

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 IPR2015-00509
Patent 8,448,786 B2

Before JOSIAH C. COCKS, JENNIFER MEYER CHAGNON, and
TIMOTHY J. GOODSON, *Administrative Patent Judges*.

COCKS, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

C.R. Bard, Inc. (“Petitioner”) filed a Corrected Petition (Paper 7, “Pet.”) requesting *inter partes* review of claims 1 and 2 of U.S. Patent No. 8,448,786 B2 (“the ’786 patent”). Medline Industries, Inc. (“Patent Owner”) timely filed a Preliminary Response (Paper 10, “Prelim. Resp.”) to the Corrected Petition. We have jurisdiction under 35 U.S.C. § 314.

To institute an *inter partes* review, we must determine that the information presented in the Petition shows “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). For the reasons set forth below, we conclude that the information presented in the Petition does not establish a reasonable likelihood that Petitioner will prevail in challenging claims 1 and 2 of the ’786 patent. We do not authorize an *inter partes* review to be instituted as to claims 1 and 2.

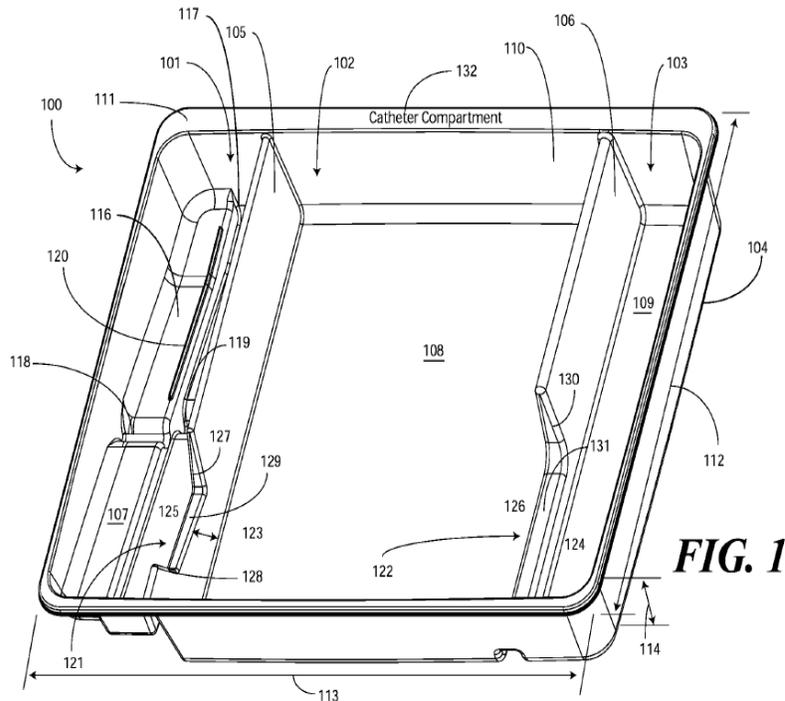
A. Related Matters

The ’786 patent is the subject of litigation between the parties in the U.S. District Court for the Northern District of Illinois, *Medline Industries, Inc. v. C.R. Bard, Inc.*, Case No. 1:14-cv-03618. See Paper 4, 2. In addition, three other petitions for *inter partes* review involving the same parties and related U.S. Patent Nos. 8,631,935 B2 and 8,678,190 B2 currently are pending as IPR2015-00511, IPR2015-00513, and IPR2015-00514. See *id.* at 2–3.

B. The ’786 Patent (Ex. 1001)

The ’786 patent is titled “Catheter Tray, Packaging System, Instruction Insert, and Associated Methods.” Ex. 1001, Title. The ’786

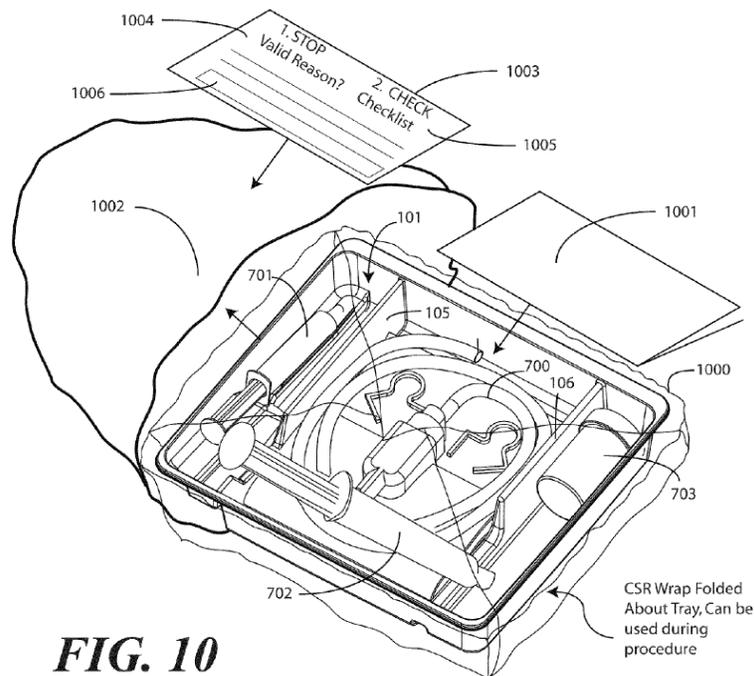
patent describes tray 100 that holds catheter assembly 700 as well as other items used in catheterization, such as syringes 701, 702 containing sterile water and lubricating jelly. *Id.* at Abstract. Figure 1, reproduced below, is a perspective view of a catheter tray according to an embodiment of the invention. *Id.* at col. 2, ll. 20–22.



As shown in Figure 1 above, tray 100 has first compartment 101 for accommodating syringes, second compartment 102 for accommodating the catheter assembly, and third compartment 103 for accommodating a specimen jar. *Id.* at col. 5, ll. 45–49. The '786 patent explains that the stair-stepped contour of first compartment base member 107 allows first compartment 101 to be used as a lubricant applicator for the catheter. *Id.* at col. 7, ll. 20–23. Specifically, a medical services provider dispenses lubricating jelly along second step portion 117, which serves as a channel in which the lubricating jelly can spread. *Id.* at col. 7, ll. 24–28. The provider then passes the catheter through opening 121 between first and second

compartments 101, 102, through the channel formed by second step portion 117, and out the top of tray 100 to the patient. *Id.* at col. 6, ll. 47–50; col. 7, ll. 28–32. According to the '786 patent, this ability to apply lubricating jelly to the catheter while the catheter is contained within tray 100 improves on prior art solutions in both ease of use and reduced risk of contamination. *Id.* at col. 7, ll. 33–35, 56–62.

Figure 10, reproduced below, is a perspective view of a tray with a catheter and other devices disposed therein, along with instructions and packaging. *Id.* at col. 2, ll. 50–54.



As shown in Figure 10, tray 100 is sealed with Central Sterile Reprocessing (CSR) wrap 1000, which can be unfolded and used in the catheter insertion process, such as by providing a sterile field for tray 100 to sit in. *Id.* at col. 10, ll. 13–33. The '786 patent discloses that printed instructions 1001, including a health services portion and a patient portion, can be attached to tray 100. *Id.* at col. 9, ll. 34–38. The health services

portion of printed instructions 1001 can provide instructions to health services providers regarding use of the contents of tray 100. *Id.* at col. 9, ll. 38–47. The patient portion of printed instructions 1001 can provide information that is useful for a patient, and it can be detachable from the health services portion so that the provider can detach it and discuss its contents with the patient. *Id.* at col. 10, ll. 48–63.

C. Illustrative Claims

Claim 1 is independent. Claim 2 depends from claim 1. Claims 1 and 2 are reproduced below:

1. A method of using a catheter package assembly, comprising:
 - opening a thermally sealed bag disposed about a tray having a catheter assembly disposed therein;
 - accessing an instruction manual;
 - unfolding one or more layers of wrap to reveal an additional layer of wrap and the catheter assembly; and
 - placing one of the one or more layers of wrap or the additional layer of wrap beneath a patient, thereby transforming an area beneath the patient from a non-sterile field to a sterile field.
2. The method of claim 1, wherein the instruction manual comprises a health care services portion and a patient portion detachably coupled thereto.

Ex. 1001, col. 26, l. 61–col. 27, l. 7.

D. References Relied Upon

The Petition relies on the following references:

Serany	US 3,329,261	July 4, 1967	Ex. 1008
Brezette	US 3,978,983	Sept. 7, 1976	Ex. 1010
Franks-Farah	US 6,840,379 B2	Jan. 11, 2005	Ex. 1009
EUROPEAN COMMISSION: PHARMACEUTICAL COMMITTEE, <i>A Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use</i> (Sept. 29, 1998) (“1998 EC Guideline”).			Ex. 1007

E. Alleged Grounds of Unpatentability

Petitioner contends that claims 1 and 2 of the '786 patent are unpatentable on the following grounds under 35 U.S.C. (*see* Pet. 13):

References	Basis	Claims Challenged
Serany	§ 102/§ 103	1
Serany and Franks-Farah	§ 103	1
Serany, Franks-Farah, and Brezette	§ 103	1
Any of the above grounds taken with 1998 EC Guideline	§ 103	2

In support of its proposed grounds of unpatentability, Petitioner also relies upon the Declaration testimony of Dr. Robert Kimmel (Ex. 1002) and Ms. Susan Carrow (Ex. 1004).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, No. 2014–1301, ___ F.3d ___, 2015 WL 2097949, at *5–*8 (Fed. Cir. July 8, 2015). Under the broadest reasonable construction standard, claim terms usually are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). For purposes of this Decision, we need only make explicit the meaning of the term “reveal.” No other terms require express construction.

Claim 1 includes the following step: “unfolding one or more layers of wrap to *reveal* an additional layer of wrap and the catheter assembly.” Ex. 1001, col. 26, ll. 66–67 (emphasis added). Petitioner does not offer a construction of the term “reveal.” Patent Owner proposes a construction of the term, in the context of its use in claim 1, as “[t]o make visible or to make (something that was hidden) able to be seen.” Prelim. Resp. 12. As noted by Patent Owner, the term “reveal” is used throughout the Specification of the ’786 patent. *Id.* at 12–13. For instance, the ’786 patent describes the following:

The top of tray 100 could have a hinged or snap-coupled lid that is opened or removed to reveal the compartments there beneath. [Ex. 1001, col. 5, ll. 14–17.]

Using a CSR wrap as an illustrative example, in one embodiment as indicated in FIG. 10, the CSR wrap 100 is

folded about the tray 100 for sealing, and can be correspondingly unfolded to reveal the tray 100. [*Id.* at col. 10, ll. 25–28.]

Where the catheter package assembly is configured as shown in FIG. 10, removal of the sterile wrap (1002) will reveal the printed instructions (1001). [*Id.* at col. 25, ll. 13–15.]

At FIG. 31, a health care services provider 3101 opens the outer bag 2902 that is disposed about the tray 100 and removes the bag 2902 to reveal the packaged catheter assembly 2901 therein. [*Id.* at col. 26, ll. 5–8.]

Where an additional layer of wrap material 2701 is included, this unfolding step reveals and makes accessible the additional layer of wrap material 2701. [*Id.* at col. 26, ll. 13–16.]

In light of the content of the Specification of the '786 patent, including those portions reproduced above, Patent Owner contends that “[i]t is clear from these disclosures that ‘reveal’ means that an object is made visible, and particularly something that was hidden is able to be seen,” and that such meaning constitutes the “plain meaning” of the term. Prelim. Resp. 13. It is apparent from the '786 patent, including those portions reproduced above, that the term “reveal” connotes an action distinct from making an object accessible. In reviewing the '786 patent, we discern that, consistent with the meaning offered by Patent Owner, an object that is “revealed” becomes exposed visibly upon removal of another component. We also observe that in looking to other definition sources for the term “reveal” as it is used in the claims of the '786 patent, the meaning of the term

is understood commonly as “to show (something) plainly or clearly : to make (something that was hidden) able to be seen.”¹

In considering the record before us, we are satisfied that the construction of “reveal” proffered by Patent Owner as “[t]o make visible or to make (something that was hidden) able to be seen” (Prelim. Resp. 12) is the customary meaning of the term.

B. Grounds of Unpatentability Based on Serany

Petitioner proposes three grounds of unpatentability for claim 1, and one ground of unpatentability for claim 2. Pet. 13. All of the grounds apply Serany. Furthermore, all of those grounds apply Serany as disclosing the step in claim 1 of “unfolding one or more layers of wrap to reveal an additional layer of wrap and the catheter assembly.” Ex. 1001, col. 26, ll. 66–67.

Serany describes a catheterization package that “provides the convenience of having all the components arranged in logical step-by-step order to facilitate the nurse’s or physician’s task.” Ex. 1008, col. 1, ll. 31–35. In that respect, Serany discloses that “box 10 having an open top with a tray 12 mounted thereon is enclosed within a wrap 14.” *Id.* at col. 1, ll. 60–62. Serany further states the following:

The wrap 14, which may be a piece of sterile absorbent paper is folded around the box 10 in such a way that a slight tug on the corner 18 will release the folds so that the wrap may thereafter be readily spread out on the flat surface on which the box rests. . . . The wrap when removed from around the box as described above and flattened out thereunder, serves as a sterile

¹ See *Reveal Definition*, Merriam-Webster.com, <http://www.merriam-webster.com/dictionary/reveal> (last accessed July 1, 2015).

field and work area for the remaining operations to be described.

Id. at col. 2, ll. 1–20.

Thus, Serany describes generally that wrap 14 is positioned around box 10 and that the wrap, when removed from the box, may serve as a sterile field and work area for operation operations. Figure 5 of Serany is reproduced below:

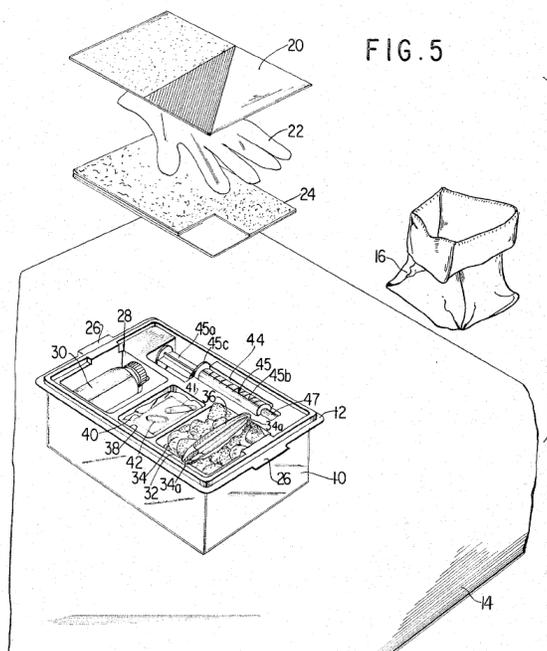


Figure 5 depicts an exploded view of box 10, after wrap 14 has been removed, and “showing the relationship of various components included therewith.” *Id.* at col. 1, ll. 54–56. Serany further sets forth the following:

Upon removal of the wrap 14, there is exposed a waterproof underpad 20 which is folded flat and rests on top of the tray 12 . . . Prepowdered plastic gloves 22 are arranged in a flat condition beneath the underpad 20 and are exposed when the latter is removed . . . A fenestrated drape 24 folded flat beneath the gloves, is removed, unfolded, and placed in position on the patient.

underpad 20), the claims require that the “catheter assembly” is revealed upon unfolding of a layer of wrap. Petitioner equates Serany’s catheter 48 with the required catheter assembly. Pet. 30. Thus, to account for the claims, it is catheter 48 that must be revealed upon unfolding wrap 14. Yet, as discussed above, in Serany, even after wrap 14 is unfolded, tray 12 lies above catheter 48. In that regard, grooves 27 of the tray interface with the upper edge of box 10, such that the tray covers completely the top opening of the box. The tray, then, must be removed for exposure of the contents beneath it. Petitioner offers no explanation as to how the unfolding of wrap 14 amounts to an act of revealing catheter 48.

All of the grounds of unpatentability proposed for claims 1 and 2 of the ’786 patent rely on Serany as disclosing the pertinent step of unfolding one or more layers of wrap to reveal the catheter assembly. As discussed above, Petitioner has not explained adequately how Serany accounts for that step.

III. CONCLUSION

For foregoing reasons, we are not persuaded that Petitioner has established a reasonable likelihood of prevailing in its challenges to claims 1 and 2 set forth in the Petition.

IV. ORDER

It is

ORDERED that no *inter partes* review will be instituted pursuant to 35 USC § 314 as to claims 1 and 2 of the ’786 patent on any grounds of unpatentability alleged in the Petition.

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