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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 IPR2019-00223
Patent 9,808,596 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 7–16, 21, and 22 (the "challenged claims") of U.S. Patent No. 9,808,596 B2 (Ex. 1001, "the '596 patent"). 35 U.S.C. § 311. Medline Industries, Inc. ("Patent Owner") timely filed a

Preliminary Response. Paper 12 ("Prelim. Resp."). Institution of an *inter partes* review is authorized by statute when "the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a); 37 C.F.R. § 42.108. Based on our review of the record, we conclude that Petitioner is reasonably likely to prevail with respect to at least one of the challenged claims.

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. § 103 based on the following grounds (Pet. 23–92):

References	Basis	Claim(s) challenged
U.S. Patent No. 7,278,987 B2 (Ex. 1005, "Solazzo") and U.S. Patent No. 3,329,261 (Ex. 1006, "Serany")	§ 103	7, 9–16, 21, and 22
Solazzo, Serany, and U.S. Patent No. 3,965,900 (Ex. 1034, "Boedecker")	§ 103	8
Solazzo and U.S. Patent No. 3,166,189 (Ex. 1008, "Disston")	§ 103	7, 9, 11–16, and 22
Solazzo, Disston, and Boedecker	§ 103	8
Solazzo, Disston, and Serany	§ 103	10 and 21

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. 93; 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 9,808,400 B2 (IPR2019-00208) as related matters. Pet. 93–94; Paper 3, 2–3. Patent Owner further identifies as a related matter U.S. Patent Application No. 15/804,520, which is a continuation-in-part of the application that issued as the '400 patent. Paper 3, 2. Patent Owner further identifies U.S. Patent Application Nos. 15/703,514; 14/265,920; 15/684,787; 15/803,383; 13/374,509; 15/640,224; and 15/051,964 as related matters because these applications "share similar disclosures and claim language" with the '596 patent. *Id*.

C. THE '596 PATENT

The '596 patent is directed to "storage containers for medical devices, and more particularly to a storage container for a long, flexible medical implement, such as a catheter, and related medical devices." Ex. 1001, 1:32–35. The Specification describes tray 100 shown in Petitioner's annotated and colorized version of Figure 7, which we reproduce below.

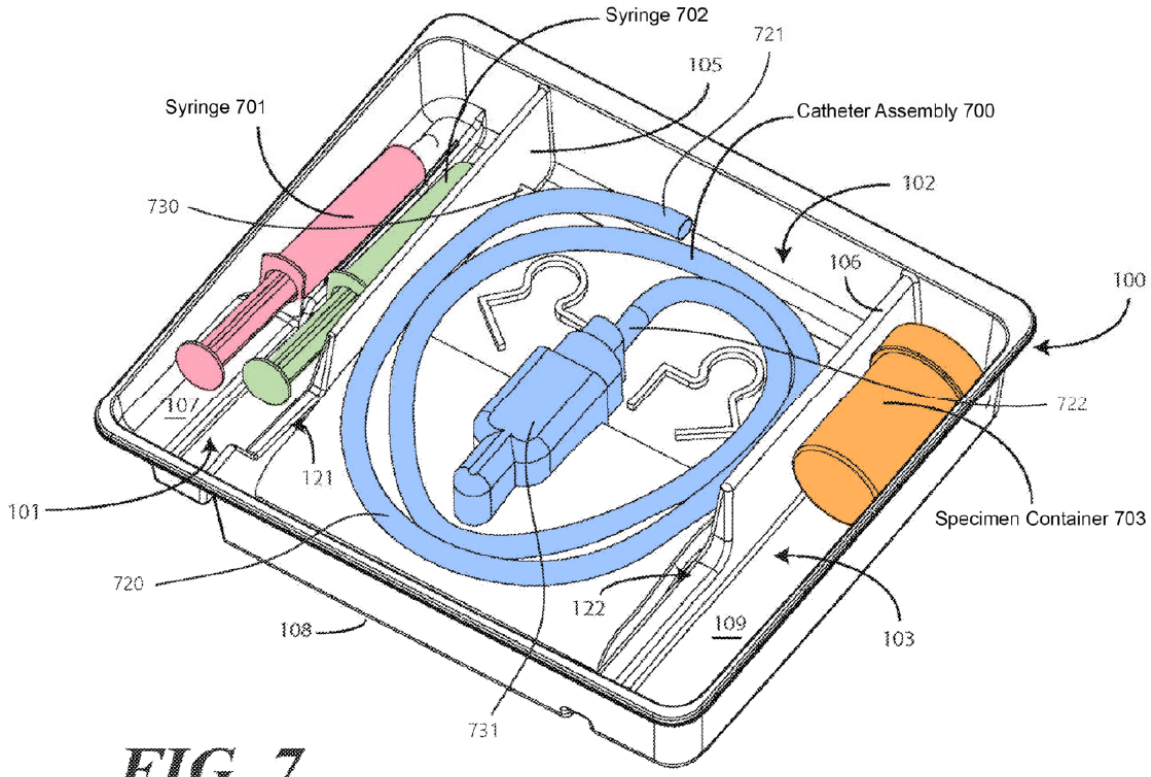


FIG. 7

Figure 7 illustrates catheter assembly 700, two syringes 701, 702, and specimen container 703 located within single-level tray 100. *Id*. at 10:53–55.

Before use, tray 100 is optionally double-wrapped to ensure that components in the tray remain sterile up to and through their initial use with tray 100 being wrapped in CSR wrap 1000 and then outer sterile wrap 1002. *Id*. at 11:49–59, Fig. 10. Tray 100 includes three compartments 101, 102, 103 adapted to accept various items used in a catheterization procedure. *Id*. at 8:48–54. First compartment 101 accommodates syringes 701, 702 (red, green) containing sterile water or lubricants. *Id*. at 8:50–52. Second compartment 102 accommodates catheter assembly 700 (blue) comprising indwelling (or Foley) catheter coupled to fluid bag 730 by tube 720. *Id*. at 8:52–54. First end portion 721 of tube 720 is coupled to the indwelling catheter and second end portion 722 of tube 720 is coupled to the fluid

bag 730 via anti-reflux device 731. *Id*. at 8:56–59. Third compartment 103 accommodates specimen container 703 for capturing samples taken from the patient via catheter 700. *Id*. at 8:59–61. Additional objects can be included with the tray, including one or more towels, a drape to cover the patient, rubber gloves, hand sanitizing materials, printed instructions, and so forth. *Id*. at 5:10–15.

Claim 7 is one of two independent claims among the challenged claims with claim 14 being the other. *Id*. at 18:30–20:41. Claim 7, which is illustrative, recites:

> 7. A catheterization kit comprising:
>
> [a] a single level container defining a first compartment bounded by a first compartment base member and at least a first portion of a perimeter wall, the single level container defining a second compartment bounded, at least in part, by a second compartment base member and at least a second portion of the perimeter wall;
>
> [b] a first syringe disposed within the first compartment of the single level container, the first syringe containing an inflation fluid;
>
> [c][i] a second syringe disposed within the first compartment of the single level container,
>
> [ii] the second syringe containing a lubricating jelly; and
>
> [d][i] a coiled medical device disposed within the second compartment of the single level container, the coiled medical device including a Foley catheter, a fluid receptacle, and a tube coupling the Foley catheter to the fluid receptacle,
>
> [ii] the Foley catheter and the fluid receptacle positioned within the second compartment such that the fluid receptacle is between the second compartment base member and the Foley catheter.

Id. at 18:30–51 (with line breaks and bracketed labels added to ease discussion).

II. PRELIMINARY MATTERS

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

A. DISCRETIONARY DENIAL UNDER § 325(D)

Patent Owner argues that "the Board has more than good cause" to deny the Petition in its discretion under § 325(d) because the Petition "is yet another of the repeated administrative attacks on Medline's patent portfolio . . . that includes the '596 Patent ('Medline Portfolio')." Prelim. Resp. 2. The Medline Portfolio is complex with multiple applications and issued patents claiming priority along many different pathways. *See* Ex. 1001, 1:7–27 (cross-referencing nine priority applications); Ex. 1017 (illustrating overall complexity of portfolio). 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. 4–29.

[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 '596 patent. *Id*. at 11 (citing Ex. 1019).

Factor 1 relates to "similarities and material differences between the asserted art and the prior art involved *during examination*." *Becton*, slip op. at 17 (emphasis added). This factor relates to a comparison of Solazzo (the asserted art) to prior art applied *during examination* of the claims of the '596 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 '596 patent. The Examiner of the '761 patent simply did not apply Solazzo against the claims of the '596 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. 12–16. The Office considered two of those prior art references against claims that differed from the challenged claims of the '596 patent. *See id*.

[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).

(describing Office's analysis of Rauschenberger and Misra against claims of U.S. Patent Nos. 8,631,935 (Ex. 2003); 9,283,352 (Ex. 2004); 9,522,753 (Ex. 2005); or 9,808,400 (Ex. 1045) without sufficiently analyzing any differences among claims in those patents and the challenged claims). For example, when the Office considered Misra against claims during examination of the '400 patent, Patent Owner amended the claims to overcome Misra by adding limitations (e.g., to require an anti-reflux device in claim 18, which issued as claim 13) that are not reflected in independent claims 7 and 14 at issue in this proceeding. Ex. 1046, 69–70 (amending claim 18, which issued as claim 13); Ex. 1001, 18:30–20:41 (claims 7 and 14 not including "anti-reflux" device).

Patent Owner correctly notes that the Office extensively considered and applied Busch as the base reference for rejections of claim 7 as obvious in view of Busch and U.S. Patent No. 5,779,053 (Ex. 1042, "Partika"). Ex. 1004, 264–267 (Initial Action of 6/30/2016), 176–179 (Final Action of 1/13/2017). Busch is directed to an "epidural anesthesia kit." Ex. 1038 ¶ 1. Partika is directed to a "skin preparation tray for use in surgical procedures." Ex. 1042, 1:8–9. Ultimately, the Examiner determined that neither Busch nor Partika described "an indwelling Foley catheter with the structure recited or the syringes containing the recited material." Ex. 1004, 159. Solazzo and Serany are materially different prior art from Busch and Partika because no dispute exists that Solazzo and Serany both describe trays for Foley catheters. Ex. 1005, 3:14–24; Ex. 1006, 3:23–26. Accordingly, we determine that the Office's prior consideration of Busch during examination of the '596 patent is not a basis for exercising discretion to deny the Petition.

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 '596 patent were patentable. Prelim. Resp. 22–29 (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 Nos. 8,448,786; 8,631,935; and 8,678,190 (Ex. 2017, the "'935 Patent LPR 3.1 Contentions"), which Patent Owner submitted to the Office and were "considered" by the Examiner during prosecution of the '596 patent. Prelim. Resp. 24.[3] First, Exhibit 2017 describes Solazzo one time in its 124 pages by quoting 48 words from Solazzo regarding a claim limitation directed to printed instructions for using lubricant—a limitation that is not at issue in this proceeding. Ex. 2017, 64–74. Moreover, the Examiner never

[3] Patent Owner cites no evidence to support this proposition, but our independent review of the record reveals that the IDS filed September 29, 2016, did not include the '935 Patent Invalidity Contentions, but instead included other invalidity contentions (Ex. 2039) relating to the '352 patent. *See* Ex. 1004, 237 (referring to invalidity contentions from Civil Action 1:16-cs-3529); *see also* Ex. 2039 (invalidity contentions from the same Civil Action). These contentions do not discuss Solazzo at all. *See generally* Ex. 2039 (never mentioning Solazzo).

mentions Solazzo during examination of the ’596 patent. *See generally* Ex. 1004 (merely listing Solazzo on an Information Disclosure Statement without ever discussing or applying Solazzo). 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 ’596 patent, the Examiner did not discuss or apply Solazzo as a basis for rejection when examining the claims of the ’596 patent. Patent Owner admits as much. *Id*. at 24.

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

B. DISCRETIONARY DENIAL UNDER § 314(A)

Patent Owner argues that “the Board should further exercise its discretion to deny instituting *inter partes* review because Petitioner failed to address evidence of ***known*** secondary considerations produced during the concurrent district court litigations involving the ’088 patent and other related patents with common claim limitations.” Prelim. Resp. 29. Patent Owner informs us that:

> [O]n October 1, 2018, in *Medline III*, PO produced and served upon Petitioner Bard (1) a response to its interrogatories addressing secondary considerations for the ’596 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 ’596 patent.

Id. at 30 (citing Ex. 2012, 9–14). The cited Exhibit is the responses to interrogatories that Patent Owner served in the *Medline III* Litigation days before the Petition was filed. *See* Ex. 2012, 36 (filing date of October 1,

2018, thirty-seven 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. 29–32 (citing only interrogatory responses (Exs. 2012, 2013, 2014)). Essentially, Patent Owner asks us to exercise discretion and deny the Petition because Petitioner failed to address in the Petition alleged evidence of objective indicia of non-obviousness even though Patent Owner has not made any such evidence of record in this proceeding. We decline to do so.

Whether we exercise discretion under § 314(a) to deny a petition is guided by the Board's decision in *General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha*, Case IPR2016-01357, slip op. at 15–16 (PTAB Sept. 6, 2017) (Paper 19) (precedential) (articulating a non-exhaustive list of factors to be considered in determining whether to exercise discretion under § 314(a) to deny a petition). Patent Owner neither cites the *General Plastic* decision nor analyzes any factor set forth in that decision as a basis for denying the Petition in our discretion under § 314(a). Instead, Patent Owner

quotes language out of context from three Board decisions attempting to support its argument that "Petitioner had the burden of setting forth secondary consideration arguments and evidence in the Petition." Prelim. Resp. 31–32 (quoting *Omron Oilfield & Marine, Inc. v. MD/Totco*, Case IPR2013-00265, slip op. at 3–4 (PTAB Feb. 13, 2014) (Paper 14); *Semiconductor Component Indus., LLC v. Power Integrations, Inc.*, IPR2016-01588, slip op. at 28–29 (PTAB Feb. 17, 2017) (Paper 15); *Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, IPR2016-00777, slip op. at 9–10 (PTAB Sept. 22, 2016) (Paper 10)).

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

With no evidence of objective indicia of non-obviousness currently before us in this proceeding and no indication that the Office or the Board has previously weighed any such evidence in connection with a challenged claim, we discern no basis for denying the Petition in our discretion under

§ 314(a). When, if at all, Patent Owner proffers admissible evidence relating to objective indicia of non-obviousness, we will evaluate the effect of that evidence on Petitioner's challenges to claims. At this stage, we reject Patent Owner's argument that we should discretionarily deny the Petition under § 314(a).

III. ANALYSIS

A. CLAIM INTERPRETATION

"A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b) (2018)[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

[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).

then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

The parties present slightly differing interpretations of "mnemonic device" as recited in dependent claim 15 with Patent Owner proposing that we apply the broader of those interpretations that "mnemonic device" means "a feature intended to assist the memory." Pet. 20; Prelim. Resp. 33–34. The District Court in the related *Medline III* Litigation has issued a *Markman* Order agreeing with Patent Owner's proposed broader definition of "mnemonic device," and we agree with and apply that definition when analyzing claims below. Ex. 2027, 7–8.

Petitioner also proposes interpretations of four phrases recited within various claims, namely, "barrier," "lubricating jelly application chamber/compartment," "reveal," and "perimeter wall." Pet. 20. Patent Owner does not address Petitioner's proposed interpretations of these four phrases. We do not express an opinion about the meaning of these phrases at this stage of the proceeding because we determine that *inter partes* review is warranted based upon Petitioner's showing regarding claim 7.

B. LEGAL STANDARDS

Petitioner challenges the patentability of claims 7–16, 21, and 22 on the grounds that the claims would have been obvious in view of various references including: Solazzo, Serany, Disston, and Boedecker. Pet. 22–92. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* that we apply in determining whether a claim is reasonably likely to be unpatentable as obvious under

35 U.S.C. § 103(a) as follows: (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, (3) resolving the level of ordinary skill in the pertinent art, and (4) considering objective evidence indicating obviousness or nonobviousness. *KSR*, 550 U.S. at 406. With these standards in mind, we address each challenge below.

C. CLAIMS 7, 9–16, 21, AND 22: OBVIOUSNESS IN VIEW OF SOLAZZO AND SERANY

Petitioner argues that claims 7, 9–16, 21, and 22 are unpatentable as obvious in view of the combined teachings of Solazzo and Serany. Pet. 23–65. Claims 7 and 14 are the independent claims among this group of challenged claims. Ex. 1001, 18:30–20:41. Patent Owner argues that the combination of Solazzo and Serany fails to render independent claims 7 and 14 unpatentable as obvious. Prelim. Resp. 35–52 (claim 7), 62–63 (claim 14). For the reasons expressed below, we determine that Petitioner has demonstrated a reasonable likelihood of establishing that at least claim 7 is unpatentable as obvious.

1. Overview of Solazzo

Solazzo is directed to an ergonomic, single layer catheterization/irrigation tray 1 having multiple compartments, including recessed area 3 (green), compartment 27 (pink), and wells 31, 33 (orange) as shown in Petitioner's annotated Figure 1, which we reproduce below. Ex. 1005, 4:15–25; Fig.1. Solazzo's Figure 1 is a perspective view of the catheterization and irrigation tray illustrating its major features. *Id.* at 3:31–33. Divider wall 17 is optional and, when present, divides recessed area 3 into two compartments, with compartment 27 being configured to receive fluid passing over top 25 of wall 17. *Id*. at 4:15–20.

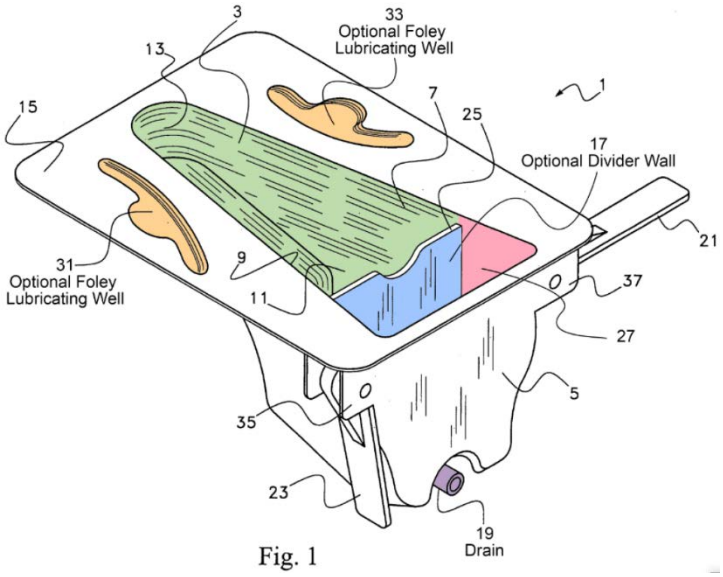


Fig. 1

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),

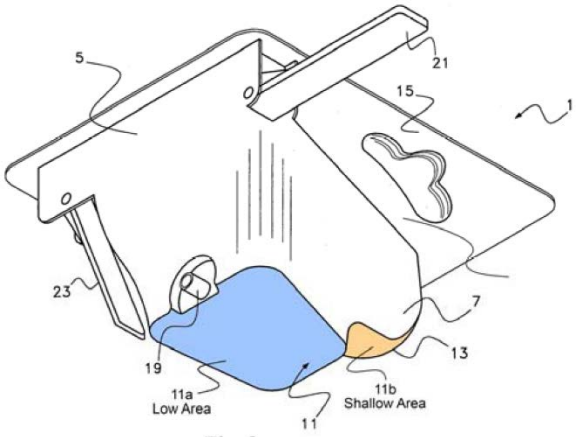
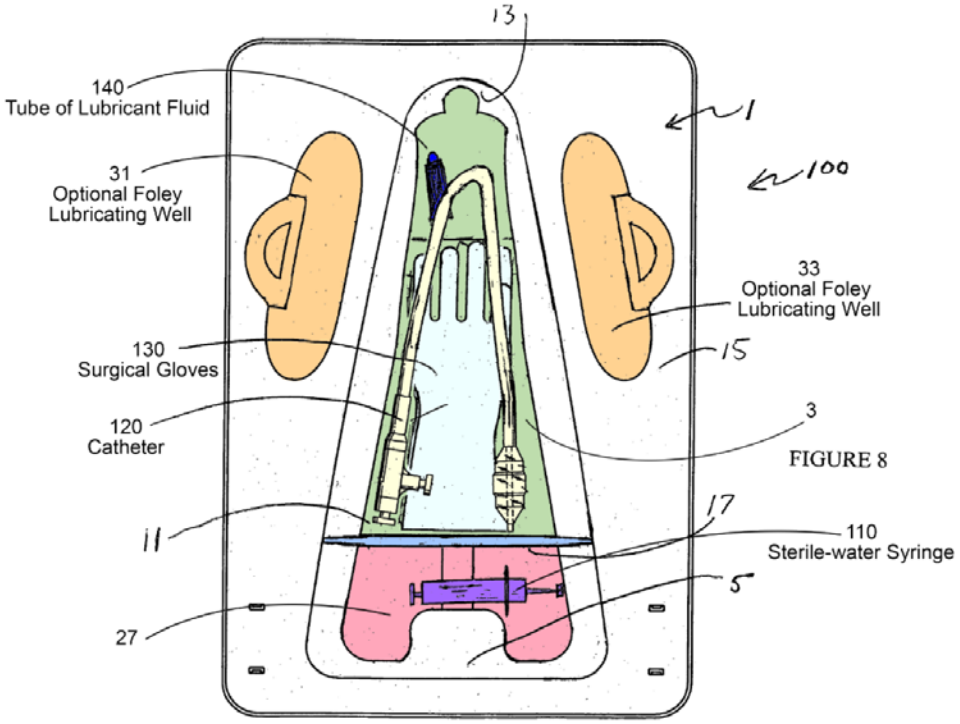


Fig. 2

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.



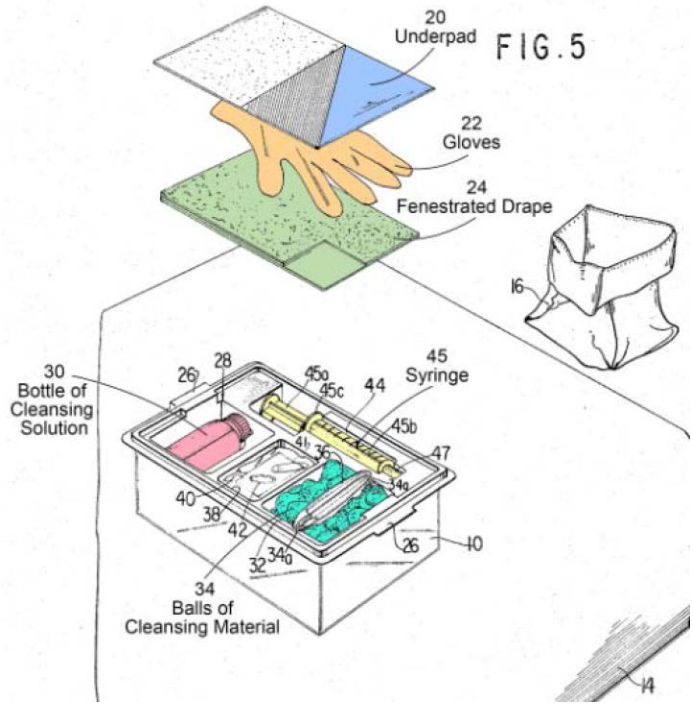
Solazzo's Figure 8 is a top view of kit 100 illustrating various components stored in compartments of tray 1. *Id*. at 4:41–48.

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.

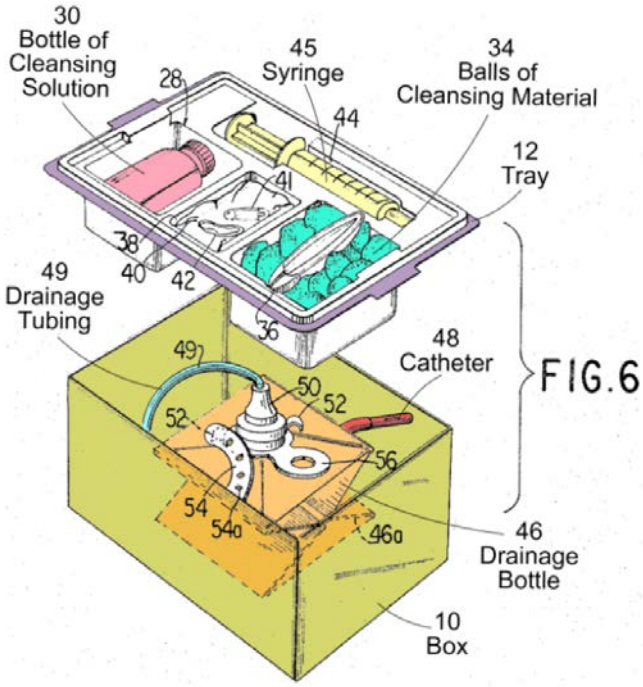
2. Overview of Serany

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.



3. Petitioner's Argument and Evidence

Petitioner argues that the combined teachings of Solazzo and Serany render claim 7 unpatentable as obvious. Pet. 30–44. Petitioner contends that Solazzo describes the tray and its compartments (element 7a), *id*. at 30–32 (citing Ex. 1005, 2:61–63, 3:56–4:1, Figures 1, 2, 5, 8; Ex. 1002 ¶¶ 48–57, 152–155), the first and second syringes and the manner in which they are ordered within the tray (element 7b and aspects of element 7c), *id*. at 32–37 (citing Ex. 1005, 3:15–24, 4:41–46, Figure 8; Ex. 1002 ¶¶ 158–170), and a catheter disposed in the second compartment (aspects of element 7d.i), *id*.

at 37–41 (citing Ex. 1005, 3:17, Figure 8; Ex. 1002 ¶¶ 176–186; Ex. 1003 ¶¶ 35, 41, 42).

Petitioner contends that Serany describes an indwelling catheter coupled to a drainage receptacle (aspects of element 7d.i), *id*. at 38–41 (citing Ex. 1006, 1:20–23, 1:31–32, 3:23–26, 3:33–35, Figure 6), between a base member of the second compartment and the coiled tube (element 7d.ii), *id*. at 43 (citing Ex. 1006, 3:26–35, Figure 6).

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 38. Petitioner argues, however, that Serany suggests that Solazzo's tray could hold Serany's closed-system Foley catheter, i.e., the claimed "coiled medical device," because an ordinarily skilled artisan would have been motivated to simplify Solazzo's catheterization procedure and reduce the risk of infection. *Id*. at 40–41 (citing Ex. 1006, 1:20–23, 1:31–32, 3:23–36; Ex. 1002 ¶¶ 176–86; Ex. 1003 ¶¶ 35, 41, 42; Ex. 1046, 239 ¶ 29; Ex. 1010, 51, 52).

4. Analysis of Patent Owner's Counterarguments

Patent Owner argues that Petitioner's challenge to claim 7 fails for three reasons, none of which is persuasive at this stage of the proceeding. We address each argument below.

a) Element 7c

Element 7c refers to the following portion of claim 7: "[i] a second syringe disposed within the first compartment of the single level container, [ii] the second syringe containing a lubricating jelly." Petitioner identifies Solazzo's tube of lubricant 140 as the second syringe. Pet. 34–35. Although Solazzo's tube 140 is located in recessed 3 rather instead of compartment 27

with inflation syringe 110, Petitioner argues that it was well known to group like items in the same compartment, *id*. at 35, and an ordinarily skilled artisan would have been motivated to put both the inflation and lubricant containers in the same compartment, *id*. at 36. Petitioner relies upon Serany as suggesting such grouping. *Id*. at 35 (citing Ex. 1006, 1:31–35; Ex. 1002 ¶ 165). Petitioner also contends that an ordinarily skilled artisan would place both syringes in compartment 27 so that "the lubricant syringe does not damage the Foley catheter during shipment of the tray." *Id*. at 36 (citing Ex. 1002 ¶¶ 162–170).

Petitioner also argues that it would have been obvious to use a syringe for Solazzo's lubricant rather than the tube as described by Solazzo. *Id*. at 37. 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*. (citing Ex. 1002 ¶¶ 172–174).

Patent Owner responds with two arguments. Prelim. Resp. 35–40. First, Patent Owner argues that Petitioner's contention that an ordinarily skilled artisan would have put the lubricant, which is shown in recessed area in Solazzo's Figure 8, in compartment 27 with inflation syringe 110 is "unsupported by credible evidence." Prelim. Resp. 35. Patent Owner's argument is unpersuasive at this stage of the proceeding. Petitioner supports its argument with citations to objective evidence, Serany and Imai, and testimony by Mr. Plishka. Pet. 34–36 (citing Ex. 1006, 1:31–35, 2:57–61; Ex. 1012; Ex. 1002 ¶¶ 162–170). Patent Owner cites no evidence to support its argument to rebut Mr. Plishka's testimony, which we currently find to be

persuasive on this point. Prelim. Resp. 35–39. We also consider Patent Owner's purported analysis of Serany and Imai to be unpersuasive attorney argument because it is not supported by objective or testimonial evidence.

Second, Patent Owner responds that Petitioner's "bare assertion" about substituting a syringe to hold Solazzo's lubricant for a tube fails because Petitioner's argument is "conclusory," which we understand to mean unsupported by evidence. Prelim. Resp. 39–41. 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 41. We disagree.

Petitioner cites specific testimony by Mr. Plishka. Pet. 37 (citing Ex. 1003 ¶¶ 172–174). 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 ¶ 172 (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*. ¶ 174. 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 ¶ 174 (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.

b) Element 7d.i

Element 7d.i refers to the requirement that "a coiled medical device disposed within the second compartment of the single level container, the coiled medical device including a Foley catheter, a fluid receptacle, and a tube coupling the Foley catheter to the fluid receptacle." Petitioner contends that catheter 120 within recessed area 3 as shown in Solazzo's Figure 8 is a Foley catheter assembly. Pet. 38 (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 39–40 (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 40–41. 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 ¶¶ 176–186; Ex. 1003 ¶ 35, 41, 42; Ex. 1046, 239 ¶ 29; Ex. 1006, 1:20–23, 1:31–32, 3:23–36; 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 41 (citing Ex. 1002 ¶ 186; 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. 41–46. 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. 41 (citing Ex. 1002 ¶ 186; Ex. 1003 ¶¶ 41, 42). Patent Owner contests Petitioner's evidence by providing testimony from Ms. Weintraub. Prelim. Resp. 43–44 (citing Ex. 2002 ¶¶ 12–17). 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 7d.i.

c) Element 7d.ii

Element 7d.iii refers to the following portion of claim 7: "the Foley catheter and the fluid receptacle positioned within the second compartment such that the fluid receptacle is between the second compartment base

member and the Foley catheter." Petitioner correctly notes that Solazzo describes placing its catheter 120 in recessed area 3 (i.e., the second compartment). Pet. 42 (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 43 (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 44 (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. 46–47. 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*. at 47. 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 48. We reject this argument for the same reasons

expressed above in connection with element 7d.i. *See* Part III.C.3.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 48–49. Patent Owner admits, however, that Serany does arrange at least underpad 20, gloves 22, and drape 24 in their order of use. *Id*. at 37 (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. 44. 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 7d.iii.

d) 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 '596 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.

5. Conclusion

For the reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood of proving that the combination of Solazzo and Serany renders claim 7 unpatentable as obvious.

IV. CONCLUSION

For the reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood of showing that claim 7 of the '596 patent is unpatentable as obvious in view of the combination of Solazzo and Serany. In accordance with the Court's decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018) and Office guidance,[5] we institute an *inter partes* review of all challenged claims of the '596 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 7–16, 21, and 22 of the '596 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 '596 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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[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.").

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