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Paper 21
Entered: June 6, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C.R. BARD, INC.,
Petitioner,

v.

MEDLINE INDUSTRIES, INC.,
Patent Owner.

Case IPR2019-00208
Patent 9,808,400 B2

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

WEATHERLY, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. BACKGROUND

C.R. Bard, Inc. ("Petitioner") filed a petition (Paper 2, "Pet.") to institute an *inter partes* review of claims 13, 14, 16, and 17 (the "challenged claims") of U.S. Patent No. 9,808,400 B2 (Ex. 1001, "the '400 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. 24–91):

References	Basis	Claims challenged
U.S. Patent No. 7,278,987 B2 (Ex. 1005, "Solazzo"), U.S. Patent No. 3,329,261 (Ex. 1006, "Serany"), and U.S. Patent No. 3,965,900 (Ex. 1034, "Boedecker")	§ 103	13, 14, 16, and 17
Solazzo, Serany, and U.S. Patent No. 4,334,537 (Ex. 1036, "Peterson")	§ 103	13, 14, 16, and 17
Solazzo, U.S. Patent No. 3,166,189 (Ex. 1008, "Disston"), and Boedecker	§ 103	13 and 14
Solazzo, Disston, Boedecker, and Serany	§ 103	16 and 17
Solazzo and M. Madeo and A. J. Roodhouse, *Reducing the risks associated with urinary catheters*, NURSING STANDARD, March 25–31, 2009, at 47–55 (Ex. 1025, "Nursing Standard")	§ 103	13, 14, 16, and 17

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. 92; Paper 3, 2. The parties collectively also identify petitions for *inter partes* review of claims of: U.S. Patent 9,745,088 B2 (IPR2019-00035 and IPR2019-00036); U.S. Patent 9,795,761 B2 (IPR2019-00109); and U.S. Patent 9,808,596 B2 (IPR2019-00223) as related matters. Pet. 92–93; Paper 3, 3. Patent Owner further identifies as a related matter U.S. Patent Application No. 15/804,520, which is a continuation-in-part of the application that issued as the '400 patent. Paper 4, 2. Patent Owner further identifies U.S. Patent Application Nos. 15/703,514; 15/684,787; 15/803,383; 13/374,509; 15/640,224; 14/265,920; and 15/051,964 as related matters because these applications "share similar disclosures and claim language" with the '400 patent. *Id*.

C. THE '400 PATENT

The '400 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, 1:21–24. The Specification describes tray 100 shown in Petitioner's annotated and colorized version of Figure 7, which we reproduce below.

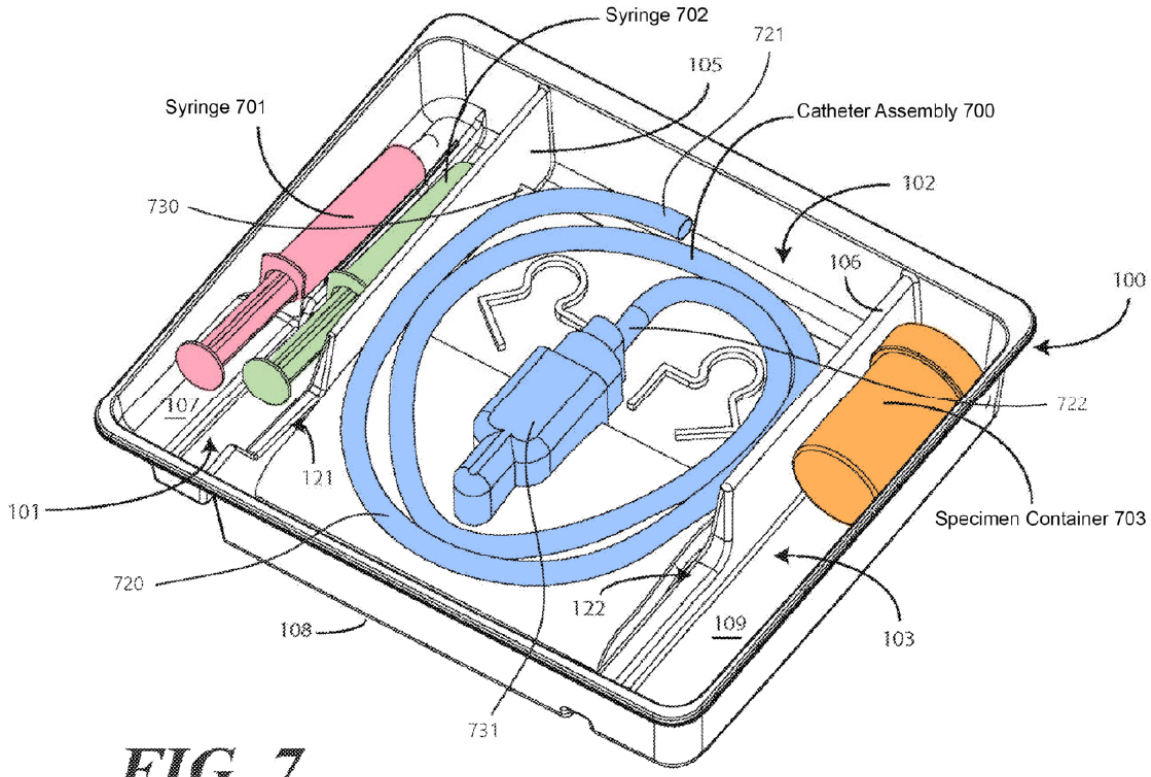


FIG. 7

Figure 7 illustrates catheter assembly 700, two syringes 701, 702, and specimen container 703 located within single-level tray 100. *Id*. at 8:7–15.

Before use, tray 100 is optionally double-wrapped to ensure that components in the tray remain sterile up to and through their initial use with tray 100 being wrapped in CSR wrap 1000 and then outer sterile wrap 1002. *Id*. at 9:39–49, Fig. 10. Tray 100 includes three compartments 101, 102, 103 adapted to accept various items used in a catheterization procedure. *Id*. at 8:19–25. First compartment 101 accommodates syringes 701, 702 (red, green) containing sterile water or lubricants. *Id*. at 3:26–30, 8:21–23. Second compartment 102 accommodates catheter assembly 700 (blue) comprising indwelling (or Foley) catheter coupled to fluid bag 730 by tube 720. *Id*. at 8:23–27. First end portion 721 of tube 720 is coupled to the indwelling catheter and second end portion 722 of tube 720 is coupled to the

fluid bag 730 via anti-reflux device 731. *Id*. at 8:27–30. Third compartment 103 accommodates specimen container 703 for capturing samples taken from the patient via catheter 700. *Id*. at 8:30–32. Additional objects can be included with the tray, including one or more towels, a drape to cover the patient, rubber gloves, hand sanitizing materials, printed instructions, and so forth. *Id*. at 4:54–57.

Claim 13 is the independent claim among the challenged claims. *Id*. at 11:47–12:7. Claim 13, which is illustrative, recites:

> 13. A kit, comprising:
>
> [a][i] a single level tray including a first compartment base member and a second compartment base member,
>
> [ii] the single level tray defining a first compartment and a second compartment,
>
> [iii] the first compartment base member forming a portion of a boundary of the first compartment, the second compartment base member forming a portion of a boundary of the second compartment,
>
> [iv] the single level tray including a barrier separating the first compartment from the second compartment;
>
> [b] a first syringe disposed within the first compartment of the single level tray, the first syringe containing an inflation fluid;
>
> [c] a second syringe disposed within the single level tray, the second syringe containing a lubricant; and
>
> [d][i] a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle, the indwelling catheter including an inflatable portion configured to receive the inflation fluid from the first syringe to maintain the indwelling catheter within a patient,
>
> [ii] the fluid receptacle including an anti-reflux device, an end of the coiled tube coupled to the anti-reflux device,

> [iii] the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray with at least a portion of the coiled tube being outside of the fluid receptacle and such that the fluid receptacle is between the second compartment base member and the coiled tube.

Id. at 11:47–12:7 (with line breaks and bracketed labels added to ease discussion n).

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. Prelim. Resp. 1–30. 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 '400 Patent ("Medline Portfolio")." Prelim. Resp. 2. Patent Owner admits that the Medline Portfolio is "complex." *Id*. at 10. Nevertheless, Patent Owner contends that "Solazzo adds nothing new that has not already been considered by the Office." *Id*. at 3. Patent Owner argues at length why 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) weigh in favor of discretionarily denying the Petition under § 325(d).[1] Prelim. Resp. 9–26.

[1] The Board adopted and applied these factors in *NHK Spring Co. v. Intri-Plex Technologies, Inc.*, Case IPR2018-00752, slip op. at 11–12 (PTAB Sept. 12, 2018) (Paper 8) (precedential).

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[2] 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 '400 patent. *Id*. at 10 (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). Here, this factor relates to a comparison of Solazzo (the asserted art) to prior art applied during examination of the claims of the '400 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 '400 patent. The Examiner of the '761 patent simply did not apply Solazzo against the claims of the '400 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. 11–15. The Office considered those three prior art references during prosecution of other applications containing claims that differed from the

[2] 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).

challenged claims of the ’400 patent. *See id*. (describing Office’s analysis of Rauschenberger, Misra, and Busch against claims of U.S. Patent Nos. 8,631,935 (Ex. 2003); 9,283,352 (Ex. 2004); or 9,522,753 (Ex. 2005) without sufficiently analyzing any differences among claims in those patents and the challenged claims). Patent Owner’s analysis of *Becton* factors 2–6 is similarly weakened by Patent Owner’s failure to demonstrate that the Office considered Solazzo (or a materially similar prior art reference) when determining whether the claims of the ’400 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. at 17. Patent Owner points out that Solazzo was among the prior art references discussed in Petitioner’s invalidity contentions in litigation relating to U.S. Patent No. 8,631,935 (Ex. 2017), which Patent Owner submitted to the Office and were “considered” by the Examiner during prosecution of the ’400 patent. Prelim. Resp. 23–24; *see* Ex. 1004, 113 (Examiner labeling U.S. Published App. No. 2006/0009742 A2[3] to Solazzo as “considered”). Patent Owner’s argument relating to *Becton* factor 3 is unpersuasive because it fails to recognize that, although Solazzo was before the Examiner during examination of the ’400 patent, the Examiner did not discuss or apply

[3] This publication eventually issued as Solazzo on October 9, 2007. Ex. 1006 (65).

Solazzo as a basis for rejection when examining the claims of the '400 patent. Patent Owner admits as much. *Id*. at 23.

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 '400 patent and other related patents with common claim limitations." Prelim. Resp. 27. 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 '400 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 '400 patent.

Id. at 27–28 (citing Ex. 2012, 9–14). The cited Exhibit is the responses to interrogatories that Patent Owner served in the *Medline III* Litigation a few 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 of record in this proceeding any admissible evidence of objective indicia of non-obviousness. *See* Prelim. Resp. 27–29 (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. 29 (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. at 4; *Semiconductor Component*, slip op. 28–29; *Praxair*, slip op. at 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. at 4; *Semiconductor Component*, slip op. at 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. at 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)[4]; *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).

Petitioner recounts interpretations of various terms that Patent Owner proposed during district court litigation while alleging that the prior art meets those limitations. Pet. 23–24. Patent Owner does not address any of

[4] 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).

these proposed interpretations other than to contend that none of them is "in dispute." Prelim. Resp. 30. Patent Owner does point out, however, that the District Court in the *Medline III* Litigation has issued a *Markman* Order addressing "catheter assembly" and "barrier" as those terms are used in the claims of the '400 patent. *Id*. at 31 (citing Ex. 2027). Based on our review of that *Markman* Order, we discern no material differences between the District Court's interpretations of those terms and the interpretations employed by Petitioner. For example, the District Court agrees with Petitioner that the "indwelling catheter" of the claimed "catheter assembly" refers to a Foley catheter. Ex. 2027, 15. More specifically, the District Court interprets "catheter assembly" to mean "a medical device that includes a Foley catheter connected via coiled tubing to a fluid receptacle, the Foley catheter including an inflatable portion configured to receive the inflation fluid from the first syringe to maintain the Foley catheter within a patient." *Id*. The phrase beginning with "the Foley catheter including" was not included in Petitioner's proposed interpretation of "catheter assembly." Pet. 23. However, this phrase merely quotes language directly from claim 13 except to replace "indwelling" with "Foley." *Compare* Ex. 2027, 15, *with* Ex. 1001, 11:63–66.

Accordingly, we discern no reason to expressly interpret any term of the '400 patent.

B. LEGAL STANDARDS

Petitioner challenges the patentability of claims 13, 14, 16, and 17 on the grounds that the claims would have been obvious in view of various combinations of the following references: Solazzo, Serany, Disston, Boedecker, Peterson, and Nursing Standard. Pet. 24–91. 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. We address Petitioner's challenges with these standards in mind.

C. CLAIMS 13, 14, 16, AND 17: OBVIOUSNESS IN VIEW OF SOLAZZO, SERANY, AND BOEDECKER

Petitioner argues that claims 13, 14, 16, and 17 are unpatentable as obvious in view of the combined teachings of Solazzo, Serany, and Boedecker. Pet. 25–57. Claim 13 is the only independent claim among this group of challenged claims. Ex. 1001, 11:47–12:28. Patent Owner argues that the combination of Solazzo, Serany, and Boedecker fails to render independent claim 13 unpatentable as obvious. Prelim. Resp. 32–50. For the reasons expressed below, we determine that Petitioner has demonstrated a reasonable likelihood of establishing that claims 13, 14, 16, and 17 are 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.

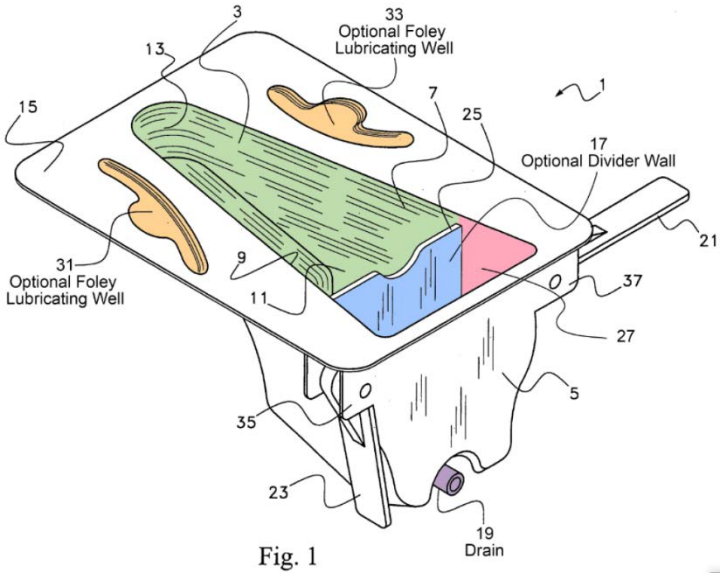


Fig. 1

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),

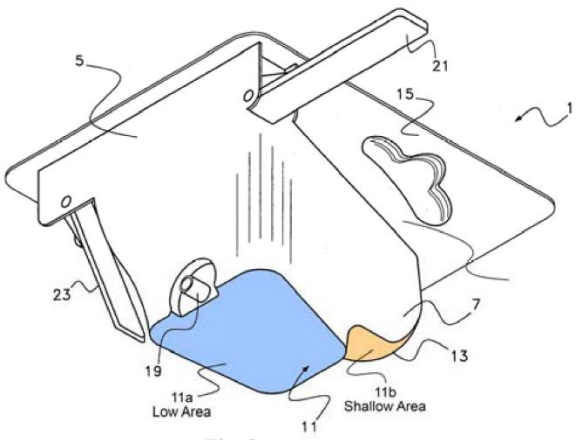
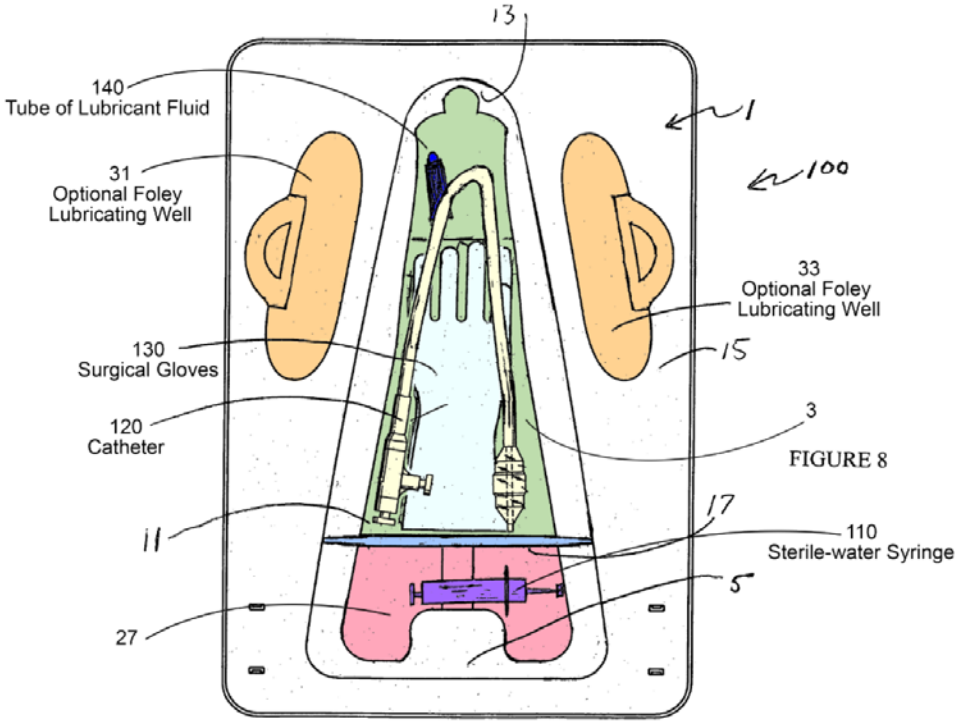


Fig. 2

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.



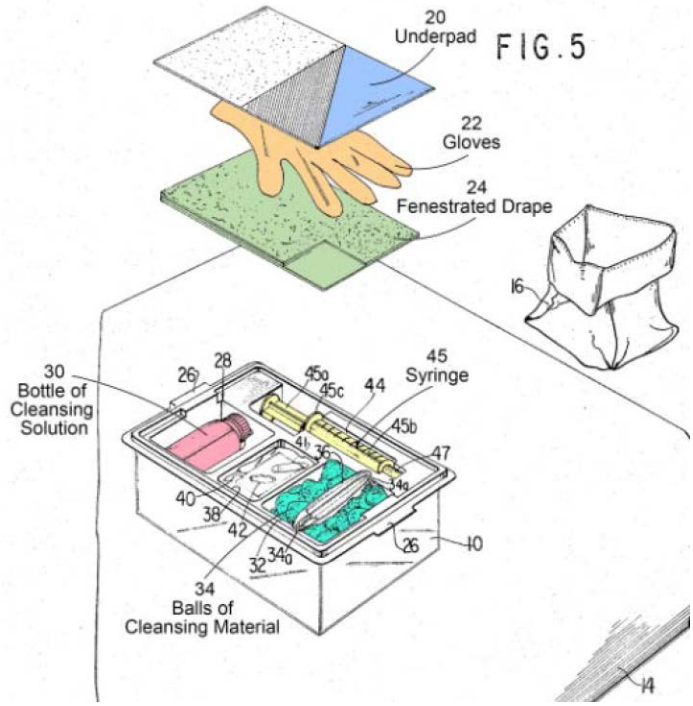
Solazzo's Figure 8 is a top view of kit 100 illustrating various components stored in compartments of tray 1. *Id*. at 4:41–48.

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.

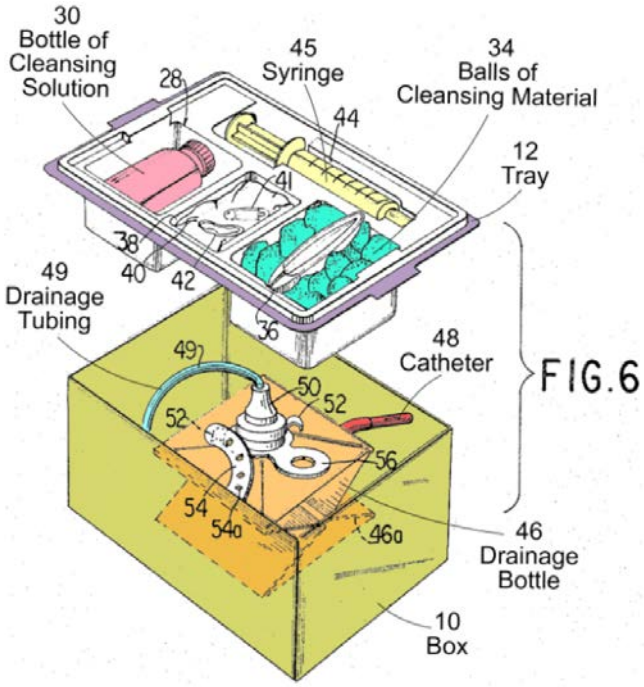
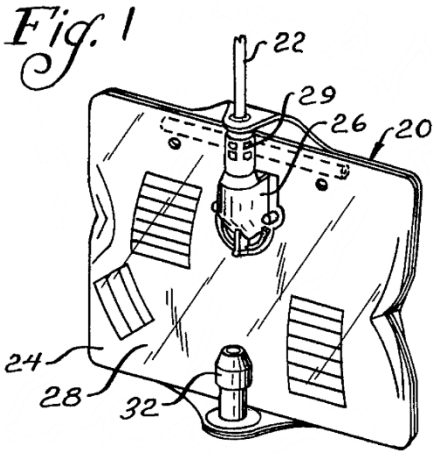


FIG.6

3. Overview of Boedecker

Boedecker decribes an anti-reflux device for use with a flexible collection receptacle during urinary catheterization. Ex. 1034, 1:5–9, Figures 1–2. The configuration of Boedecker's collection bag 24 is illustrated in Boedecker's Figure 1, which we reproduce at right. Drainage tube 22 is connected to drainage bag 24 via drip chamber 26. Boedecker describes that pressure exerted against the flexible walls of such receptacles may cause urine to back up into the drainage tube,



catheter, and patient's bladder, which may cause trauma or retrograde bacterial movement to the bladder. *Id*. at 1:19–35.

To address this issue, Boedecker's drip chamber 26 includes valve element 34 with lip 36, which is shown in its open position in Boedecker's Figure 5, reproduced at right. *Id*. at 2:54–3:3, 3:20–23; Figures 1–2, 5. When pressure is exerted onto flexible valve element 34 from inside the bag 24 (e.g., by inadvertent squeezing, bumping, tilting of the bag), lip 36 of flexible valve element 34 closes inlet port 30 to prevent reflux. *Id*. at 3:23–33.

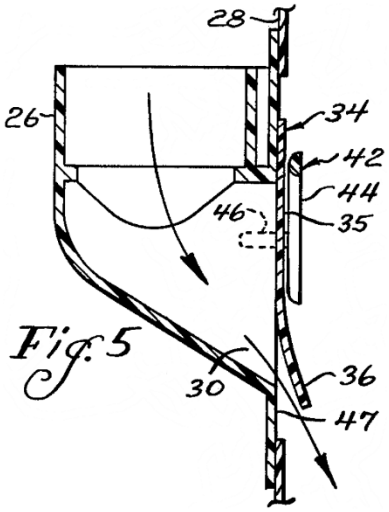


Fig. 5

4. Independent Claim 13

a) Petitioner's Argument and Evidence

Petitioner argues that the combined teachings of Solazzo, Serany, and Boedecker render claim 13 unpatentable as obvious. Pet. 25–52. Petitioner contends that Solazzo describes the tray and its compartments (element 13a), *id*. at 33–37 (citing Ex. 1005, 2:61–63, 3:63–66, Figures 1, 2, 8; Ex. 1002 ¶¶ 139–154), the first and second syringes and the manner in which they are ordered within the tray (elements 13b, 13c), *id*. at 37–40 (citing Ex. 1005, 3:15–24, 4:41–46, Figure 8; Ex. 1002 ¶¶ 153–163), and a catheter disposed in the second compartment (aspects of element 13d.i), *id*. at 40–42 (citing Ex. 1005, 3:15–24, Figure 8; Ex. 1003 ¶ 11).

Petitioner contends that Serany describes an indwelling catheter coupled to a drainage receptacle (aspects of element 13d.i), *id*. at 42–43 (citing Ex. 1006, 3:23–26, 3:33–35, Figure 6), between a base member of the

second compartment and the coiled tube (element 13d.iii), *id*. at 50 (citing Ex. 1006, 3:26–35, Figure 6).

Petitioner contends that Boedecker describes an anti-reflux device (element 13d.ii) and suggests the use of such a device with Foley catheter systems. *Id*. at 45–48 (citing Ex. 1034, 1:13–17, 1:19–35, 1:45–47, 2:48–52, 3:30–32, Figures 1, 2; Ex. 1002 ¶¶ 180–185; Ex. 1004, 262 ¶ 41).

Petitioner recognizes that Solazzo does not describe a closed-system Foley catheter in which the catheter is pre-connected to a drainage receptacle. *Id*. at 42. Petitioner argues, however, that Serany suggests that Solazzo's tray could hold Serany's closed-system Foley catheter, i.e., the claimed "catheter assembly," because an ordinarily skilled artisan would have been motivated to simplify Solazzo's catheterization procedure and reduce the risk of infection. *Id*. at 43–45 (citing Ex. 1006, 1:31–32, 3:23–36; Ex. 1002 ¶¶ 171–174, 390; Ex. 1003 ¶¶ 35, 41, 42; Ex. 1004, 239 ¶ 29; Ex. 1010, 51, 52).

Petitioner also recognizes that neither Solazzo nor Serany expressly describe using an anti-reflux device in a catheter assembly. However, Petitioner argues that Patent Owner never contested the Office's finding that such devices in catheter systems were well known. *Id*. at 45 (citing Ex.1004, 73–76, 106–08, 262, ¶ 41). Moreover, Petitioner argues that it would have been obvious to replace Serany's expandable bottle 46 with Boedecker's liquid collection bag 24, which includes an anti-reflux device. *Id*. at 47–48 (citing Ex. 1006, 1:19–35; Ex. 1002 ¶ 185). Petitioner contends that Boedecker expressly suggests such a modification to reduce infection. *Id*. at 46–48 (citing Ex. 1006, 1:19–35; Ex. 1002 ¶¶ 180–185).

b) Analysis of Patent Owner's Counterarguments

Patent Owner argues that Petitioner's challenge to claim 13 fails for three reasons, none of which is persuasive at this stage of the proceeding. We address each argument below.

(1) Element 13c

Element 13c refers to the following portion of claim 13: "a second syringe disposed within the single level tray, the second syringe containing a lubricant." Petitioner identifies Solazzo's tube of lubricant 140, which is positioned in recessed area 3, as the second syringe. Pet. 39. Petitioner argues that it would have been obvious to use a syringe for lubricant rather than a tube in Solazzo's kit. *Id*. Relying upon Mr. Plishka's testimony, Petitioner argues that change "would merely involve 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 39–40 (citing Ex. 1002 ¶¶ 160–162).

Patent Owner responds that Petitioner's "bare assertion" fails because Petitioner's argument is "conclusory," which we understand to mean unsupported by evidence. Prelim. Resp. 32–35. Patent Owner also contends that to the extent Petitioner relies upon testimony by Mr. Plishka, the "Petition does not expressly identify arguments from the declaration that support its assertion." *Id*. at 34. We disagree.

Petitioner cites specific testimony by Mr. Plishka. Pet. 40 (citing Ex. 1003 ¶¶ 160–162). Mr. Plishka explains that "providing lubricant in a syringe as part of a Foley catheter kit was well-known in the art" and cites objective prior art evidence supporting his opinion. Ex. 1002 ¶ 160 (citing Ex. 1010, 52; Ex. 1015). He also testifies that an ordinarily skilled artisan

would have been motivated to substitute a syringe for Solazzo's tube 140 because syringes permit health care practitioners to more easily and precisely apply lubricant than syringes reducing the risk of misapplying lubricant in the wrong place. *Id*. ¶ 162. Mr. Plishka also indicates that syringes are required when applying lubricant directly inside the urethra of a patient, which Dr. Yun testifies to be a preferred prior art method of applying lubricant. Ex. 1002 ¶ 162 (citing Ex. 1003 ¶ 22).

Based on the current record, we determine that Petitioner has demonstrated a reasonable likelihood of proving that Solazzo suggests placing a syringe containing lubricant in the tray as claimed.

(2) Element 13d.i

Element 13d.i refers to the following portion of claim 13: "a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle, the indwelling catheter including an inflatable portion configured to receive the inflation fluid from the first syringe to maintain the indwelling catheter within a patient." Petitioner contends that catheter 120 within recessed area 3 as shown in Solazzo's Figure 8 is a Foley catheter assembly. Pet. 41 (citing Ex. 1005, 3:17, Figure 8). Petitioner relies upon Serany as describing an assembly in which the tubing is coupled to a fluid receptacle. *Id*. at 42–43 (citing Ex. 1006, 3:23–26, 3:33–35, Figure 6).

Petitioner argues that an ordinarily skilled artisan would have found it obvious to place a closed-catheter as described by Serany for Solazzo's open-catheter 120 in Solazzo's recessed area 3. *Id*. at 43–45. Petitioner contends that an ordinarily skilled artisan would have been motivated to do so because modifying Solazzo to incorporate a "ready for use" closed-catheter system would simplify Solazzo's catheterization procedure and

reduce the risk of infection for patients. *Id*. (citing Ex. 1002 ¶¶ 171–173, 390; Ex. 1003 ¶ 35; Ex. 1004, 239 ¶ 29; Ex. 1006, 1:20–23, 3:26; Ex. 1010, 51, 52). Petitioner also contends that including a closed-catheter assembly in Solazzo's kit would render Solazzo's kit more versatile because the modified kit could be used for both permanent catheterization and irrigation procedures. *Id*. at 45 (citing Ex. 1002 ¶ 174; Ex. 1003 ¶¶ 41, 42).

Patent Owner argues that an ordinarily skilled artisan would not have been motivated to incorporate Serany's closed-system Foley catheter into Solazzo's tray because doing so changes the principle of operation of Solazzo's tray. Prelim. Resp. 42–46. More specifically, using a closed-system catheter eliminates the fluid gathering feature of Solazzo's recessed area 3 and the utility of Solazzo's drain 19. *Id*. at 42–44. Based on the record currently before us, Patent Owner's argument is not persuasive.

First, we observe that the proposed modified version of Solazzo's tray still functions as a container for a catheterization kit, one of its primary functions. Ex. 1005, 4:41–48, Figure 8. Petitioner also argues that drain 19 would still be of use because Solazzo's tray 1 could still be used for irrigation procedures. Pet. 45 (citing Ex. 1002 ¶ 174; Ex. 1003 ¶¶ 41, 42). Patent Owner contests Petitioner's evidence by providing testimony from Ms. Weintraub. Prelim. Resp. 37 (citing Ex. 2002 ¶¶ 14–17). At this stage of the proceeding, we view expert testimony that creates a genuine issue of material fact in the light most favorable to Petitioner. 37 C.F.R. § 42.108(c). Based on the record before us as we consider that record under our Rules, we are sufficiently persuaded by Petitioner's argument and evidence that the proposed modification of Solazzo would not change Solazzo's principle of

operation and that Petitioner has demonstrated a sufficient motive to combine Solazzo's tray and Serany's closed-system Foley catheter.

On the record currently before us, we determine that Petitioner has demonstrated a reasonable likelihood of proving that the combination of Solazzo and Serany describes and suggests element 13d.i.

(3) Element 13d.iii

Element 13d.iii refers to the following portion of claim 13: "the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray with at least a portion of the coiled tube being outside of the fluid receptacle and such that the fluid receptacle is between the second compartment base member and the coiled tube." Petitioner correctly notes that Solazzo describes placing its catheter 120 in recessed area 3 (i.e., the second compartment). Pet. 49 (citing Ex. 1005, Figure 8). Petitioner relies upon Serany's arrangement in which "catheter 48 and drainage tubing 49 connecting it to the bottle 46 are coiled in the box about the bottle." *Id*. at 50 (quoting Ex. 1006, 3:33–35). When stored in this manner, Serany's bottle 46 is folded flat between the bottom of box 10 and tube 49. *Id*. (citing Ex. 1006, 3:26–32). Petitioner argues that Serany suggests arranging the closed-system Foley catheter with the drainage receptacle under the tubing and on the bottom of the tray by indicating that components should be arranged in their "proper order of use." *Id*. at 51 (citing Ex. 1006, 1:9–12, 1:23–25; Ex. 1002 ¶¶ 192–194).

Patent Owner first argues that an ordinarily skilled artisan would not add Serany's rectangular closed-catheter assembly into Solazzo's recessed area because it "simply will not fit" without major modifications to Solazzo. Prelim. Resp. 42–43. Patent Owner cites no evidence to support its

argument. *Id*. Instead, Patent Owner places Serany's Figure 6 and Solazzo's Figure 8 side by side and baldly alleges that a comparison of the figures "refutes" that Serany's bottle 46 would fit in Solazzo's recessed area 3. *Id*. We reject Patent Owner's argument as unsupported by evidence. These figures are not indicated as being drawn to scale or drawn to the same scale. Accordingly, the figures are not evidence of the size of bottle 46 or the size of recessed area 3.

Patent Owner next argues that placing Serany's closed-system catheter in Solazzo's tray interferes with the intended purpose of Solazzo, effective drainage. *Id*. at 44. We reject this argument for the same reasons expressed above in connection with element 13d.i. *See* Part III.C.4.b)(2) above.

Patent Owner next argues that Petitioner's reliance on Serany's suggestion that items be arranged by their order of use is unavailing because the contents of Serany's tray 12 are not so arranged. *Id*. at 44–45. Patent Owner admits, however, that Serany does arrange at least underpad 20, gloves 22, and drape 24 in their order of use. *Id*. at 44 (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.

For these reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood that it will prove that the combination of Solazzo and Serany suggests element 13d.iii.

(4) Objective Indicia of Non-obviousness

As explained in Part II.B above, although Patent Owner has indicated that it contends in the *Medline III* Litigation that objective indicia of non-obviousness weigh against a finding that the claims of the ’400 patent are obvious, Patent Owner has not proffered admissible evidence of those objective indicia in this proceeding. Accordingly, we do not address or weigh objective indicia of nonobviousness in this Decision.

c) Conclusion

For the reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood of proving that the combination of Solazzo, Serany, and Boedecker renders claim 13 unpatentable as obvious.

5. Dependent Claims 14, 16, and 17

Petitioner identifies the portions of Solazzo and Serany that support its argument that dependent claims 14, 16, and 17 are also obvious in view of Solazzo, Serany, and Boedecker. Pet. 52–57 (citing Ex. 1005, 3:15–24; Ex. 1006, 1:13–16, 1:60–63, 2:1–20, Figures 2, 2a, 3). Petitioner also supports its argument with testimony from Mr. Plishka. *Id*. (citing Ex. 1002 ¶¶ 188–219).

Patent Owner does not separately argue that limitations introduced in dependent claims 14, 16, and 17 are a basis for finding that any of these claims remain patentable over Solazzo, Serany, and Boedecker. Prelim. Resp. 50–52. 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).

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 '400 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,[5] we institute an *inter partes* review of all challenged claims of the '400 patent on all grounds alleged by Petitioner. Nevertheless, this Decision does not reflect a final determination on the patentability of any claim. We further note that the burden remains on Petitioner to prove unpatentability of each challenged claim. *Dynamic Drinkware*, 800 F.3d at 1378.

V. ORDER

For the reasons given, it is:

ORDERED that *inter partes* review of claims 13, 14, 16, and 17 of the '400 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 '400 patent is instituted commencing on the entry date

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

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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