

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C.R. BARD, INC.,
Petitioner,

v.

MEDICAL COMPONENTS, INC.,
Patent Owner.

Case IPR2015-01654
Patent 8,852,160 B2

Before LYNNE E. PETTIGREW, DANIEL N. FISHMAN, and
KERRY BEGLEY, *Administrative Patent Judges*.

PETTIGREW, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner, C.R. Bard, Inc., filed a Petition for *inter partes* review of claims 1–22 of U.S. Patent No. 8,852,160 B2 (Ex. 1001, “the ’160 patent”).

Paper 1 (“Pet.”). Patent Owner, Medical Components, Inc., filed a Preliminary Response. Paper 7 (“Prelim. Resp.”). Institution of an *inter partes* review is authorized by statute when “the information presented in the petition . . . and any response . . . 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); *see* 37 C.F.R. § 42.108. Upon consideration of the Petition and Preliminary Response, we conclude the information presented does not show there is a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of any of claims 1–22 of the ’160 patent.

A. Related Matters

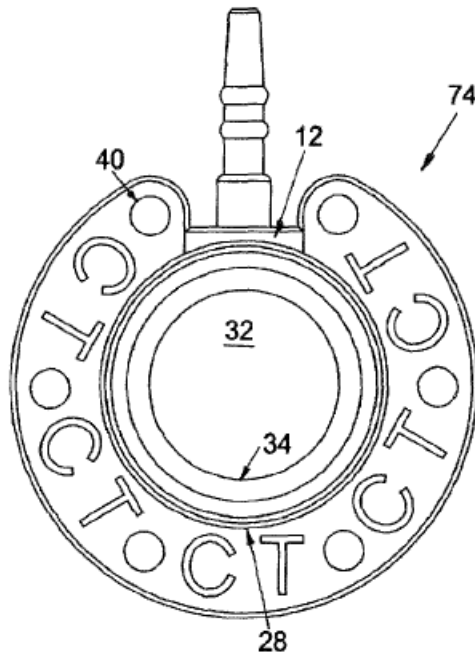
Petitioner concurrently filed a petition in IPR2015-01660, seeking *inter partes* review of U.S. Patent No. 8,257,325 B2, the parent of the ’160 patent. *See* Pet. 1; Paper 5, 1.

B. The ’160 Patent

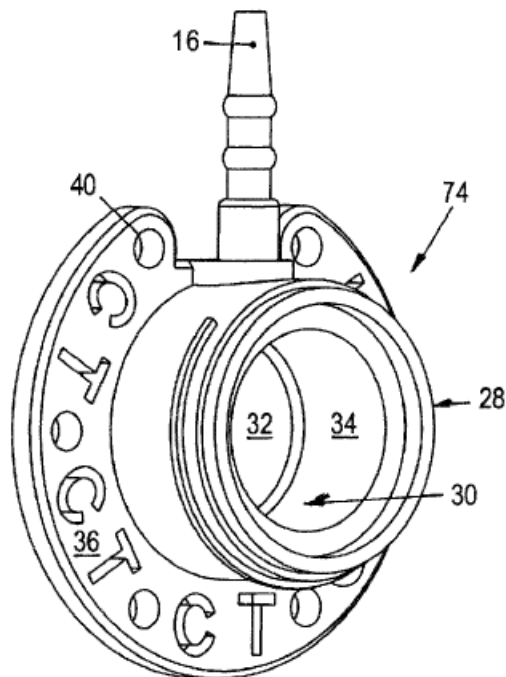
The ’160 patent discloses a venous access port assembly having a marking that identifies a characteristic of the port and is visible by X-ray examination when the port is implanted in a patient. Ex. 1001, 1:44–47. One such characteristic may be power injection capability, i.e., the port is rated for power injection of a contrast fluid. *Id.* at 1:64–66. The letters “CT,” for “computed tomography,” indicate an access port can withstand high pressures used during power injection of a contrast fluid into a patient. *Id.* at 1:66–2:6.

Embodiments of a venous access port disclosed in the ’160 patent include a housing and a septum that receives a needle. *Id.* at 2:10–11. One

embodiment of a venous access port housing is shown in the following portion of Figure 11:



Housing base 74, shown in Figure 11 above, is illustrated in isometric view in Figure 13, reproduced below:



In the embodiment shown in Figure 13, housing base 74 comprises housing base 28, including well 30, bottom floor 32, and side walls 34. *Id.* at 3:35–38, 4:54–56. Housing base 74 also includes flange 36, which features integrally molded “CT” markings alongside suture openings 40. *Id.* at 4:62–65. The “CT” markings are voids in the flange, “as if cut or punched out of” the flange material. *Id.* at 4:65–67. If flange 36 is comprised of a metal material, the letters “CT” will be visible by X-ray examination. *Id.* at 5:9–12.

C. Illustrative Claim

Claims 1, 9, and 16 are independent. Claim 1 is illustrative of the claimed subject matter:

1. A venous access port assembly for implantation into a patient, comprising:
 - a housing comprising:
 - a base defining at least one reservoir;
 - and a flange adjacent to the at least one reservoir, the flange comprising an X-ray discernable material, a top surface, a bottom surface, and one or more voids extending through the X-ray discernable material of the flange from the top surface of the flange to the bottom surface of the flange, wherein the one or more voids are X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection; and
 - a needle-penetrable septum communicating with the housing.

Id. at 5:22–32 (formatting added).

D. Asserted Grounds of Unpatentability

Petitioner contends that claims 1–22 of the '160 patent are unpatentable based on the following specific grounds (Pet. 25–60):

References	Basis	Challenged Claims
PORTS, ¹ Powers, ² PowerPort, ³ and Hickman ⁴	§ 103(a)	1–22
PORTS, Powers, Sayre, ⁵ and Hickman	§ 103(a)	1–22
PORTS, Powers, Meyer, ⁶ and Hickman	§ 103(a)	1–22

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, we construe claim terms in an unexpired patent according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b). Petitioner proposes constructions for several claim terms. Pet. 4–6. Patent Owner does not propose constructions for any terms. Prelim. Resp. 6–7. For purposes of this decision, we determine that no claim terms require express construction.

¹ Bard Access Systems, PORTS (2003) (Ex. 1002, “PORTS”).

² U.S. Patent No. 7,785,302 B2, issued Aug. 31, 2010 (Ex. 1003, “Powers”).

³ Bard Access Systems, PowerPort Guidelines for CT Technologists (Feb. 2007) (Ex. 1004, “PowerPort”).

⁴ Bard Access Systems, Hickman® Subcutaneous Ports & Hickman®/Broviac® Catheters (1992) (Ex. 1017, “Hickman”).

⁵ U.S. Patent No. 6,826,257 B2, issued Nov. 30, 2004 (Ex. 1007, “Sayre”).

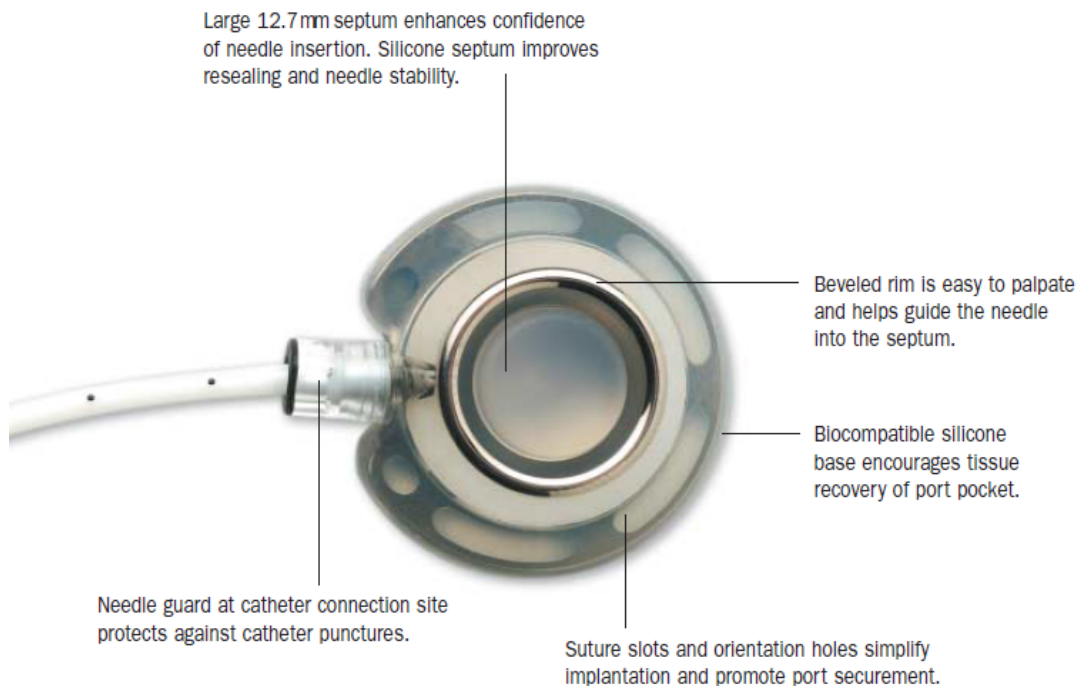
⁶ French Patent No. 1,509,165, issued Dec. 4, 1967 (Ex. 1005, “Meyer”). Citations to Meyer in this decision are to the English language translation provided by Petitioner (Ex. 1006).

B. Asserted Obviousness over PORTS, Powers, PowerPort, and Hickman

Petitioner asserts claims 1–22 of the '160 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of PORTS, Powers, PowerPort, and Hickman. Pet. 25–40. To support its contentions, Petitioner relies on the declaration testimony of Mr. Steven J. Tallarida. *Id.* (citing Ex. 1009).

1. PORTS

PORTS is a Bard Access Systems brochure disclosing several implanted access ports, including a Titanium Implanted Port. Ex. 1002, 10, 16. The following figure from page 10 of PORTS illustrates the Titanium Implanted Port:

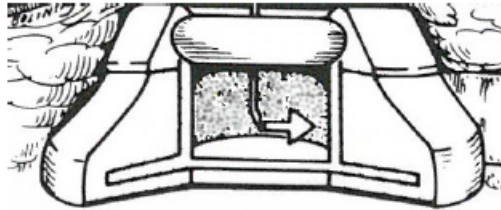


Id. at 10. As shown in the above figure from page 10 of PORTS, the Titanium Implanted Port includes a “silicone-encapsulated base” and a silicone septum. *Id.* The base includes a flange portion with “[s]uture slots

and orientation holes [that] simplify implantation and promote port securement.” *Id.*

2. *Hickman*

Hickman is a Bard Access Systems chart providing information about various subcutaneous ports and catheters. Ex. 1017. Hickman discloses a Hickman® subcutaneous port that is similar in appearance to the Titanium Implanted Port shown in PORTS. *Id.* at 4. A portion of a figure from Hickman illustrating a cutaway of a Hickman® subcutaneous port is reproduced below:



Id. The portion of the figure from Hickman shown above depicts a cross-section of the base of a Hickman® subcutaneous port.

3. *Powers*

Powers describes a venous access port with a feature structured to identify the port as being rated for power injection subsequent to subcutaneous implantation. Ex. 1003, 1:67–2:2, 3:60–63. Figures 52A and 52B of Powers illustrate a top and bottom perspective view of an embodiment of an access port with an alphanumeric message in the bottom:

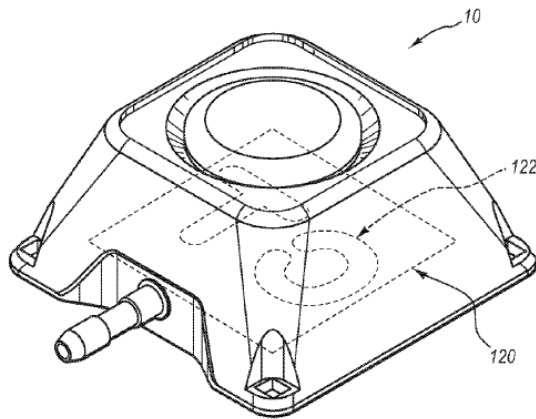


FIG. 52A

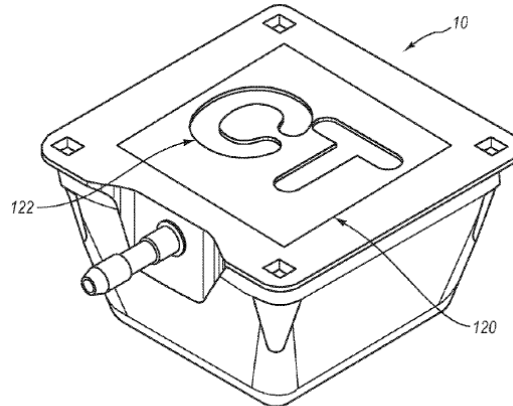


FIG. 52B

See *id.* at 3:17–21. The port shown in Figures 52A and 52B includes the letters “CT” etched in disk or plate 120 in the bottom of the port to identify the port as being power injectable. *Id.* at 3:48–52, 4:8–10, 11:58–61. If the plate is metal, the alphanumeric message will be visible on an X-ray. *Id.* at 11:56–58, 11:66–12:2.

4. PowerPort

PowerPort is a one-page sheet with guidelines for CT technologists using PowerPort implanted power injectable venous access ports provided by Bard Access Systems. Ex. 1004, 1. One of the ports disclosed in PowerPort is the PowerPort - M.R.I. Device, shown in the following picture:



Id. The above picture from PowerPort appears to show the PowerPort - M.R.I. Device under X-ray examination, with the characters “C” and “T” formed as voids. *See id.*

5. Analysis

Beginning with independent claim 1, Petitioner contends the combination of PORTS and Powers teaches all of the recited limitations, and further cites PowerPort and Hickman for emphasis or confirmation of particular aspects of the combination. Pet. 25 (citing Ex. 1009 ¶ 117). For example, Petitioner asserts PORTS and Powers each disclose a venous access port with a housing comprising a base defining at least one reservoir. *Id.* at 26. According to Petitioner, Hickman confirms that the base inside the Titanium Implanted Port in PORTS defines a reservoir. *Id.* Petitioner also asserts that the Titanium Implanted Port in PORTS has a flange comprising an X-ray discernable material (titanium) that is adjacent to the reservoir, voids extending through the X-ray discernable material of the flange, and a needle-penetrable septum communicating with the housing. *Id.* at 26–28.

Claim 1 further requires the voids extending through the X-ray discernable material of the flange to be “X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection.” For this limitation, Petitioner cites the disclosure in Powers of a power injectable port with an alphanumeric message that, under X-ray examination, indicates the port is rated for power injection. *Id.* at 27 (citing Ex. 1003, 11:44–47). Petitioner also alleges Powers discloses that suture apertures may be positioned so as to identify the port after subcutaneous implantation. *Id.* at 27–28 (citing Ex. 1003, 10:16–18). In addition, Petitioner cites PowerPort for disclosing the PowerPort - M.R.I.

Device with the characters “C” and “T” identifying the port as rated for power injection. *Id.* at 28 (citing Ex. 1004). Notably, Petitioner does not contend either Powers or PowerPort discloses X-ray discernable indicia *in a flange*, as required by claim 1. *Id.* at 27–28.

Acknowledging that the Titanium Implanted Port of PORTS is not power injectable and does not have indicia indicating “the assembly is rated for power injection,” as required by claim 1, Petitioner argues a person having ordinary skill in the art at the time of the invention would have known the Titanium Implanted Port of PORTS “could be constructed to handle power injection,” and specifically “would be modified in view of Powers to handle the higher pressure and flow rates associated with power injection for injecting contrast media.” *Id.* at 29 (citing Ex. 1009 ¶¶ 139–40). Then, according to Petitioner, it would have been obvious to a person of ordinary skill in the art to provide the Titanium Implanted Port, modified to handle power injection, with X-ray discernable indicia to indicate the assembly is rated for power injection, particularly in view of the ports in Powers and PowerPort with X-ray discernable alphanumeric messages indicating they are rated for power injection. *Id.* at 29–30 (citing Ex. 1009 ¶¶ 141–45). Next, Petitioner contends it would have been obvious in view of Powers to form such X-ray discernable indicia as voids extending through the flange of the Titanium Implanted Port because the flange of the Titanium Implanted Port already includes voids (orientation holes) that function as indicia of orientation under X-ray examination. *Id.* at 30. Petitioner also submits that the obviousness of including X-ray discernable indicia in the form of voids in the flange of the Titanium Implanted Port is “emphasized” by PowerPort’s disclosure of X-ray discernable alphanumeric characters in

the form of voids indicating a port is power injectable. *Id.* at 30–31.

Finally, Petitioner argues that voids in the flange would be expected to provide high contrast so that alphanumeric characters would be readily discernable under X-ray examination after implantation, achieving the same result as indicia already included in the flange of the Titanium Implanted Port. *Id.* at 31.

Patent Owner’s primary contention in its Preliminary Response is that the Petition fails to provide adequate reasoning for combining the references in the manner asserted to arrive at the claimed subject matter. Prelim. Resp. 7–38. Having reviewed both parties’ arguments and evidence, we agree with Patent Owner that Petitioner has not articulated sufficient rationale with support in the record for modifying the Titanium Implanted Port of PORTS as suggested in the Petition. In particular, we are persuaded by the following arguments presented by Patent Owner.

First, we agree with Patent Owner that the Petition does not provide adequate reasoning based on rational underpinnings for why it would have been obvious in view of Powers to modify the Titanium Implanted Port of PORTS—which Petitioner does not allege can handle power injection—to be rated for power injection. *See id.* at 8–11. Although claim 1 does not require the recited port assembly actually be rated for power injection, modifying the Titanium Implanted Port to handle power injection is an important first step in Petitioner’s obviousness analysis. *See* Pet. 29. Specifically, as noted above, Petitioner states that a person of ordinary skill in the art would have known the Titanium Implanted Port could be constructed to handle power injection by modifying it in view of Powers to handle higher pressures and flow rates associated with power injection. *Id.*

Petitioner's assertion, however, is conclusory, and relies only on Mr. Tallarida's declaration testimony, which merely repeats the conclusory statements in the Petition without citation to the asserted prior art references or any other evidence. *See* Ex. 1009 ¶ 139. Accordingly, his testimony has little, if any, probative value. *See* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."). Moreover, neither the Petition nor Mr. Tallarida's testimony explains how the Titanium Implanted Port would have been modified so as to be rated for power injection, nor do they point to any disclosure in Powers that would have suggested how such a modification would have been made. *See* Pet. 29; Ex. 1009 ¶ 139.

We also find persuasive certain aspects of Patent Owner's argument that the Petition fails to explain sufficiently why it would have been obvious to modify the flange of the Titanium Implantable Port in PORTS to have X-ray discernable indicia in the form of voids configured to indicate the port assembly is rated for power injection. *See* Prelim. Resp. 14–30. Initially, Patent Owner finds fault with Petitioner's assertion that the flange of the Titanium Implanted Port has orientation holes that function as indicia of orientation under X-ray examination, a linchpin of Petitioner's obviousness analysis. *Id.* at 15–16 (citing Pet. 30). As Patent Owner points out, PORTS provides that the function of the suture slots and orientation holes of the Titanium Implanted Port is to "simplify implantation and promote port securement." Ex. 1002, 10; *see* Prelim. Resp. 16. Thus, according to Patent Owner, PORTS indicates the orientation holes are used to secure orientation of the port, not to provide X-ray discernable indicia of orientation after implantation. Prelim. Resp. 16.

We agree with Patent Owner that Petitioner has not shown sufficiently that the orientation holes in the flange of the Titanium Implanted Port of PORTS function as X-ray discernable indicia. Petitioner does not direct us to any specific disclosure in PORTS describing the orientation holes as X-ray discernable after implantation. *See* Pet. 18, 30. Furthermore, Mr. Tallarida's testimony that the flange of the Titanium Implanted Port is known as a location for X-ray discernable indicia lacks citation to PORTS or any other evidence in the record and is not otherwise supported by underlying facts or data. *See* Ex. 1009 ¶¶ 62, 146–48, 150. Consequently, his testimony on this point is entitled to little or no weight. *See* 37 C.F.R. § 42.65(a).

In addition, we are persuaded by Patent Owner's argument that Petitioner has not explained sufficiently how a person of ordinary skill in the art would have modified the flange of the Titanium Implanted Port of PORTS to include voids indicating the port is rated for power injection. *See* Prelim. Resp. 20–22. As just discussed, and as shown in the figure on page 10 of PORTS, the Titanium Implanted Port has multiple suture slots and orientation holes that “simplify implantation and promote port securement.” Ex. 1002, 10. Petitioner and Mr. Tallarida provide no explanation of how a person of ordinary skill would have added voids shaped like alphanumeric characters to the flange of the Titanium Implanted Port while still accommodating the suture slots and orientation holes already present in the flange for simplifying implantation and securing the port. *See* Pet. 30–31; Ex. 1009 ¶¶ 147–49. Nor do they suggest that a person of ordinary skill would have replaced either suture slots or orientation holes with alphanumeric voids. *See* Pet. 30–31; Ex. 1009 ¶¶ 147–49.

Furthermore, we agree with Patent Owner that Petitioner has not provided adequate reasoning based on Powers for including X-ray discernable indicia of power injection capability in the form of voids *in the flange* of the Titanium Implanted Port of PORTS. *See* Prelim. Resp. 22–25. Powers discloses an alphanumeric message indicating power injection capability etched in a disk in the bottom of a port and visible under X-ray examination. Ex. 1003, 11:56–58. The alphanumeric message disclosed in Powers, however, is not in the form of voids or in a flange. *Id.* Petitioner also refers to suture apertures in Powers that may be positioned so as to identify the access port after implantation, but Petitioner does not contend these apertures are in a flange or are indicia of power injection capability. Pet. 30 (citing Ex. 1003, 10:16–18). Although Powers may disclose X-ray discernable indicia and apertures that are voids, Petitioner does not assert that these teachings of Powers suggest placing X-ray discernable indicia configured to indicate a port is rated for power injection *in the flange* of the port. *See* Pet. 30–31.

Finally, we agree with Patent Owner that Petitioner has not shown that PowerPort cures the deficiencies of PORTS and Powers. *See* Prelim. Resp. 26–29. PowerPort’s X-ray discernable indicia of power injection capability are in the form of voids, but they are not located in a flange of an access port. Ex. 1004. Therefore, we are not persuaded by Petitioner’s argument that PowerPort “emphasize[s]” the obviousness of including X-ray discernable indicia in the form of voids *in the flange* of the Titanium Implanted Port of PORTS. *See* Pet. 30–31.

For at least these reasons, Petitioner has not provided adequate reasoning based on rational underpinnings for combining the asserted

references to achieve the invention as recited in claim 1. Independent claims 9 and 16, like claim 1, both require a “flange comprising an X-ray discernable material” with voids that are “X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection.” Ex. 1001, 5:54–6:4, 6:29–36. Claims 9 and 16 otherwise differ only slightly from claim 1, and Petitioner contends they would have been obvious for the same reasons presented with respect to claim 1. Pet. 34–36. Thus, for reasons similar to those discussed above with respect to claim 1, we also determine Petitioner has not articulated a sufficient rationale for combining the references to arrive at the invention as recited in claims 9 and 16.

Because we conclude Petitioner has not provided sufficient reasoning for combining the references in the manner asserted, we need not address Patent Owner’s argument that the Petition fails to specify where PORTS discloses certain claim limitations. See Prelim. Resp. 38–42. We also need not address Patent Owner’s argument that Petitioner has presented insufficient evidence to establish that PORTS, Hickman, and PowerPort qualify as printed publications that were publicly accessible at the relevant times. See *id.* at 43–54.

For the foregoing reasons, we conclude the information presented does not show a reasonable likelihood that Petitioner would prevail in showing that any of claims 1–22 would have been obvious over PORTS, Powers, PowerPort, and Hickman.

C. Asserted Obviousness over PORTS, Powers, Sayre, and Hickman

Petitioner asserts claims 1–22 of the ’160 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of PORTS,

Powers, Sayre, and Hickman. Pet. 40–50. Sayre discloses a marking device for defining the margins and orientation of radiography specimens removed from a patient’s body. Ex. 1007, Abstract. A marker with a distinctive shape and indicia photoetched from radiopaque material is attached to a specimen to indicate the orientation of the specimen prior to removal from the patient. *Id.* at 4:6–10, Figs. 1, 2A–C. Indicia also may be formed in radiopaque markers by stamping, laser cutting, or other means. *Id.* at 4:24–26.

Petitioner argues claims 1–22 would have been obvious over PORTS, Powers, Sayre, and Hickman “for substantially the same reasons” that claims 1–22 would have been obvious over PORTS, Powers, PowerPort, and Hickman. Pet. 40–41. In its analysis, Petitioner replaces PowerPort with Sayre, arguing that the obviousness of including X-ray discernable indicia in the form of voids in the flange of the Titanium Implanted Port of PORTS is “emphasized by Sayre’s disclosure of X-ray discernable indicia, such as alphanumeric characters, defined by apertures (voids) in radiopaque material that can also aid in indicating orientation and receive sutures.” *Id.* at 42–43.

For substantially the same reasons discussed above with respect to the asserted obviousness ground based on PORTS, Powers, PowerPort, and Hickman, Petitioner has not provided adequate reasoning based on rational underpinnings for combining the references to arrive at the claimed invention. With regard to Sayre, we agree with Patent Owner that Petitioner has not shown Sayre cures the deficiencies of PORTS and Powers. *See* Prelim. Resp. 31–34. In particular, Sayre’s radiopaque indicia are not in a flange, much less in a flange of a venous access port. *See* Ex. 1007, Abstract, Figs. 2A–C. Therefore, we are not persuaded by Petitioner’s

argument that Sayre “emphasize[s]” the obviousness of including X-ray discernable indicia in the form of voids *in the flange* of the Titanium Implanted Port. *See* Pet. 42–43.

Accordingly, we conclude the information presented does not show a reasonable likelihood that Petitioner would prevail in showing that any of claims 1–22 would have been obvious over PORTS, Powers, Sayre, and Hickman.

D. Asserted Obviousness over PORTS, Powers, Meyer, and Hickman

Petitioner asserts claims 1–22 of the ’160 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of PORTS, Powers, Meyer, and Hickman. Pet. 50–60. Meyer discloses a plastic collar for a container with characters used for identification or inspection purposes. Ex. 1006, 3, col. 1. In one embodiment, characters are formed by cutouts in the body of the collar. *Id.*

Petitioner argues claims 1–22 would have been obvious over PORTS, Powers, Meyer, and Hickman “for substantially the same reasons” that claims 1–22 would have been obvious over PORTS, Powers, PowerPort, and Hickman. Pet. 51. Similar to the ground based in part on Sayre, Petitioner replaces PowerPort with Meyer in its analysis, arguing that the obviousness of including X-ray discernable indicia in the form of voids in the flange of the Titanium Implanted Port of PORTS is “emphasized by Meyer’s disclosure of indicia in the form of alphanumeric voids in a flange adjacent to a container.” *Id.* at 53.

For substantially the same reasons discussed above with respect to the asserted obviousness ground based on PORTS, Powers, PowerPort, and Hickman, Petitioner has not provided adequate reasoning based on rational

underpinnings for combining the references to arrive at the claimed invention. With regard to Meyer, we agree with Patent Owner that Petitioner has not shown Meyer cures the deficiencies of PORTS and Powers. *See* Prelim. Resp. 35–38. Petitioner alleges the alphanumeric cutouts in Meyer would be visible under X-ray examination, yet neither Meyer nor the cited paragraphs from Mr. Tallarida’s declaration testimony sufficiently support such a statement. *See* Pet. 50–51 (citing Ex. 1006; Ex. 1009 ¶¶ 227–31). Moreover, even if the collar in Meyer can be considered a flange, it is not a flange of anything resembling a venous access port. Petitioner has not shown adequately that Meyer, which discloses collars for containers, is “from the same field of endeavor” or “reasonably pertinent to the particular problem” addressed by the inventors of the ’160 patent in developing the recited venous access port, as required to be prior art under 35 U.S.C. § 103. *Innovention Toys, LLC v. MGA Entm’t, Inc.*, 637 F.3d 1314, 1321 (Fed. Cir. 2011) (quoting *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004)); *see* Ex. 1006, 3 (summary). Therefore, we are not persuaded by Petitioner’s argument that Meyer “emphasize[s]” the obviousness of including X-ray discernable indicia in the form of voids in the flange of the Titanium Implanted Port of PORTS. *See* Pet. 53.

Accordingly, we conclude the information presented does not show a reasonable likelihood that Petitioner would prevail in showing that any of claims 1–22 would have been obvious over PORTS, Powers, Meyer, and Hickman.

E. Real Party-in-Interest

Patent Owner alleges in its Preliminary Response that the Petition should have named Bard Access Systems, Inc. as a real party-in-interest in

addition to C.R. Bard, Inc. Prelim. Resp. 54–59. In view of our determination that the information presented does not show a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims, we do not reach this issue.

III. CONCLUSION

For the foregoing reasons, we determine that the information presented does not establish a reasonable likelihood that Petitioner would prevail in showing that any of claims 1–22 of the '160 patent are unpatentable.

IV. ORDER

Accordingly, it is:

ORDERED that the Petition is denied and no trial is instituted.

IPR2015-01654
Patent 8,852,160 B2

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