NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

C.R. BARD, INC.,
Appellant

v.

MEDLINE INDUSTRIES, INC.,
Appellee

2020-1900, 2020-1905

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2019-00035, IPR2019-00036.

C.R. BARD, INC.,
Appellant

v.

MEDLINE INDUSTRIES, INC.,
Appellee

2020-1908

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2019-00109.

C.R. BARD, INC.,
Appellant

v.

MEDLINE INDUSTRIES, INC.,
Appellee

2020-1910

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2019-00223.

Decided: August 13, 2021

BRIAN ROBERT MATSUI, Morrison & Foerster LLP, Washington, DC, argued for appellant. Also represented by SETH W. LLOYD, DEANNE MAYNARD; MEHRAN ARJOMAND, VINCENT JOSEPH BELUSKO, Los Angeles, CA.

ALLEN HOOVER, Fitch, Even, Tabin & Flannery LLP, Chicago, IL, argued for appellee. Also represented by PAUL HENKELMANN, NICOLE L. LITTLE, NICHOLAS T. PETERS.

Before LOURIE, BRYSON, and CHEN, *Circuit Judges*.

LOURIE, *Circuit Judge*.

C.R. Bard, Inc. ("Bard") appeals from four final written decisions of the Patent Trial and Appeal Board ("the Board") holding that claims 1–2, 6–10, 16–19, 25–58, 60–74, 76–90, and 92 of U.S. Patent 9,745,088 ("the '088 patent"), claims 7–16 and 21–22 of U.S. Patent 9,808,596 ("the '596 patent"), and claims 1–19 and 22–25 of U.S. Patent 9,795,761 ("the '761 patent") are not unpatentable as obvious. *C.R. Bard, Inc. v. Medline Indus., Inc.*, No. IPR2019-00036, 2020 WL 1808196 (P.T.A.B. Apr. 8, 2020) ("*Decision I*"); *C.R. Bard, Inc. v. Medline Indus., Inc.*, No. IPR2019-00035, 2020 WL 1808195 (P.T.A.B. Apr. 8, 2020) ("*Decision II*"); *C.R. Bard, Inc. v. Medline Indus., Inc.*, No. IPR2019-00223, 2020 WL 2968717 (P.T.A.B. June 3, 2020) ("*Decision III*"); *C.R. Bard, Inc. v. Medline Indus., Inc.*, No. IPR2019-00109, 2020 WL 2202164 (P.T.A.B. May 4, 2020) ("*Decision IV*"). For the reasons detailed below, we *affirm-in-part*, *vacate in-part*, and *remand* to the Board for further proceedings.

BACKGROUND

Medline Industries, Inc. ("Medline") owns the '088, '596, and '761 patents, which are directed to trays designed to store catheterization tools. The tools include a catheter, a lubricant syringe, an inflation syringe, and a fluid receptacle.

We begin with a brief background on catheterization and then turn to the trays' structure. Catheterization is a medical procedure used to treat patients who have trouble passing urine. It generally includes the following steps: First, the practitioner connects a water-filled inflation syringe to a Foley catheter, a type of catheter that has an inflatable balloon on one end. J.A. 24545, 24584; *see id.* at

1451.[1] Second, the practitioner lubricates the catheter and inserts it through the patient's urethra into the bladder. *Id.* at 24543–45. Third, the inflation syringe is used to inflate the catheter's balloon, which acts as a stopper to keep the catheter in place. *Id.* at 24545. Finally, urine flows into a small fluid receptacle connected to the catheter. *Id.* at 24546–47. Importantly, if the catheterization tools become contaminated, the patient may develop Catheter Associated Urinary Tract Infection ("CAUTI"). *Id.* at 24550. Such contamination could occur if the "practitioner were to remove the lubricant syringe first." Appellee's Br. 9 (20-1900) (citing J.A. 24590). The practitioner would then have to find a surface upon which to rest it "while attaching the inflation syringe" to the catheter—risking contamination. *Id.*

The inventions of the patents purport to reduce the risk of contamination by providing trays with features that direct the practitioner through the steps of a catheterization procedure. These features include compartments that have specialized structures and hold medical items arranged in a specific order. For example, in one embodiment, shown below, the tray has three compartments. '088 patent col. 9 ll. 22–24.[2] The first compartment contains two syringes (inflation syringe and lubricant syringe) arranged from left to right, in the order that they are used during the procedure. *Id.* col. 6 ll. 16–25; col. 9 ll. 24–26. The first compartment is also configured to receive lubricant from the lubricant syringe. *Id.* col. 7 ll. 43–59; col. 22 ll. 60–65. The second compartment contains a catheter and drainage bag. *Id.* col. 9 ll. 26–28; fig. 40. The third

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[1] We cite the joint appendix in the lead case, Appeal No. 20-1900, unless otherwise stated.

[2] For purposes of these appeals, the specifications of these three related patents are similar.

compartment contains a specimen container. Id. col. 9 ll. 28–30.

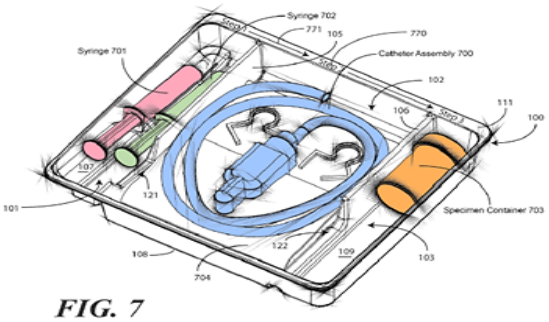

FIG. 7

'088 patent fig. 7 (annotations added by Appellant).

All of the challenged claims of the three patents are directed to a tray with a specific structure and arrangement of known medical implements intended to be used for conventional purposes. We briefly summarize the representative claims of the three patents. The claims are discussed in further detail below.

First, claims 1, 25, and 45 are representative of the '088 patent. Claims 1 and 25 are generally directed to a tray with two syringes positioned at different heights. Claim 45 is directed to a tray with two syringes in one compartment.

Second, claims 7 and 9 are representative of the '596 patent. Claim 7 is directed to a tray with a fluid receptacle positioned between the base and the catheter. Claim 9 is directed to a tray with a compartment configured to receive lubricant.

Third, claim 10 is representative of the '761 patent and is directed to a tray with a lubricating jelly application chamber.[3]

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[3] The limitations overlap across the claims of the three patents. For purposes of these appeals, we do not discuss each limitation in detail more than once.

Bard filed petitions for *inter partes* review of the three patents, asserting that the claims would have been obvious over different combinations of four main prior art references: Solazzo[4], Serany[5], Disston[6], and Imai.[7]

The prior art references are directed to medical trays or kits. Solazzo discloses a medical tray for catheterization or irrigation.[8] Three features of Solazzo are particularly relevant to this appeal. First, the tray, shown in figure 8 below, has two compartments. The first compartment ("compartment 27", pink) contains an inflation syringe. The second compartment ("compartment 3", green) contains a Foley catheter and a lubricant tube. J.A. 2010 at col. 3 ll. 56–58; col. 4 ll. 17–20, 41–48; *see also* J.A. 2001 at fig. 1. Both compartments can be joined by removing the optional divider wall (blue). J.A. 2010 at col. 4 ll. 15–16. Second, Solazzo's bottom, shown below in figure 2, has a "non constant depth" with deep area (blue) and shallow area (tan). *Id.* at col. 3 ll. 61–66. As a result, the lubricant tube is elevated above the inflation syringe. Third, Solazzo discloses an irrigation syringe but does not specify in which compartment it is stored. *Id.* at col. 3 ll. 14–24.

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4 U.S. Patent 7,278,987

5 U.S. Patent 3,329,261

6 U.S. Patent 3,166,189

7 Japanese Patent 2007-229520

8 Irrigation refers to using a catheter to remove blood clots. J.A. 1452–53.

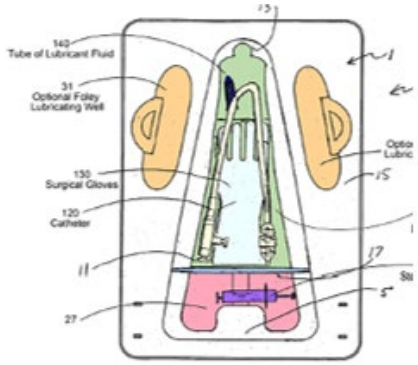

Fig. 8

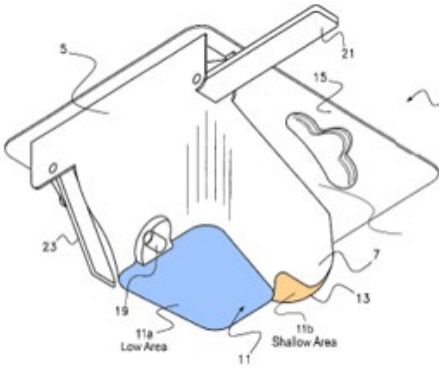

Fig. 2

J.A. 2008 at fig. 8 (annotations added by Appellant); J.A. 2002 at fig. 2 (annotations added by Appellant).

Serany discloses a package "containing components for a catheterization procedure." J.A. 2015 at col. 1 ll. 9–10. It teaches that the components are stored in their proper "order of use" in order to "assure that a sterile field may be maintained as the components are removed." *Id.* at col. 1 ll. 26–30. For example, Serany discloses placing multiple cleansing balls in one compartment. J.A. 2014 at fig. 6; J.A. 2015 at col. 2 ll. 57–59. Serany further explains that "forceps" are "conveniently stored above" the cleansing balls because the forceps are used first. J.A. 2015 at col. 2 ll. 57–72; *see also* col. 2 ll. 21–39.

Disston discloses a catheterization tray. Like Serany, the items in Disston are "arranged in such order and position as to be most conveniently available when the container is opened." J.A. 2033 at col. 2 ll. 15–23.

Imai discloses an epidural anesthesia tray. The tray contains three syringes stacked together in one compartment. J.A. 2077 at fig. 1.

The Board reviewed the prior art references and, in four separate decisions, held that Bard failed to show that the prior art taught the tray's structural features or

particular arrangement of medical items. The Board addressed the '088 patent in the first two decisions, the '596 patent in the third decision, and the '761 patent in the fourth decision. A chart showing the claims that the Board addressed in each decision is shown below.

Decision I	Claims 45–58, 60–74, 76–90, and 92	'088 patent
Decision II	Claims 1–2, 6–10, 16–19, and 25–44	'088 patent
Decision III	Claim 7–16 and 21–22	'596 patent
Decision IV	Claims 1–19 and 22–25	'761 patent

The Board did not discuss the parties' arguments regarding secondary considerations of nonobviousness. Bard appealed all four decisions. Because the issues raised in the four decisions are similar, we address them together in one opinion. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

We review the Board's legal determinations de novo, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004) (citing *In re Kollar*, 286 F.3d 1326, 1329 (Fed. Cir. 2002)), and its fact findings for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the evidence as adequate to support the finding. *Consol. Edison Co. v. N.L.R.B.*, 305 U.S. 197, 229 (1938).

Obviousness is a question of law, supported by underlying fact questions. *In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1361 (Fed. Cir. 2012). In evaluating obviousness, we consider the scope and content of the prior art, differences

between the prior art and the claims at issue, the level of ordinary skill in the pertinent art, and any relevant secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). "What the prior art teaches, whether a person of ordinary skill in the art would have been motivated to combine references, and whether a reference teaches away from the claimed invention are questions of fact." *Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017) (citing *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1047–48 (Fed. Cir. 2016) (en banc)).

Bard asserts that the Board erred in concluding that the prior art did not render obvious the claims of the '088, '596, and '761 patents. Bard also contends that we should reverse the decisions outright, without remanding to the Board to evaluate secondary considerations of nonobviousness, which it had declined to consider. According to the Board, such consideration was unnecessary given that it had already determined that the references did not render the claims obvious. Medline, puzzlingly, begins its response by asserting that the decisions should be reviewed on a ground other than that relied on by the Board, namely, that the cited references are incompatible with each other.[9] Whether or not such a tactic shows a lack of confidence in the Board's grounds for upholding the patents, we will

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[9] Medline specifically argued that, because Solazzo's tray lacks a fluid receptacle, it is incompatible with the trays disclosed in the other prior art references, which do disclose a fluid receptacle. However, Medline conceded during oral argument that it is collaterally estopped from making that argument. *See* Oral Argument (20-1900) at 44:20–47:16, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=20-1900_07062021.mp3. Accordingly, Medline is also precluded from making that argument on remand.

evaluate the Board's decisions as it presented them. We address the representative claims of each patent in turn.

I.

'088 Patent

We turn first to the '088 patent. Bard argues that the Board erred in concluding that claim 45 is not unpatentable as obvious. It makes similar arguments concerning claims 1 and 25.

Claim 45

Claim 45 is directed to a tray with two syringes in one compartment and reads as follows:

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

'088 patent col. 30 l. 58–col. 31 l. 5 (emphasis added).

With regard to claim 45, the Board rejected Bard's argument that it would have been obvious to store two syringes in one compartment. In so holding, the Board

acknowledged that Solazzo discloses two syringes. *Decision I*, 2020 WL 1808196, at *5. But it held that Solazzo still does not render the claim unpatentable because it does not "expressly describe[]" placing two syringes together in one compartment. *Id.* at *6.

Bard argues that the Board erred in holding that Solazzo does not render obvious storing two syringes in one compartment. Specifically, Bard asserts that Solazzo discloses two syringes: (1) an inflation syringe in compartment 27 and (2) an irrigation syringe with no express location. Although Solazzo is silent regarding the irrigation syringe's location, Bard contends that a skilled artisan would have been motivated to store it together with the inflation syringe. In support of its argument, Bard points to Serany's disclosure that the components in its kit are "arranged in logical step-by-step order" and that like items should be stored together. J.A. 2015 at col. 1 ll. 31–35; J.A. 2014 at fig. 6. Bard also points to Disston's disclosure that the items can be arranged "in such order" "as to be most conveniently available when the container is opened." J.A. 2033 at col. 2 ll. 15–23.

Medline responds that the Board's obviousness analysis was correct. Specifically, Medline argues that the Board correctly weighed all the record evidence and found it lacking.[10]

We agree with Bard that the Board's decision was erroneous. Although the prior art does not "expressly" direct a skilled artisan to place two syringes in one compartment, it certainly was well within the possibilities available to

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[10] Medline initially argued that it would not have been obvious to add a medical assembly comprising a drainage bag to Solazzo's tray, as required by claim 45. However, Medline is no longer pursuing that argument. Oral Argument (20-1900) at 44:20–47:16.

him to do so. As the Board acknowledged, a person of ordinary skill had only two options for storing the irrigation syringe: either together with the inflation syringe or apart. And, as Bard's expert testified, among those limited options, a skilled artisan had ample reason to avail himself of the obvious option of placing both syringes in the same compartment. *See* J.A. 1395–98. Indeed, according to Serany's teachings, logically arranged components will "facilitate the nurse's or physician's task." J.A. 2015 at col. 1 ll. 31–35; *see also* J.A. 2033 at col. 2 ll. 15–23 (Disston). When two equally viable options are available, as here, then, without more, either one would seem to have been obvious.

As the Supreme Court has stated, obviousness requires an "expansive and flexible" approach that asks whether the claimed improvement is more than a "predictable variation" of "prior art elements according to their established functions." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415, 417 (2007). Here, in contrast, the Board's obviousness analysis rigidly focused on "the disclosures of individual prior-art references" without considering a skilled artisan's "creativity[] and common sense." *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013). For example, the Board faulted Bard's references for failing to "expressly describe[]" two syringes in one compartment. *Decision I*, 2020 WL 1808196, at *6. The Board also did not discern why "general statements about arranging components in 'logical' order demonstrate[] the obviousness of arranging two syringes in one compartment." *Id.* But obviousness requires no such express disclosure.

We therefore disagree with the Board's determination that the prior art did not teach the claim limitation of storing two syringes in one compartment. We thus vacate the Board's decision that claims 45–58, 60–74, 76–90, and 92 of the '088 patent, all of which are resolved by the above treatment of claim 45, are not unpatentable as obvious. *Decision I*, 2020 WL 1808196 (P.T.A.B. Apr. 8, 2020).

Claims 1 and 25

Claims 1 and 25 are directed to storing two syringes at different heights according to their order of use. We address each claim in turn.

Claim 1 recites:

> A medical procedure kit, comprising:
>
> a tray having a compartment for receiving a medical assembly;
>
> a first syringe and a second syringe disposed within the tray;
>
> at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material; and
>
> an outer packaging disposed about both the tray and the at least one layer of wrap material, wherein:
>
> the *first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure*; and
>
> the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe; and
>
> the first compartment comprising a base member that defines a *mnemonic device* indicating *which of the first syringe or the second syringe should be used first in the catheterization procedure*.

'088 patent col. 27 ll. 47–67 (emphases added).

According to Medline, claim 1's mnemonic device corresponds to the patent's description of a "stair-stepped contour," designed to hold the syringes at different heights according to order of use. *Id.* col. 6 ll. 16–25. The different

heights purportedly remind practitioners of which syringe to use first, i.e., because it "may be intuitive" to the practitioner to use the higher syringe first, before the lower syringe. *Id.*

With regard to claim 1, the Board rejected Bard's argument that it would have been obvious to design a tray with two syringes positioned at different heights. Specifically, the Board found that Solazzo's bottom lacked a "contour or shape" to support the lubricant at an elevated height. *Decision II*, 2020 WL 1808195, at *7. According to the Board, the lubricant "is held in place" by a catheter and gloves and, without other items to hold it in place, "would simply fall" from its elevated position. *Id.* at *7–8.

Bard asserts that the Board erred in concluding that the prior art does not render obvious the claimed mnemonic device. According to Bard, the Board's findings show that the claim is simply to an obvious combination of prior art elements. As support, Bard argues that (1) Solazzo's tray has a non-constant bottom wherein the lubricant tube is stored higher than the inflation syringe, in accordance with the items' order of use,[11] (2) it would have been obvious to substitute the lubricant *tube* with a lubricant *syringe*, and (3) Solazzo's optional divider wall could be removed so that the two syringes are in the same compartment.

Medline responds, citing expert testimony, that Solazzo's "contoured recess [is] not intended to indicate which of two syringes should be used first." Appellee's Br. 62 (20–1900) (citing J.A. 9275–76). Medline also emphasizes that Solazzo's "sloped bottom portion would be

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[11] Although Medline contends that practitioners would reach for the inflation syringe before the lubricant, it does not dispute that a practitioner can reach for the lubricant first. *See* Appellee's Br. 56–66 (20–1900).

ineffective" in maintaining "one syringe at a higher height than the other." *Id.* (internal quotation marks omitted).

We agree with Bard that the Board's decision was erroneous. As it did with the first set of claims, the Board adopted an overly rigid obviousness analysis. Specifically, it demanded express guidance from individual references and did not consider the knowledge and creativity of a skilled artisan. Even assuming, as the Board did, that the claim requires the tray's compartment *alone* to support the syringes at different heights, such a limitation still encompasses only old elements predictably performing their known functions.

First, as the Board found, Solazzo discloses that the lubricant is positioned above the inflation syringe, and that practitioners would use the lubricant before the inflation syringe. *Decision II*, 2020 WL 1808195, at *4. Second, as the Board acknowledged, Serany describes storing "all the essential equipment" for a "catheterization procedure," which includes a syringe, "in the proper order of use." *Id.* (citing J.A. 2015 at col. 1 ll. 16–25) (internal quotation marks omitted). And Serany explains that arranging items according to order of use encompasses storing some items above others. For example, the "forceps" are "conveniently stored above" the cleansing balls because practitioners use the forceps first. J.A. 2015 at col. 2 ll. 65–70. Third, as Bard argued, "it was well-known in the art of device design (including the design of medical trays) to include affordances to aid a user in performing operations in the correct order." *C. R. Bard, Inc. v. Medline Indus., Inc.*, IPR2019-00035, Petition at 48–49 (filed Oct. 4, 2018) (Petition for IPR); *see also* J.A. 220. Given the prior art disclosures, a skilled artisan would have been motivated to design a compartment with a bottom portion that would elevate one syringe above another, without the aid of other items. And Medline does not contend that such structure would have been difficult to implement.

Claim 25 is like claim 1, but instead of a mnemonic device, it requires a "first compartment to support the first syringe and the second syringe at different heights according to predetermined steps of the catheterization procedure." '088 patent col. 29 ll. 29–48.

The Board rejected Bard's argument that Imai teaches arranging syringes at different heights. According to the Board, Imai "identifies no mechanism" for supporting syringes "in any particular arrangement." *Decision II*, 2020 WL 1808195, at *9.

Bard asserts that the Board erred in holding that it would not have been obvious to store two syringes at different heights according to order of use. Specifically, Bard argues that it would have been obvious to (1) replace the lubricant tube with a lubricant syringe, (2) store the lubricant syringe with the inflation syringe in Solazzo's compartment 27 (with the divider wall in place), and (3) place the syringes at different heights according to order of use by stacking them, as disclosed in Imai. Medline responds that Bard simply disagrees with the Board's factual findings and weighing of the evidence.

We agree with Bard that the Board's decision was erroneous. As the Board found, Serany discloses grouping like items together in a single compartment and explains the utility of ordering items in the proper order of use. *Id.* at *4–5, *9. The Board also found that Imai discloses three syringes. *Id.* at *9. That Imai does not "expressly" describe a stacking mechanism does not defeat Bard's argument on obviousness. Given the prior art disclosures and the finite number of predictable options, a skilled artisan would have been motivated to stack the syringes by height according to their order of use. As Bard's expert explained, the artisan would have reasoned such ordering to be more convenient. *See* J.A. at 1373–74.

We thus disagree with the Board's determination that the prior art did not teach the claim limitation of a

compartment that supports syringes at different heights according to order of use. Accordingly, we vacate the Board's decision concluding that claims 1–2, 6–10, 16–19, and 25–44 of the '088 patent, all of which are resolved by our treatment of claims 1 and 25, are not unpatentable as obvious. *Decision II*, 2020 WL 1808195 (P.T.A.B. Apr. 8, 2020).

II.

'596 Patent

Bard argues that the Board erred in concluding that claims 7 and 9 of the '596 patent are not unpatentable as obvious. We address each claim in turn.

Claim 7

Claim 7 recites a "fluid receptacle positioned within the second compartment such that the fluid receptacle is *between the second compartment base member and the Foley catheter*." '596 patent col. 18 ll. 30–51 (emphasis added).

The Board rejected Bard's argument that it would have been obvious to store a fluid receptacle under a catheter. The Board emphasized that "Serany simply fails to *expressly* describe or illustrate a fluid receptacle that is wholly located between the bottom of the container and the catheter." *Decision III*, 2020 WL 2968717, at *8 (emphasis added).

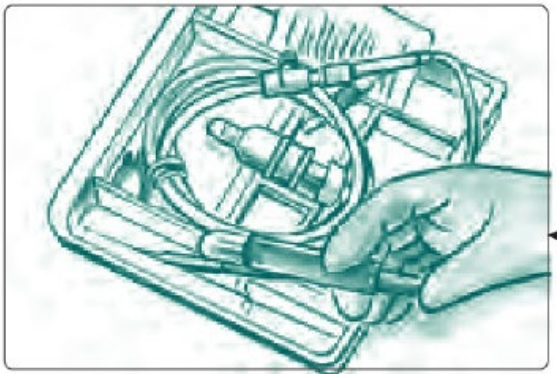
Bard argues that the Board erred in concluding that it would not have been obvious to position a fluid receptacle underneath a catheter. In support of its argument, Bard points to (1) undisputed testimony that practitioners access the catheter before the fluid receptacle during a catheterization procedure, (2) Serany's disclosure that a fluid receptacle can be stored together with the catheter, and (3) Serany's disclosure that "all the components [are] arranged in logical step-by-step order." J.A. 2015 col. 1 ll. 31–35. Medline responds that Serany shows the "opposite of what

the claims require"—a catheter "coiled in the box *about* the bottle, rather than *on top* of the bottle." Appellee's Br. 53 (20-1910) (emphases added).

We agree with Bard. As before, the Board imposed anticipation-like requirements on the prior art in determining obviousness. Here, the limitation amounts to no more than rearranging simple items (a fluid receptacle and catheter) in a tray. Serany's disclosure, coupled with common sense, would have provided a skilled artisan with ample motivation to place the fluid receptacle under the catheter; such an arrangement would conveniently place the items in the order they are used during the procedure. *See* J.A. at 1075 (20-1910) (Bard's expert testifying to the same). That Serany does not "expressly" describe a fluid receptacle in the claimed arrangement does not defeat Bard's argument on obviousness.

Claim 9

Claim 9 is similar to the claims discussed above but recites that the tray's "first compartment is *configured to receive the lubricating jelly* from the second syringe to lubricate a tip of the Foley catheter when the tip is placed into the first compartment." '596 patent col. 18 ll. 54–57 (emphasis added). Figure 15, shown below, shows an example of a practitioner using a lubricant syringe to inject lubricant into the first compartment. '596 patent fig. 15 excerpt (annotations added by Appellee).



With regard to claim 9, the Board rejected Bard's argument that Solazzo's compartment 27 is configured to receive lubricant. According to the Board, compartment 27 would be "too deep" and inefficient to facilitate lubricant application. *Decision III*, 2020 WL 2968717, at *10.

Bard argues that the Board erred in holding that the prior art does not render obvious a first compartment configured to receive lubricant. According to Bard, Solazzo's compartment 27 has the necessary structural features to store lubricant and facilitate catheter lubrication. As relevant here, compartment 27 is designed to hold a patient's urine "over flow." J.A. 2010 at col. 4 ll. 15–20. Because compartment 27 is already designed to hold urine, Bard contends that it could also easily hold lubricant. Alternatively, Bard asserts that the Board, without notice, implicitly interpreted claim 9 to require a compartment that is "shallow." Medline responds that the Board's determination was supported by substantial evidence. Specifically, Medline argues that the Board correctly found that compartment 27 is too deep to store lubricant and facilitate catheter lubrication.

We agree with Medline on this issue that the Board's determination was supported by substantial evidence. If two "inconsistent conclusions may reasonably be drawn from the evidence in record, [the Board's] decision to favor one conclusion over the other is the epitome of a decision that must be sustained upon review for substantial evidence." *In re Jolley*, 308 F.3d 1317, 1328–29 (Fed. Cir. 2002). Such is the case here.

Given the record evidence, the Board reasonably found that Solazzo's compartment 27 is not configured to store lubricant or to facilitate catheter lubrication. First, the Board credited expert testimony that compartment 27's depth would render it unsuitable to store lubricant for the catheter. *Decision III*, 2020 WL 2968717, at *10. For example, faced with a deep compartment, a practitioner

would have difficulty maneuvering the catheter so that its tip could become lubricated. Second, the Board credited expert testimony that, because a doctor needs to measure the urine, "[h]aving lubrication" in the urine compartment could "ruin[]" the measurement. *Id.*

We are unpersuaded by Bard's arguments to the contrary. As the Board pointed out, Bard's argument boils down to the assertion that "*any* chamber of a catheterization tray regardless of its size and shape" is "configured for receiving lubricating jelly and facilitating the lubrication of the tip of a catheter." *Decision III*, 2020 WL 2968717, at *9–10. We disagree with Bard. Indeed, Solazzo itself describes that a practitioner should use *other* compartments (wells 31, 33) in the tray to lubricate the catheter rather than compartment 27, which the Board found persuasive. *Id.* We are also unpersuaded by Bard's attempt to reframe the issue as one of claim construction rather than obviousness. The parties' arguments here relate to a comparison of the patent claims and the prior art—that is part of the obviousness analysis, reviewed, in part, for substantial evidence. And even assuming, arguendo, that the Board implicitly engaged in claim construction, Bard was hardly without notice that the depth of the lubricating chamber was at issue. In Medline's patent owner response, it emphasized that a practitioner would be disinclined to use a deep well such as Solazzo's compartment 27 for lubricating the catheter. *See, e.g.*, *C. R. Bard, Inc. v. Medline Indus., Inc.*, IPR2019-00223, Paper 33 at 33–35 (Aug. 29, 2019). The Board thus reasonably concluded that claim 9 would not have been obvious over the prior art.

We therefore disagree with the Board's determination that the prior art did not teach the limitation of storing a fluid receptacle between the compartment bottom and the catheter, as recited in claims 7–8 and 11–13 of the '596 patent. These claims also recite two syringes in one compartment and claims 11–12 further recite two syringes positioned at different heights. For the reasons explained

above, we also disagree with the Board's determination that the prior art did not teach those limitations. Accordingly, we vacate the portion of the Board's decision concluding that claims 7–8 and 11–13, all of which are resolved by the above treatment of claim 7, are not unpatentable as obvious. We affirm the portion of the Board's decision concluding that claims 9–10, 14–16, and 21–22, all of which are resolved by the above treatment of claim 9, are not unpatentable as obvious. *Decision III*, 2020 WL 2968717 (P.T.A.B. June 3, 2020).

III.

'761 Patent

Claim 10

Representative claim 10 of the '761 patent recites a "first compartment defining a *lubricating jelly application chamber* to *lubricate the Foley catheter* when passed from the second compartment into the first compartment." '761 patent col. 28 l. 61–col. 29 l. 16 (emphasis added).

With regard to claim 10, the Board rejected Bard's argument that Solazzo's compartment 27 would "permit lubrication" of a catheter that "is passing over [the] divider wall." *Decision IV*, 2020 WL 2202164, at *11–12. According to the Board, compartment 27 is too "narrow and deep." *Id.*

Bard asserts that the Board erred in concluding that the prior art did not teach a lubricating jelly application chamber. Bard's arguments here are similar to those it made for claim 9 of the '596 patent, described above. Specifically, Bard argues that Solazzo's compartment 27 (pink), shown below, corresponds to the first compartment defining a lubricating chamber. Bard further argues that Solazzo has a notch on its divider wall that would allow the catheter to move from Solazzo's second compartment (compartment 3, green) and into the first compartment (compartment 27, pink) for lubrication.

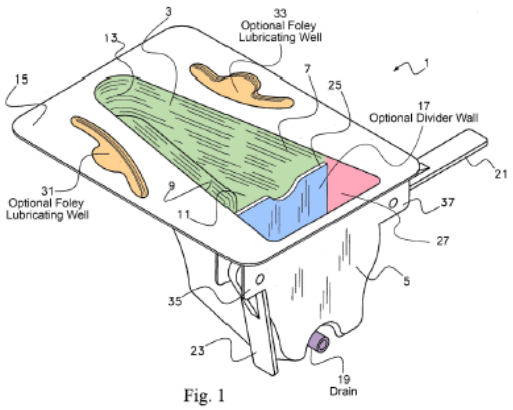


Fig. 1

J.A. 2001 at fig. 1 (annotations added by Appellant).

For the reasons explained above, the Board's determination concerning this claim was supported by substantial evidence. Specifically, the Board reasonably found that Solazzo's compartment 27 does not define a lubricating jelly application chamber to lubricate the catheter. For example, the Board credited expert testimony that compartment 27's depth would render it unsuitable to store lubricant. *Decision IV*, 2020 WL 2202164, at *11–12. The Board also relied on expert testimony that compartment 27 was structurally dissimilar to wells 31 and 33, which, as Solazzo discloses, are used for lubrication. *Id.*

The challenged claims of the '761 patent (claims 1–19 and 22–25) also recite two syringes in one compartment or two syringes positioned at different heights. To the extent the Board found that the prior art did not teach those limitations, that was error, as explained above. However, any error was harmless because we conclude that the deficiency of the prior art concerning the lubricating chamber limitation was supported by substantial evidence and hence sufficient to establish nonobviousness. Accordingly, we affirm the Board's decision that claims 1–19 and 22–25 of the '761 patent, all of which are resolved by the above treatment of claim 10, are not unpatentable as obvious. *Decision IV*, 2020 WL 2202164 (P.T.A.B. May 4, 2020).

IV.

Secondary Considerations of Nonobviousness

We finally turn to Bard's arguments regarding secondary considerations of nonobviousness, which the Board did not address. Bard argues that, if we determine that the Board erred in its analysis, we should reverse the decisions outright without remand because Medline's secondary considerations evidence is irrelevant. Specifically, according to Bard, Medline's secondary considerations evidence either lacks nexus to the claims or is barred by issue preclusion.

We disagree with Bard that we must reverse the decisions without remand. We decline to make factual findings in the first instance regarding secondary considerations on appeal. Additionally, we leave for the Board to decide on remand whether Medline is collaterally estopped from making certain secondary considerations arguments. On remand, the Board should also evaluate the dependent claims that it did not separately analyze in the first instance.

CONCLUSION

We have considered the parties' remaining arguments but find them unpersuasive. For the foregoing reasons, with respect to the '088 patent, we vacate the Board's decision concluding that claims 45–58, 60–74, 76–90, and 92 are not unpatentable as obvious and its decision that claims 1–2, 6–10, 16–19, and 25–44 are not unpatentable as obvious (Appeal Nos. 20–1900, 20–1905). With respect to the '596 patent, we vacate the portion of the Board's decision concluding that claims 7–8 and 11–13, of the '596 patent are not unpatentable as obvious and affirm the portion of the Board's decision concluding that claims 9–10, 14–16, and 21–22 are not unpatentable as obvious (Appeal No. 20–1910). We remand these three decisions to the Board for further proceedings consistent with this opinion. With

respect to the '761 patent, we affirm the Board's decision that claims 1–19 and 22–25 are not unpatentable as obvious (Appeal No. 20–1908).

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED

COSTS

No costs.