35; Ex. 1005, 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. Ex. 1005, 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.

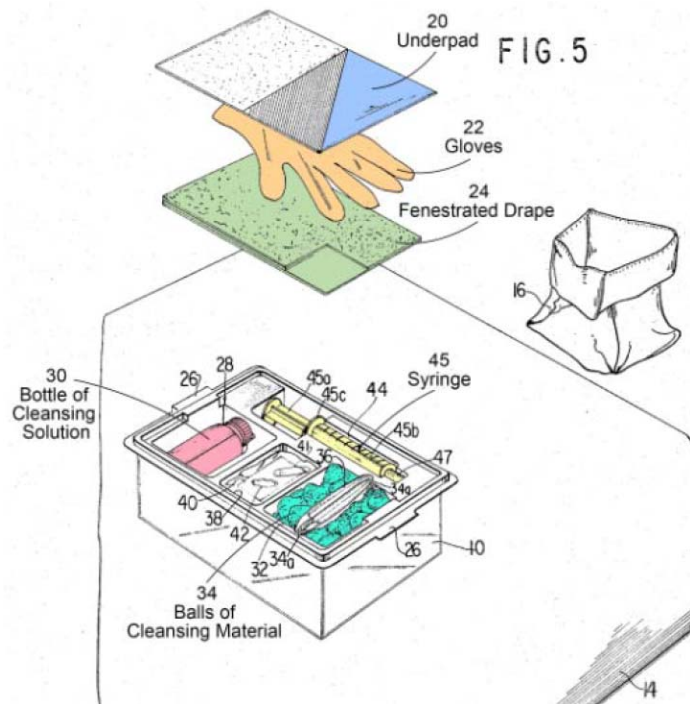
In use, the recessed area 3 and compartment 27 fit between the legs of a “patient requiring an urological procedure” while flange 15 and wing supports 21, 23 rest atop the legs while the patient is seated. *Id.* at 1:8–12, 3:66–4:10, 4:26, 4:32–33; Fig.1. A surgeon proceeds to “evacuate the bladder of 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.

Pet. 36.



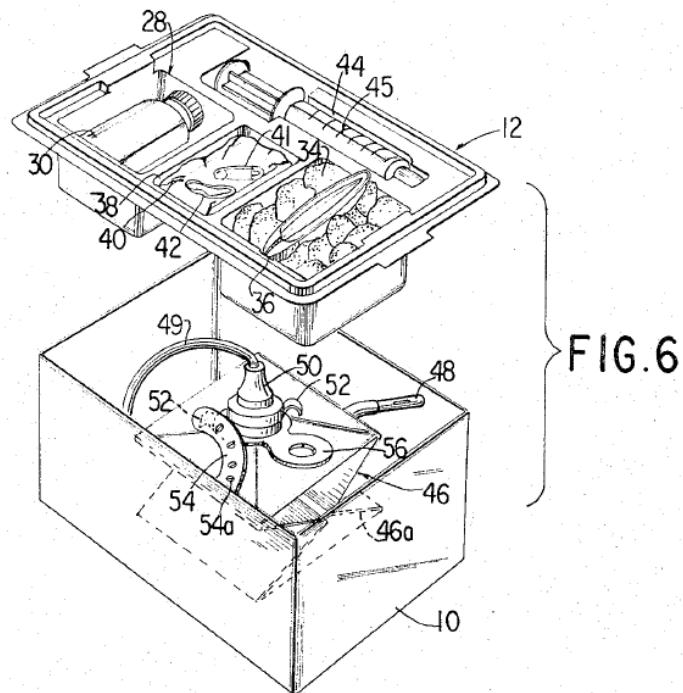
For example, prefilled syringe 45 (yellow) of sterile water in depression 44, which includes indentations 44d along the sides to accommodate the syringe's flange. Ex. 1006, 2:40–41, 3:6–22; Figs. 6–7. Serany's package further includes a waterproof underpad 20 (blue), gloves 22 (orange), fenestrated drape 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 that is preconnected to a 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. The 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 annotated Figure 6. *Id.* at 3:33–35.

### 3. Overview of Franks-Farah

Franks-Farah is directed to “[a] method and system for performing intermittent male catheterization by a patient, a patient’s caregiver, or a health care provider[.]” Ex. 1007, (57). Franks-Farah further describes that “[t]he system contains apparatus for at least one intermittent male catheterization and includes at least one male catheter, antibacterial soap, a lubricant, step-by step-instructions, and a container, where the above named items are positioned inside the container.” *Id.* Examples of such step-by-step instructions appear in Figures 2A and 2B, which are reproduced below.

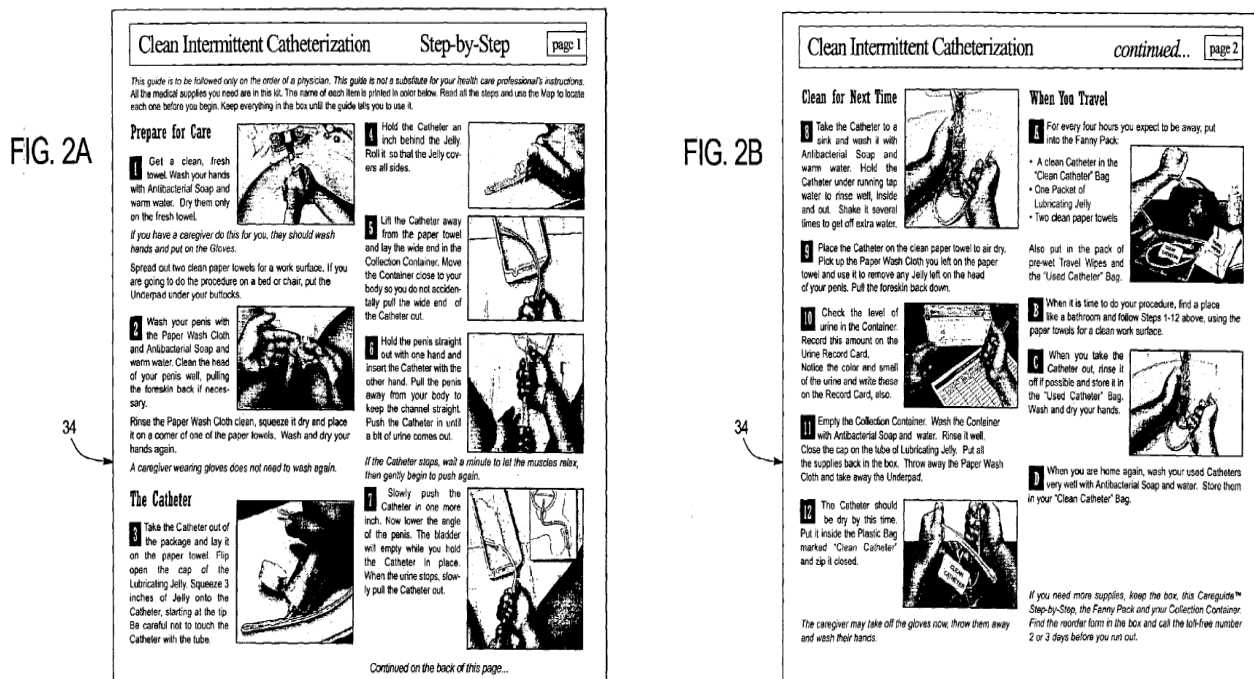


Figure 2B depicts a plan view of step-by-step instructions. *Id.* at 3:12–13. Franks-Farah provides that those instructions include the following:

[P]reparing and caring for the male catheterization site. Preparing and caring for the catheterization site includes: (I) obtaining a clean, fresh towel; (II) washing using the antibacterial liquid soap 24 and warm water, and using the clean towel for drying, (III) finding a safe, flat, uncluttered, solid surface; (IV) putting on the gloves 12 only if the catheterization is being performed by a user other than the patient which includes: (a) taking a pair of gloves 12 out of the box 40; and (b) putting them on; (V) preparing the Surface which includes: (a) obtaining two clean, fresh paper towels; (b) opening the two paper towels; (c) placing the opened paper towels on the Surface; (d) taking a protective underpad 18 out of the box 40; (e) opening the protective underpad 18; and (f) placing the opened protective underpad 18 under the patient's buttocks and near the opened paper towels; (VI) cleaning the catheter site which includes: (a) taking a paper wash cloth or disposable wipe 16 out of the box 40; (b) taking the container of antibacterial Soap 24; (c) Squeezing out approximately one or two drops of Soap 24 onto the center of the wipe 16; and (d) gently washing the site using the wipe 16, the soap 24 and warm water; (VII) rinsing clean the wipe 16 which includes: (a) rinsing the wipe 16; (b) Squeezing out the excess water, leaving the wipe 16 damp; and (c) placing the damp wipe 16 on one corner of the paper towel; and (VIII) washing using the antibacterial soap 24 as described previously.

*Id.* at 5:13–40.

Thus, Franks-Farah sets forth that its instructions provide numerous steps detailing information and procedural guidance for a patient in connection with a catheterization procedure.

#### *4. Independent Claim 1*

##### *a) Petitioner's Argument and Evidence*

Petitioner argues that the combined teachings of Solazzo, Serany, and Franks-Farah render claim 1 unpatentable for obviousness. Pet. 38–54. Petitioner contends that Solazzo describes a tray having a surface (claim

element 1[a]) and two compartments (compartments 3 and 27) (claim elements 1[b] and 1[c]) separated by a barrier (divider wall 17) (claim element 1[d]). *Id.* at 38–39, 48 (citing Ex. 1005, 2:61–63, Figures 1, 8; Ex. 1002 ¶¶ 156–60, 191–92.). Petitioner also contends that Solazzo includes first and second syringes (“inflation syringe” and “irrigation syringe”). *Id.* at 40 (citing Ex. 1005, 4:41–46). To the extent that the claims require a syringe of lubricant, Petitioner contends that it would have been obvious to one of ordinary skill in the art to incorporate a lubricant syringe in lieu of tube of lubricant 140 disclosed in Solazzo. *Id.* at 40–41 (citing Ex. 1005, 4:41–46, Ex. 1002 ¶¶ 165–67; Ex. 1003 ¶ 22). Petitioner also reasons that, in view of Serany’s teachings, a skilled artisan would have known that the syringes may reside in first compartment 27. *Id.* at 42–43 (citing Ex., 1006, 1:31–35; 2:57–6; Ex. 1002, ¶¶ 173–74).

With respect to the requirement that the syringes be “at different heights based upon order of use in a Foley catheterization procedure,” Petitioner argues that Solazzo discloses a tray with a “terraced bottom” having a “shallow” portion and a “low” portion that a person of ordinary skill in the art would understand as the areas receiving the syringes. Pet. 44–46 (citing Ex. 1005, 3:63–66; Ex. 1002 ¶¶ 178–88; Ex. 1003 ¶ 28). Petitioner also explains how Solazzo sets forth that a Foley catheter is within the second compartment (compartment 27). *Id.* at 46–47 (citing Ex. 1005, Fig. 8; Ex. 1002 ¶¶ 189–90).

In connection with the claim requirement that the first compartment defines a lubricating jelly application chamber (element 1[e]), Petitioner takes the position that a skilled artisan would have known Solazzo’s compartment 27 would function as a “lubricating jelly application chamber.”



*Id.* at 49–50 (citing Ex. 1005, 4:21–25; Ex. 1003 ¶¶ 21–22; Ex. 1002 ¶¶ 197–99). Petitioner also contends that Serany’s teachings support that position. *Id.* at 50–51 (citing Ex. 1006, 4:2–8) Ex. 1002 ¶¶ 200–02).

Lastly, as to the recitation of a “patient aid” (claim element 1[f]), Petitioner expresses that the element is not entitled to patentable weight. *Id.* at 51. Alternatively, Petitioner points to the teachings of Franks-Farah. Pet. 51–54. To that end, Petitioner contends that Franks-Farah’s “step-by-step instructions” shown, for instance in its Figures 2A and 2B, constitute a “patient aid” contained with a catheter tray and which includes procedural and post-procedural information in connection with a catheterization procedure. *Id.* (citing Ex. 1007, 1:51–53; 2:5–7; 4:13–17; 7:15–23; Figs. 2A, 2B, 4; Ex. 1002 ¶¶ 204–24). Petitioner also contends that a skilled artisan would have had adequate motivation to include such a patient aid in the catheter tray of Solazzo. *Id.* at 54.

*b) Analysis of Patent Owner’s Counterarguments*

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

*(1) “a second syringe”(portion of element 1[b])*

Element 1[b] refers to each of “a first syringe and a second syringe.” As noted above, Petitioner contends that Solazzo expressly describes that its catheterization/irrigation tray kit includes an inflation syringe, an irrigation syringe, and a tube containing lubricant. Pet. 34 (citing Ex. 1005, 3:15–24, 4:41–46). Although Petitioner does identify two syringes as a part of Solazzo’s disclosure, it is apparent that in accounting for the claimed second syringe, Petitioner relies on an assessment 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. Petitioner's reasoning in that respect is that an ordinarily skilled artisan would have considered 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 40–41 (citing Ex. 1002 ¶¶ 165–67; Ex. 1003 ¶ 22).

Patent Owner responds that the prior fails to describe or suggest a second syringe that is a "lubricant syringe." Prelim. Resp. 38–42. Patent Owner argues that Solazzo's use of a tube for lubricant is sufficient due to the size of its wells 31, 33 and that Petitioner does not explain why a lubricant syringe would have been needed. *Id.* at 39. At this stage of the proceeding, Patent Owner does not support its contentions sufficiently with citations to evidence. Instead, we consider those contentions at this time to be unpersuasive attorney argument not supported by evidence. Petitioner, however, bases its position, at least in part, on the Declarations of Mr. Plishka (Ex. 1002) and Dr. Yun (Ex. 1003), each of whom testifies that skilled artisans would have known that a "lubricant syringe" is a known, preferable option to a tube in a catheterization kit. *See* Ex. 1002 ¶¶ 165–167 (citing Ex. 1010, 52; Ex. 1015); Ex. 1003 ¶ 22 (citing Ex. 1010, 53).

On the record currently before us, we credit the testimony of Petitioner's declarants over Patent Owner's unsupported attorney argument and determine that Petitioner has demonstrated a reasonable likelihood that it will prove that Solazzo describes or suggests a second syringe that contains lubricant.

(2) A “first compartment supporting a first syringe and a second syringe” (portion of element 1[b])

Petitioner takes the position that a person of ordinary skill in the art would have appreciated that Solazzo’s compartment 27 (as the “first compartment”) may contain multiple syringes. Petitioner bases that position in part on the following: (1) Solazzo’s disclosure of multiple syringes including inflation syringe 10 and an “irrigation syringe” in Solazzo’s tray (Pet. 41–42 (citing Ex. 1005, 3:22)); (2) the depicted location in Solazzo’s Figure 8 of inflation syringe 110 within compartment 27 (*id.* at 42); (3) Serany’s disclosure of placing multiple items in one compartment (*id.* (citing Ex. 1006, 1:31–35; 2:57–61)); (4) the Declaration testimony of Mr. Plishka pertaining to Serany’s teachings of grouping syringes in one compartment (*id.* at 43 (citing Ex. 1002 ¶¶ 173–74)).

Patent Owner generally is of the view that the prior art does not show a first compartment that contains or supports each of a first syringe and a second syringe. In particular, Patent Owner contends that Petitioner has not demonstrated adequately that Solazzo’s compartment 27 would support multiple syringes. Although Patent Owner discounts the above-noted record evidence on which Petitioner relies, at this time we are not persuaded by Patent Owner’s arguments that such evidence should be regarded generally as “insufficient” to warrant institution of *inter partes* review. *See* Prelim. Resp. 42–43.

(3) “Different heights” and “order of use” (portion of element 1[b])

Element 1[b] refers to the requirement that first and second syringes are supported in a first compartment “at different heights based upon order of use in a Foley 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. 43–46 (citing Ex. 1005, 3:63–66, Figure 2; Ex. 1002 ¶¶ 178–88; Ex. 1003 ¶ 28).

Petitioner contends that Solazzo’s placement of these two syringes at different depths constitutes the above-quoted claim feature 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.* 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.* at 42–43 (citing Ex. 1006, 1:31–35; Ex. 1002 ¶¶ 173–174).

Patent Owner argues that Solazzo “is not designed in a manner that the components are positioned within the tray in accordance with their order of use.” Prelim. Resp. 45. Patent Owner also argues the Petition’s explanation in connection with the pertinent limitations suggests that “the syringes in Solazzo appear to be tossed haphazardly into Solazzo’s well 27 and are not secured.” *Id.* at 44. Patent Owner cites no evidence for this contention. *Id.* Petitioner offers testimonial evidence to the contrary. *See, e.g.,* Ex. 1002 ¶¶ 173–87). We are mindful that Patent Owner has not yet had opportunity to cross-examine Petitioner’s declarants on this issue (or

any other disputed issues), and that Patent Owner has not yet offered any countervailing testimony of its own.

We are cognizant that Petitioner accounts for the “order of use” feature of claim 1, in part, through recourse to the teachings of Serany. Serany clearly provides that as a part of its catheterization package, “all the components [are] arranged in logical step-by-step order to facilitate the nurse’s or physician’s task.” Ex. 1006, 1:31–35. It is clear that Petitioner and its declarant, Mr. Plishka, base their position that a skilled artisan would have positioned syringes within a catheter tray on that teaching in conjunction with the teachings of Solazzo. *See, e.g.*, Pet. 43; Ex. 1002 ¶¶ 173–74. At this time, we are persuaded that Petitioner as accounted for the “order of use” aspect of claim 1, for purposes of institution of *inter partes* review. We also credit the supporting testimony of Mr. Plishka in that regard. Accordingly, on this record, we are satisfied that Petitioner has accounted for the “different heights” and “order of use” aspects of claim 1.

*(4) Element 1[e]*

Element 1[e] of claim 1 recites the feature of “the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter.” Although Petitioner contends that the feature should not be given patentable weight (Pet. 26–28), Petitioner also contends that the feature is met by the combined teachings of Solazzo and Serany (*id.* at 49–51). With respect to the latter contention, Petitioner notes that Solazzo discloses separate lubricating wells 31 and 33, but also notes that such wells are characterized in Solazzo as “optional.” *Id.* at 49 (citing Ex. 1005, 4:21–25). Petitioner asserts that a skilled artisan would have “recognized that other compartments of the tray of Solazzo, including compartment 27 would also

have functioned as a “*lubricating jelly application chamber*.” *Id.* at 49. In support of the assertion Petitioner points to the Declaration testimony of Dr. Yun and Mr. Plishka. *Id.* (citing Ex. 1003 ¶¶ 21–22); *id.* at 50 (citing Ex. 1002 ¶¶ 197–199).

Petitioner also points to Serany’s teaching of a compartment that “conveniently houses and stores the accessories to provide protection against damage during shipment and make such accessories readily available while at the same time facilitating their use.” *Id.* at 50 (citing Ex. 1006, 4:2–8). Petitioner reasons that “[a] person of ordinary skill in the art would have been motivated by Serany to use compartment 27 of Solazzo to have a multi-purpose functionality: both as place to *store* the lubricant 140 and as a location to *lubricate* the catheter within the tray.” *Id.* at 50–51 (citing Ex. 1002 ¶¶ 200–02).

Patent Owner disagrees that the teachings of Solazzo and Serany satisfy element 1[e]. Prelim. Resp. 50–53. We are mindful that Patent Owner discounts Petitioner’s position as to that element on assertions such as that the position “makes little sense” (*id.* at 51), is “inconsistent,” (*id.*), is “inchoheren[t],” (*id.* at 53) or would provide “waste” of lubrication (*id.*). Patent Owner’s arguments, however, do not address squarely the evidence offered by Petitioner that a skilled artisan reasonably would regard Solazzo’s compartment 27 as a viable location for the application of lubricating jelly. That evidence includes: (1) Solazzo’s own teachings of variability in the contents and use of its disclosed compartments or wells; (2) Serany’s teachings that Petitioner offers as suggesting “multi-purpose functionality” of its compartments (Pet. 50–51); (3) the testimony of both Mr. Plishka and

Dr. Yun that a skilled artisan would recognize Solazzo's compartment 47 as suitable for application of lubricating jelly.

We have considered Patent Owner's argument as to element 1[e]. At this time, however, we credit the testimony of Petitioner's declarants as to what a person of ordinary skill in the art would have understood from the teachings of the prior art. Accordingly, we conclude that Petitioner has accounted adequately for that element on the present record.

*(4) Element 1[f]*

Element 1[f] includes "a patient aid comprising post-procedure information, disposed on a first portion of the patient aid, for caring for the Foley catheter when applied to a patient." As discussed above, Petitioner points to Franks-Farah as disclosing a "patient aid" associated with a catheterization tray. Pet. 51–54. More particularly, Petitioner points to the "step-by-step" instructions appearing in Figure 2A and 2B of Franks-Farah as containing a patient aid with "post procedural information." *Id.* at 52–53. Petitioner's declarant, Mr. Plishka, also characterizes the content of the step-by-step instructions as including "post-procedural information" for a patient after a catheterization procedure. *See, e.g.*, Ex. 1002 ¶¶ 209–211. Petitioner further contends that a person of ordinary skill in the art would have had adequate reason to incorporate such instruction in Solazzo's catheterization tray to provide guidance, for instance, pertaining to "reducing catheter related infections" and the "importance of monitoring urine flow." *Id.* at 53–54 (citing Ex. 1007, 1:51–53; 4:13–17; Ex. 1002 ¶¶ 212–224). Patent Owner does not offer any arguments pertaining to the "patient aid" feature of the claims in connection the ground of unpatentability that are advanced

by Petitioner. On this record, we are satisfied that Petitioner has accounted adequately for that feature.

*(5) Remaining elements of claim 1*

Patent Owner does not provide any separate arguments for any other of the elements or features of claim 1. We have considered the Petition and its underlying supporting documents and conclude that Petitioner has shown adequately where those elements are found in the prior art for purposes of instituting *inter partes* review.

*(6) Objective Indicia of Non-obviousness*

As explained in Part II.B above, although Patent Owner indicated that it contends in the *Medline III* Litigation that objective indicia of non-obviousness weigh against a finding that the claims of the '761 patent would have been obvious, Patent Owner has not proffered admissible evidence of those objective indicia in this proceeding. Accordingly, we do not yet address or weigh objective indicia of nonobviousness in this Decision.

*c) Conclusion*

We have considered the record before us, including the Petition and Patent Owner's Preliminary Response. We conclude that Petitioner has disclosed adequately where all the features of claim 1 are found in the prior art and explained reasonably how a person of ordinary skill in the art would combined the teachings of the prior art. For the reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood of proving that the combination of Solazzo, Serany, and Franks-Farah renders claim 1 unpatentable for obviousness.



*5. Independent claim 10*

Independent claim 10 is generally drawn to subject matter that corresponds to that of claim 1. Similar to claim 1, Petitioner contends that independent claims 10 and 19 are unpatentable over Solazzo, Serany, and Franks-Farah. Petitioner supports its argument in that respect in similar fashion as for claim 1. Pet. 66–71. Patent Owner makes reference to its arguments as to claim 1 in connection with its challenge in connection with claim 10. Prelim. Resp. 56. For similar reasons as those discussed above, at this stage of the proceeding, we do not find those challenges persuasive. We conclude that Petitioner has shown a reasonable likelihood of success in showing that claim 10 is unpatentable based on Solazzo, Serany, and Franks-Farah.

*6. Dependent claims 2–4, 6–8, 11, and 13*

Claims 2–4 and 6–8 ultimately depend from claim 1. Claims 11 and 13 ultimately depend from claim 10. Petitioner identifies where it believes all the added features of those dependent claims are found in the prior art. Pet. 54–60, 62–65, and 71. Patent Owner relies on its arguments pertaining to independent claims 1 and 10, and does not present separately any arguments for dependent claims 2–4, 6–8, 11, and 13. Having reviewed the record before us, we conclude that, at this stage of the proceeding, Petitioner has accounted adequately for the features required by claims 2–4, 6–8, 11, and 13.

*7. Dependent claims 5, 9, and 14*

Claims 5 and 9 ultimately depend from claim 1. Claim 14 ultimately depends from claim 10. Claims 5, 9, and 14 add limitations that Patent Owner characterizes as “printed instructions about applying lubrication from

one of the syringes onto the catheter within the first compartment.” Prelim. Resp. 55. Petitioner contends that the “printed instructions” recited in claims 5, 9, and 14 should not be given patentable weight. Pet. 60–61. Alternatively, Petitioner points to Franks-Farah’s disclosure of “self-care documentation” pertaining to the application of “Lubricating Jelly” onto a catheter, and contends that a skilled artisan would have had adequate reason to combine such documentation with Solazzo’s tray. *Id.* at 61–62 (citing Ex. 1005: 4:46–48; Ex. 1002 ¶¶ 264–66). Petitioner, thus, concludes that the combined teachings of the prior art satisfy claims 5, 9, and 14.

Patent Owner generally disagrees that Petitioner has shown the unpatentability of claims 5, 9, and 14. Prelim. Resp. 55–56. Patent Owner, however, does not address with any specificity the above-noted content of Franks-Farah on which Petitioner relies, or its application to the teachings of Solazzo and Serany. On this record, we conclude that Petitioner has made an adequate showing that warrants institution of *inter partes* review as to those claims.

#### 8. Claims 15–18

Petitioner contends that claims 15–18 are unpatentable over Solazzo, Serany, and Franks-Farah. Independent claim 15 is drawn to a “tray for a Foley catheter” and includes features that are similar or common to those discussed above in conjunction with claim 1.<sup>6</sup> Claim 15, however, also adds a feature pertaining to a “base member defining a mnemonic device indicating which of the first syringe or the second syringe should be used to dispense lubricating jelly disposed in one of the first syringe or the second

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<sup>6</sup> Claims 16–18 ultimately depend from claim 15.

syringe into the first compartment.” As noted above, the parties seemingly agree that a “mnemonic device” includes a “feature intended to assist the memory.” Patent Owner contends that Solazzo is silent as to any such feature and that Petitioner has “failed to demonstrate that the combined prior art discloses the claimed ‘mnemonic device.’” Prelim. Resp. 57–59.

As discussed above, at this time, we are persuaded that Petitioner has demonstrated a reasonable likelihood of proving that numerous claims of the ’761 patent would have been obvious, and that institution of trial on those claims is warranted. We also institute trial based on the challenge to claims 15–18.<sup>7</sup> We, however, do not further assess the merits of Patent Owner’s challenge to claim 15 and leave such further assessment to the trial. The burden remains on Petitioner to prove the unpatentability of each challenged claim. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

#### 9. Claims 19 and 23–25

Petitioner contends that claims 19 and 23–25 are unpatentable over Solazzo, Serany, and Franks-Farah. Independent claim 19 is drawn to a “single-layer tray” and includes features that are similar or common to those

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<sup>7</sup> We institute trial on all grounds and all claims. See *AC Techs v. Amazon.com, Inc.*, 912 F.3d 1358, 1364 (Fed. Cir. 2019) (“[I]f the Board institutes an IPR, it must similarly address all grounds of unpatentability raised by the petitioner.”); see also *Guidance on the impact of SAS on AIA trial proceedings* (April 26, 2018) <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial> (“As required by the [*SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018)] decision, the PTAB will institute as to all claims or none. At this time, if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition.”);

discussed above in conjunction with claim 1.<sup>8</sup> Claim 19, however, also adds a feature that the first compartment comprises “one or more recesses for accommodating flanges of one or more of the first syringe or the second syringe.” Patent Owner contends that “Petitioner has failed to show that Solazzo alone discloses ‘one or more recesses’ and that Petitioner has “not met its burden of showing that [the limitation] is obvious over the asserted prior art.” Prelim. Resp. 60–64.

Again, as discussed above, at this time, we are persuaded that Petitioner has demonstrated a reasonable likelihood of proving that numerous claims of the ’761 patent would have been obvious, and that institution of trial on those claims is warranted. We also institute trial based on the challenge to claims 19 and 23–25. *See AC Techs*, 912 F.3d at 1364. We, however, do not further assess the merits of Patent Owner’s challenge to claims 19 and 23–25 and leave such further assessment to the trial.

*C. Obviousness in View of Solazzo, Serany,  
Franks-Farah, and Disston*

Petitioner challenges dependent claims 3, 12, 22, and 24 as being unpatentable over Solazzo, Serany, Franks-Farah, and Disston. Pet. 78–86. Claim 3 ultimately depends from claim 1, and add features pertaining to a “wrap disposed about the tray” “liquid hand sanitizer,” and “a sealed bag disposed about the wrap.” Claim 22 depends from claim 19, adds similar features, and additionally adds that “the printed instructions disposed between the wrap and the sealed bag.” Claim 12 ultimately depends from claim 10, and claim 24 ultimately depends from claim 19. Claims 12 and 24

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<sup>8</sup> Claims 23–25 ultimately depend from claim 19.

recite “further comprising liquid hand sanitizer disposed outside the at least a portion of the wrap and inside the sealed bag.”

Petitioner points to Solazzo as meeting the claimed “wrap” and Franks-Farah as meeting the claimed “liquid hand sanitizer.” *See, e.g.*, Pet. 79–80. Petitioner relies on Disston as teaching an “arrangement of items in a tray to avoid a user coming into contact with its contents before sterile gloves are donned.”<sup>9</sup> *Id.* at 82 (citing Ex. 1008, 2:15–19). Petitioner also contends that “[d]isposing hand sanitizer between the wrap and the bag works in tandem with the procedural steps described by Disston and Franks-Farah.” *Id.* at 83. Patent Owner does not argue claims 3, 12, 22, or 24 apart from the independent claim on which those claims ultimately depend. On the present record, we conclude that Petitioner has accounted adequately for the features added by claims 3, 12, 22, and 24. We also institute trial as to those claims.

#### 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 ’761 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, we institute an *inter partes* review of all challenged claims of the ’761 patent on all grounds alleged by Petitioner. Nevertheless, this Decision does not reflect a final determination on the patentability of any

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<sup>9</sup> Disston is titled “Catheterization Package” and “relates to a catheterization package, including a package specially designed for cooperation with a pre-assembled catheter-tube-bag assembly contained therein.” Ex. 1008, Title, 1:9–12.

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 1–19 and 22–25 of the '761 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 '761 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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Patent 9,795,761 B2

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