UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

C.R. BARD, INC.
Petitioner

v.

INNOVATIVE MEDICAL DEVICES, LLC,
MEDICAL COMPONENTS, INC.
Patent Owners

_____

Case IPR _____
U.S. Patent No. 8,257,325
Issue Date: September 4, 2012

Title: VENOUS ACCESS PORT WITH MOLDED AND/OR RADIOPAQUE INDICIA

_____

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,257,325 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 ET SEQ.

Mail Stop PATENT BOARD, PTAB
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Statutes

Regulations

EXHIBIT LIST

Exhibit 1001:	U.S. Patent No. 8,852,160 B2
Exhibit 1002:	PORTS – Bard Access Systems, 2003 ("PORTS")
Exhibit 1003:	U.S. Patent No. 7,785,302 ("Powers")
Exhibit 1004:	PowerPort Guidelines for CT Technologists, February 2007 ("PowerPort")
Exhibit 1005:	FR 1,509,165 ("Meyer")
Exhibit 1006:	English translation of Meyer with certification
Exhibit 1007:	U.S. Patent No. 6,826,257 ("Sayre")
Exhibit 1008:	Affidavit of Christopher Butler
Exhibit 1009:	Declaration of Steven J. Tallarida
Exhibit 1010:	Dictionary definition of housing downloaded June 23, 2015 from www.merriam-webster.com/dictionary/housing
Exhibit 1011:	Dictionary definition of base downloaded June 23, 2015 from www.merriam-webster.com/dictionary/base
Exhibit 1012:	Dictionary definition of reservoir downloaded June 23, 2015 from www.merriam-webster.com/dictionary/reservoir
Exhibit 1013:	Dictionary definition of flange downloaded June 23, 2015 from www.merriam-webster.com/dictionary/flange
Exhibit 1014:	Dictionary definition of adjacent downloaded June 23, 2015 from www.merriam-webster.com/dictionary/adjacent
Exhibit 1015:	Dictionary definition of void downloaded June 23, 2015 from www.merriam-webster.com/dictionary/void
Exhibit 1016:	U.S. Provisional Application No. 60/658,518, filed on March 4, 2005.

On behalf of C.R. Bard, Inc. ("Bard" or "Petitioner") and in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*., *inter partes* review is respectfully requested for claims 1-2, 5-13, 15-19 and 21-22 of U.S. Patent No. 8,257,325 B2 ("the '325 patent").

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Bard is the real party-in-interest for the instant Petition.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

At present, there are no related matters relating to the '325 patent or its continuation, U.S. Patent No. 8,852,160; however, filed concurrently herewith is a Petition For *Inter Partes* Review Of U.S. Patent No. 8,852,160.

C. Lead And Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioner's designation of counsel: Lead counsel is Michael J. Fink (Reg. No. 31,827) and back-up counsel is Arnold Turk (Reg. No. 33,094). Per 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this Petition.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Papers concerning this matter should be served on the following:

Michael J. Fink
Greenblum & Bernstein, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
Tel: (703) 716-1191
Fax: (703) 716-1180

Arnold Turk
Greenblum & Bernstein, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
Tel: (703) 716-1191
Fax: (703) 716-1180

Email: MFink@gbpatent.com Email: ATurk@gbpatent.com

Petitioner consents to electronic service by email.

II. PAYMENT OF FEES

Payment of $24,200 for the fees set forth in 37 C.F.R. § 42.15(a)(1-4) for this Petition for *Inter Partes* Review accompanies this request by way of credit card payment. The undersigned authorizes payment for any additional fees due in connection with this Petition to be charged to Deposit Account No. 19-0089.

III. REQUIREMENTS FOR *INTER PARTES* REVIEW - 37 C.F.R. § 42.104

A. Grounds For Standing Under 37 C.F.R. § 42.104(a)

Petitioner hereby certifies that the '325 patent is available for *inter partes* review and that the Petitioner is not barred or estopped from requesting *inter partes* review challenging the claims of the '325 patent.

B. Identification Of Challenge Under 37 C.F.R. § 42.104(b)

1. Claims For Which *Inter Partes* Review Is Requested Under 37 C.F.R. § 42.104(b)(1)

Petitioner requests *inter partes* review of claims 1-2, 5-13, 15-19 and 21-22 of the '325 patent ("the challenged claims").

2. The Specific Art And Statutory Ground(s) On Which The Challenge Is Based Under 37 C.F.R. § 42.104(b)(2)

Inter partes review of the '325 patent (Ex. 1001) is requested in view of the following prior art references: (1) PORTS – Bard Access Systems, 2003 (a

Titanium Implanted Port is disclosed at pages 10 and 16)("PORTS")(Ex.1002); (2) U.S. Patent No. 7,785,302 ("Powers")(Ex.1003); (3) PowerPort Guidelines for CT Technologists, February 2007 ("PowerPort")(Ex.1004); (4) FR 1,509,165 ("Meyer")(Exs.1005 & 1006); (5) U.S. Patent No. 6,826,257 ("Sayre")(Ex.1007); and (6) The Hickman® Subcutaneous Ports & Hickman®/Broviac® Catheters, 1992 ("Hickman")(Ex.1017). The challenged claims are unpatentable as obvious under 35 U.S.C. §103(a), and should be cancelled for at least the following reasons:

Ground 1: Claims 1-2, 5-13, 15-19 and 21-22 are unpatentable as obvious under 35 U.S.C. §103(a) over PORTS in view of Powers and in further view of PowerPort and Hickman.

Ground 2: Claims 1-2, 5-13, 15-19 and 21-22 are unpatentable as obvious under 35 U.S.C. §103(a) over PORTS in view of Powers and in further view of Sayre and Hickman.

Ground 3: Claims 1-2, 5-13, 15-19 and 21-22 are unpatentable as obvious under 35 U.S.C. §103(a) over PORTS in view of Powers and in further view of Meyer and Hickman.

The above grounds are not duplicative. PowerPort is a prior art reference under pre-AIA 35 U.S.C. § 102(a). Sayre is also a prior art reference under pre-AIA 35 U.S.C. § 102(b) and provides a general teaching of X-ray discernable indicia defined by apertures (voids) in radiopaque material. Meyer is a prior art

reference under pre-AIA 35 U.S.C. § 102(b) and provides a general teaching of using a flange with identification indicia created by cutouts (voids). PORTS in view of Powers teaches the elements of the challenged claims, including indicia in the form of cutouts (voids) on a flange and X-ray viewable indicia in the form of alphanumeric characters as a power port identifier, rendering the challenged claims of the '325 patent obvious. The tertiary references emphasize the obviousness of cutouts (voids) in the form of alphanumeric characters, which is taught by PowerPort (alphanumeric characters cutout in X-ray discernable material), Sayre (alphanumeric characters cutout in X-ray discernable material), and Meyer (alphanumeric characters cutout in a flange). Hickman confirms that the Titanium Implanted Port disclosed in PORTS has a base defining a reservoir, *i.e.,* a bottom floor and side walls defining a reservoir.

3. How The Challenged Claims Are To Be Construed Under 37 C.F.R. § 42.104(b)(3)

A claim subject to *inter partes* review receives the "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). Petitioner asserts the following constructions:

Housing: Fig. 1 depicts "housing 12." Ex. 1001, 3:11-12, 26-29. The term "housing" as recited in the claims should be construed as a case or enclosure. Ex.1010.

Base: Figs. 3-7 depict "housing base 28." Ex. 1001, 3:24-26. "[H]ousing base 28 … includes a well 30 having a bottom floor 32 and side walls 34 that define the interior reservoir 22 beneath septum 14. … Housing base 28 includes a base flange 36 extending radially outwardly from the bottom of well 30, and base flange 36 includes openings 38, 40." Ex. 1001, 3:26-33. Thus, as used in the '325 patent, the term "base" as recited in the claims should be construed as the part on which something rests or is supported. Ex.1011.

Reservoir: Figs. 3 and 4 depict reservoir 22. Ex. 1001, 3:24-29. The reservoir 22 is defined as "a well 30 having a bottom floor 32 and side walls 34." Ex. 1001, 3:27-28. Thus, the term "reservoir" as recited in the claims should be construed as a part of an apparatus in which a liquid can be held. Ex.1012.

Flange: A "base flange 36" is shown in Figs. 4 and 10 that includes openings 38, 40 that serve to enable suturing to the patient. Ex. 1001, 3:31-35, 63-64. The term "flange" as recited in the claims should be construed as a rim extending outwardly from the base for attachment of the port to a patient. Ex.1013.

Adjacent: The term "adjacent" appears once in the specification (not including the claims) to describe the position of discharge port 16 to recess 56. Ex. 1001, 3:64. The term "adjacent" as recited in the claims should be construed as close or near, sharing a border, wall, or point. Ex.1014

X-ray discernable material: As recited in the claims, "X-ray discernable material" should be construed as a material that is visible using X-rays. Ex. 1001, 2:13-20.

Void and Cutout: The '325 patent discloses "suture openings 38 and holes 40 through base flange 36." Ex. 1001, 3:63-64, Figs. 10, 11, 12. The '325 patent additionally discloses integrally molded markings within or alongside the suture openings, "where the markings are voids in the base flange 36 material, as if cut or punched out of the base flange 36 material." Ex.1001, 2:60-62; 4:44-60. Thus, the terms "void" and "cutout' as recited in the claims of the '325 patent should be construed as an empty space. Ex.1015. The "void" and "cutout" can be made in any manner as long as it constitutes an empty space that extends through the height of the flange. Ex.1001, 4:49-57.

All claim terms, including the above terms, should be afforded their ordinary and customary meanings. Ex.1009, ¶¶ 37-46.

4. How The Construed Claims Are Unpatentable Under 37 C.F.R. § 42.104(b)(4)

Explanations of how claims 1-2, 5-13, 15-19 and 21-22 are unpatentable under the grounds identified in Section III.B.2 are provided in Section VI and VII.

5. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5)

The exhibit numbers of the evidence relied upon to support the challenge and the relevance of the evidence, including identification of specific portions of

the evidence that support the challenge, are provided in Sections VI and VII. The Exhibit List is set forth on pages vi-vii. Pursuant to 37 C.F.R. § 42.63(a), this Petition is supported by the expert declaration of Steven J. Tallarida ("Tallarida Dec.") (Ex.1009), attesting to, among other issues, the invalidity of the challenged claims and supporting bases for the proposed grounds of unpatentability.

6. One Of Ordinary Skill In The Art At The Time Of Invention

A person of ordinary skill in the relevant art ("POSA") would have been aware of the structures of venous access port assemblies, including those access ports comprising a housing with a base, a reservoir, a discharge port extending from the reservoir and a septum. A POSA would also have been aware of power injectable access ports and would have known that power injectable access ports could be used with CT scanning processes, where it is desirable to power inject contrast media at a higher pressure and using a greater flow rate than can be handled by conventional access ports. A POSA would also have known of the desirability to be able to identify an access port as power injectable using X-rays subsequent to subcutaneous implantation of the port, such as by alphanumeric characters on the port, such as below the reservoir or on a portion of the port spaced from a side wall of the reservoir. Moreover, a POSA would also have known of the desirability of overmolding ports with radiotransparent silicone

material to reduce ingrowth of tissue into the port to assist removal of the port as well as to reduce tissue growth into suture/orientation openings.

A POSA in the subject matter claimed and disclosed in the '325 patent at the time of the invention would have included doctors, nurses, radiologists, practitioners, and technicians who were involved with the implantation, use, maintenance and/or removal of venous access ports, or other persons who had at least a bachelor's degree in mechanical and/or biomedical engineering and approximately 3-5 years' experience working with and/or designing venous access ports, and would have had experience with power injectable access ports. Ex.1009, ¶¶18-25.

IV. SUMMARY OF THE '325 PATENT

A. Description Of The Alleged Invention Of The '325 Patent

The '325 patent is entitled "Venous Access Port With Molded And/Or Radiopaque Indicia." One of the embodiments disclosed in the '325 patent is a venous access port assembly having a housing base with a discharge port, a septum and a cap. An interior reservoir is defined by a well in the housing base and a bottom of the septum, and a passageway extends from the reservoir through the discharge port. The housing base includes a base flange having integrally molded therein indicia identifying an attribute of the assembly. The indicia could be formed of base flange material, or could be formed by voids in the base flange

material. Ex.1001, Abstract p. 1; Ex.1009, ¶¶ 26-31. The general structures of the ports are depicted in Figs. 1-4 of the '325 patent, reproduced below:

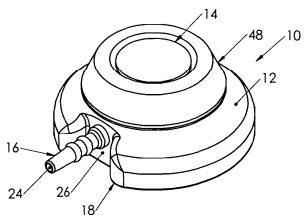


FIG. 1

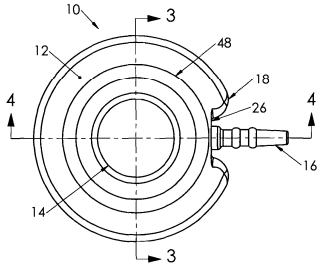


FIG. 2

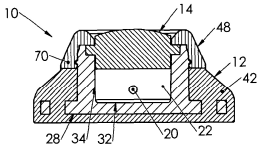


FIG. 3

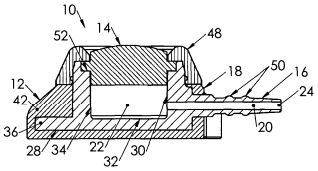


FIG. 4

Figures 3 and 4 (reproduced above) show a "skirt 42 is overmolded about housing base 28 and may be of silicone elastomer. It is seen that skirt 42 encapsulates the outer surfaces of the bottom wall 44 and the bottom portion of the side walls 46 of housing base 28, and is shown to fill in the suture holes 38,40." Ex. 1001, col. 3, lines 36-40, Figs. 3, 4; Ex.1009, ¶¶ 32-33.

Figure 5 (reproduced below) is an isometric view of the base of the access port of Fig. 1. Ex. 1001, 2:36-37. Ex. 1009, ¶ 34.

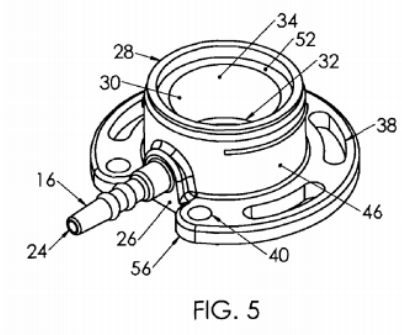
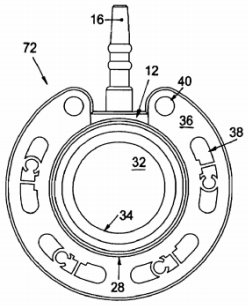


FIG. 5



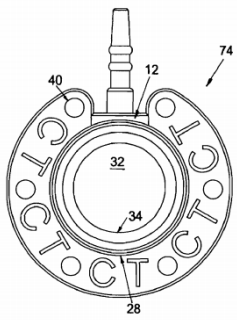


Fig. 11

Fig. 11 (reproduced above) shows top views of two alternative embodiments of the housing base showing integrally molded "CT" markings. Ex. 1001, 2:48-51; Ex.1009, ¶ 36.

B. Summary Of The Prosecution Of The '325 Patent

The application for the '325 patent, Application No. 12/143,377, was filed on June 20, 2008. The '325 patent claims the benefit of U.S. Provisional Application No. 60/936,491, filed June 20, 2007. Therefore, depending upon the claimed subject matter, the earliest possible effective date of the '325 patent is June 20, 2007.

All claims presented were repeatedly rejected for anticipation or obviousness. To obtain allowance of the claims, Applicant amended the independent claims to require that "the port assembly is rated for power injection" and the X-ray discernible indicia is visually "discernable to a naked eye from both the top surface of the flange and the bottom surface of the flange prior to implantation of the port assembly." Response and Amendment dated July 6, 2010.

The examiner's statement of reasons for allowance was as follows:

> The subject matter of the independent claims 1, 14 and 19 could not be found or was not suggested in the prior art of record. The subject matter which was not found is an implantable venous access port assembly comprising a flange with a height extending from a top surface of the flange to a bottom surface of the flange, the flange

further comprising X-ray discernible indicia extending through the height of the flange from the top surface of the flange to the bottom surface of the flange wherein the indicia is visually discernible to the naked eye from the top and bottom surfaces prior to implantation of the port assembly.

Notice Of Allowability, July 5, 2012, p.2.

V. STATEMENT OF MATERIAL FACTS UNDER 37 C.F.R. § 42.22(c)

Petitioner provides the following statement of material facts:

1. PORTS, which discloses the Titanium Implanted Port, has a copyright date of 2003. Ex. 1002; Ex. 1019 ¶¶8-10.

2. PORTS is a printed publication which was publicly available no later than 2003. Ex. 1002; Ex. 1019 ¶¶8-18.

3. Titanium Implanted Port, disclosed at pages 10 and 16 of PORTS, is a venous access port, comprising a housing, a base, a discharge port, a septum and reservoir. Ex. 1002, p. 10, *see also* Ex.1017.

4. The base of the Titanium Implanted Port defines a reservoir and a bottom wall of a reservoir, and has a discharge port extending from the reservoir. The reservoir is located below the septum, and the septum comprises a needle-penetrable septum communicating with the reservoir. Ex. 1002, *see also* Ex.1017.

5. The base of the Titanium Implanted Port, including the flange, comprises titanium. Ex. 1002.

6. Titanium is an X-ray discernable material.

7. The flange of the Titanium Implanted Port has suture slots and orientation holes extending from the top surface of the flange to the bottom surface of the flange. The suture slots and orientation holes are X-ray discernible. Ex. 1002.

8. The flange of the Titanium Implanted Port is adjacent to the reservoir, and extends radially from the housing base and outwardly from the base about a perimeter of the reservoir. Ex. 1002.

9. The housing of the Titanium Implanted Port has a biocompatible silicone skirt overmolded about the flange. The silicone skirt is radiotransparent. Ex.1002.

10. The housing base of the Titanium Implanted Port is substantially the same as the housing base depicted in Fig. 5 of the '325 patent. Both have suture slots and orientation holes in the flange. Exs.1001, 1002.

11. The suture slots and orientation holes in the flange of the housing base of the Titanium Implanted Port provide indicia discernable by X-ray concerning the access port. Ex. 1002.

12. The suture slots and orientation holes in the flange of the housing base of the Titanium Implanted Port are capable of receiving sutures there through. Ex. 1002.

13. The suture slots and orientation holes in the flange of the housing base of the Titanium Implanted Port are visually discernable to a naked eye from both the

top surface of the flange and the bottom surface of the flange prior to implantation of the port assembly. Ex. 1002.

14. "Hickman ports" are of the same overall structure as Titanium Implanted Port, including the titanium flange having orientation openings and suture slots, a base defining a reservoir and a bottom wall of a reservoir, and a silicone overskirt. Titanium Implanted Port is one commercial form of "Hickman port."

15. Hickman ports have been publicly available since as early as 1991.

16. Powers was filed on March 6, 2006. Ex. 1003.

17. Powers claims benefit to Provisional Application No. 60/658,518 ("the '518 provisional"), filed on March 4, 2005. Ex.1003, cover page and 1:7-9.

18. Powers' effective date as a prior art reference with respect to the claims of the '325 patent is March 4, 2005, which is the filing date of the '518 provisional.

19. Powers discloses power injectable ports. Ex.1003, 3:42-59; Ex.1016, p.7/65 (¶[0034]),p. 48/65 (Nos. 5-7).

20. A power injectable port is adapted to withstand the higher pressures and flow rates used for injection of contrast fluid. Ex. 1003, 3:42-59; Ex.1016, p.7/65 (¶[0034]).

21. Powers discloses power injectable ports with X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for

power injection. Ex.1003, 3:43-47, 11:41-12:2; Ex.1016, p.7/65 (¶[0034]), p.8/65 (¶[0037]), p.17/65 (¶[0070]), p.48/65 (Nos. 5-7).

22. Powers discloses power injectable ports with radiopaque alphanumeric characters that convey to a practitioner that the venous access port assembly is power injectable when an X-ray is taken after implantation. Ex.1003, 3:43-47, 11:41-12:2; Ex.1016, p.7/65 (¶[0034]), p.8/65 (¶[0037]), p.17/65 (¶¶[0069]-[0070]), p.48/65 (Nos. 5-7).

23. Powers discloses a venous access port 10 with cap 14, base 16, septum 18 and reservoir (cavity) 36. Ex.1003, 4:31-49, Fig. 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 1B. The base 16 forms a reservoir 36 having a bottom floor and side walls beneath septum 18. Ex.1003; Ex.1016, Fig. 1B.

24. Powers discloses a needle-penetrable septum in communication with the housing and a discharge port extending from the reservoir. Ex.1003, 4:29-45, Figs. 1A, 1B; Ex.1016, p.8/65 (¶[0038]), Figs. 1A, 1B.

25. Powers discloses an alphanumeric message visible by X-ray examination when the port is implanted to identify the port as power-injectable. Ex.1003, 3:43-47, 11:41-12:2; Ex.1016, p.7/65 (¶[0034]), p.8/65 (¶[0037]), p.17/65 (¶¶[0069]-[0070]), p.48/65 (Nos. 5-7).

26. An access port marked with alphanumeric characters as disclosed in Powers, when viewed using X-rays after implantation, would convey to a POSA that the access port is power injectable.

27. Powers discloses "a flange feature or lip feature 102 extends about at least a portion of the periphery of the access port 10." Ex.1003, 9:18-22; Ex.1016, p.15/65 (¶[0061]). Powers further discloses that such "a feature may comprise at least one identifiable feature of an access port contemplated by the instant disclosure." Ex.1003, 9:25-27; Ex.1016, p.15/65 (¶[0061]).

28. Powers discloses that "suture apertures 66 may be positioned so as to identify the access port 10 after subcutaneous implantation." Ex.1003, 10:16-18, Fig. 20; Ex.1016, p.16/65 (¶[0067]), Fig 20.

29. PowerPort (Ex.1004) is a printed publication which was publicly available at least as early as February 2007. Ex.1018, ¶¶9-26.

30. One of the ports disclosed in PowerPort is the PowerPort*- M.R.I.* Device. The PowerPort*- M.R.I.* Device is a power injectable venous access port with a radiopaque identifier. Ex.1004.

31. The radiopaque identifier utilized in the PowerPort*- M.R.I.* Device under X-ray examination is shown below:

32. PowerPort discloses a power injectable port marked with the alphanumeric characters “C” and “T”.

33. The radiopaque identifier utilized in the PowerPort*- M.R.I.* Device is made from an X-ray discernable material.

34. The radiopaque identifier utilized in the PowerPort*- M.R.I.* Device includes one or more voids which form the alphanumeric characters “C” and “T” which extend through the top surface of the X-ray discernable material to the bottom surface of the X-ray discernable material.

35. The voids in the radiopaque identifier utilized in the PowerPort*- M.R.I.* Device are X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection, *i.e.,* that the assembly is adapted to withstand higher pressures and increased flow rates used for injection of contrast fluid.

36. Sayre states: “Indicia 124, also photoetched from the radiopaque material, aid in indicating orientation of each marker 116.” Ex.1007, 2:41-44; 4:8-10.

37. Sayre discloses indicia 124 photoetched from radiopaque material or formed in radiopaque markers 116 by stamping, laser cutting, or by other means in

which the indicia 124 are defined by one or more apertures, such as in the form of alphanumeric characters, formed through the respective marker 116 to provide unique identifying information. Ex.1007, 4:11-31, Fig. 2A, claim 6.

38. The radiopaque markers and indicia defined by one or more apertures disclosed in Sayre would be discernable under X-ray examination. Ex.1007,5:6-27.

39. The radiopaque markers of Sayre can be made from titanium. Ex.1007, 5:6-15.

40. The apertures of Sayre can form letters capable of receiving sutures to secure the markers. Ex.1007, 4:41-57, Figs. 2A-2C.

41. Meyer discloses an embodiment shown in Fig. 2, wherein characters 5 are formed by molding or cutting. Ex.1006, Fig. 2.

42. Meyer discloses an embodiment shown in Fig. 3, wherein characters 6 are formed by cutouts (voids) provided in the flange (collar 1). Ex.1006, p.3/4, left column, last paragraph, Fig. 3.

43. Meyer discloses that the flange (collar 1) has a top surface and a bottom surface through which the cutout characters extend. Ex.1006, Fig. 3.

44. Meyer discloses a flange 1 provided on its periphery with four character sets, manufactured, for example by molding or cutting. Ex.1006, Fig. 4.

45. The character sets shown in Meyer Fig. 4 are alphanumeric characters A7, B7, C7 and D7. The characters A, B, and D are formed in part by creating voids, which are molded or cut out. Ex.1006, Fig. 4.

46. The characters shown in Figs 2, 3 and 4 of Meyer, formed in whole or part by cutouts or creating voids, would be expected to be discernable under X-ray examination.

VI. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '325 PATENT IS UNPATENTABLE

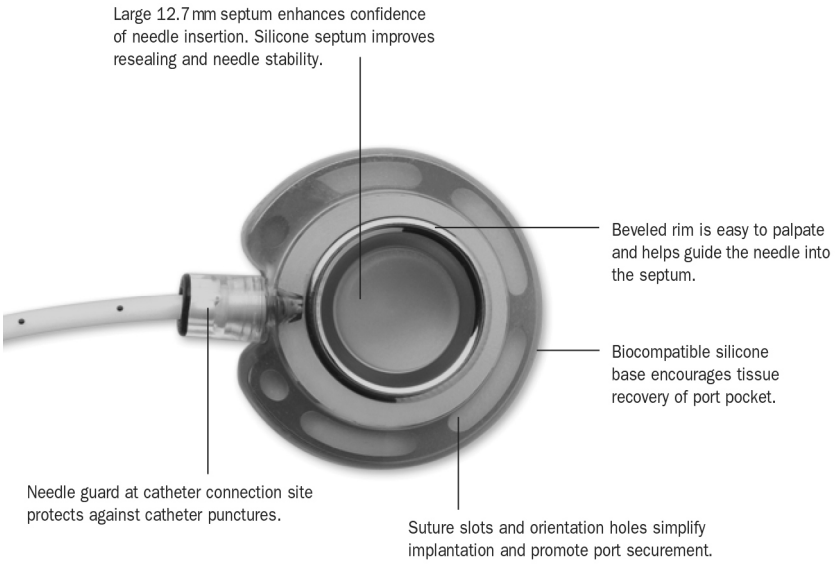
A. Identification Of The References As Prior Art

1. **PORTS (Ex.1002):** The brochure disclosing the Titanium Implanted Port, *i.e.,* PORTS, has been publicly available since 2003. Ex. 1019, ¶¶8-18. PORTS is prior art to the '325 patent under pre-AIA 35 U.S.C. §102(b). The configuration of Titanium Implanted Port depicted in PORTS has been well known and in use since before 1991. Ex.1009, ¶¶ 16, 47-75.

Titanium Implanted Port is a venous access port for implantation into a patient. Titanium Implanted Port comprises a housing, a base, a flange, a needle-penetrable septum, a discharge port and a reservoir. The housing base, including the flange, is made of titanium, which is an X-ray discernible material. Ex.1009, ¶¶ 55-60.

The flange is adjacent to the reservoir and extends outwardly/radially from the base about a perimeter of the reservoir, and has suture slots and orientation

holes (that are X-ray discernable after implantation to permit ascertaining of orientation of catheter as well as permit suturing) which extend from the top surface of the flange to the bottom surface of the flange. Ex.1002, pp. 10, 16; Ex.1009, ¶¶ 61-62.



PORTS (Ex.1002), p. 10

The suture slots and orientation holes are visually discernible to the naked eye from both the top and bottom surfaces of the flange prior to implantation of the port assembly. Ex.1009, ¶63. Additionally, the suture slots and orientation holes are visible by X-ray examination when the assembly is subcutaneously implanted in a patient. Ex.1009, ¶¶ 64-67.

The housing of Titanium Implanted Port has a flange that includes a radiotransparent silicone skirt overmolded about at least a portion of the base including the flange. Ex.1002, p. 10; Ex.1009, ¶¶ 68-75.

2. **Powers (Ex.1003):** Powers issued from Application No. 11/368,954, filed March 6, 2006, and is prior art to the '325 Patent under pre-AIA 35 U.S.C. §102(e) for its March 6, 2006 filing date. Moreover, Application No. 11/368,954 claims and was accorded the benefit of priority to the '518 provisional, filed March 4, 2005 and is prior art to the '325 patent under pre-AIA 35 U.S.C. §102(e) also for its March 4, 2005 filing date. Powers discloses a power injectable access port 10 with cap 14, base 16, septum 18 and reservoir (cavity) 36. Ex.1003, 4:29-45, Fig 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 1B. As depicted in Fig. 1B, base 16 forms a reservoir 36 having a bottom floor and side walls beneath septum 18. An outlet stem 31 (discharge port) extends from the reservoir 36.

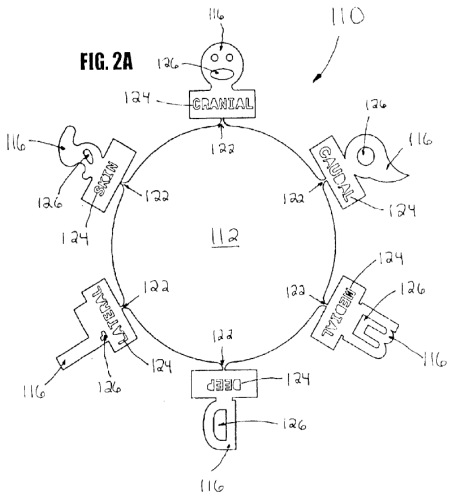
Powers further discloses an alphanumeric message on the port visible using X-rays to identify the port as power-injectable. Ex.1003, 3:43-47, 11:41-12:2; Ex.1016, p.7/65 (¶[0034]), p.8/65 (¶[0037]), p.17/65 (¶¶[0069]-[0070]), p.48/65 (Nos. 5-7). Powers further discloses that suture apertures 66 may be positioned so as to identify the access port 10 after subcutaneous implantation. Ex.1003, 10:16-18, Fig. 20; Ex.1016, p.16/65 (¶[0067]), Fig. 20. Ex.1009, ¶¶ 82-92.

3. **PowerPort (Ex.1004):** PowerPort is a printed publication which was publicly available at least as early as February 2007. Ex.1018, ¶¶9-26. PowerPort is prior art to the '325 patent under pre-AIA 35 U.S.C. §102(a). One of the access ports disclosed is the PowerPort*- M.R.I.* Device. The PowerPort*- M.R.I.*

Device is a power injectable port. The PowerPort*- M.R.I.* Device incorporates a radiopaque identifier. The radiopaque identifier appears under X-ray examination as a triangle with rounded corners and a circle inside the triangle. The circle has three inward protrusions at positions corresponding to the corners of the triangle. The radiopaque identifier also has two squares outside the base of the triangle, one showing the alphanumeric character "C" and the other showing "T":

The radiopaque identifier utilized in the PowerPort*- M.R.I.* Device is made from an X-ray discernable material, *i.e.,* titanium, and the alphanumeric characters "C" and "T" are formed by voids which extend through the top surface to the bottom surface of the X-ray discernable material. Ex.1004. Titanium is used as the X-ray discernible material and voids in the shape of alphanumeric characters "C" and "T" are used to provide high contrast so that the indicia is readily observable, under X-ray examination, after implantation. The radiopaque identifier with the alphanumeric characters "C" and "T" indicate, under X-ray examination, that the PowerPort*- M.R.I.* Device is rated for power injection, *i.e.,* that the assembly is adapted to withstand higher pressures and increased flow rates used for injection of contrast fluid. Ex.1009, ¶¶ 93-101.

4. **Sayre (Ex.1007):** U.S. Patent No. 6,826,257 ("Sayre"), issued November 30, 2004, is prior art to the '325 patent under pre-AIA 35 U.S.C. §102(b). Sayre discloses: "Indicia 124, also photoetched from the radiopaque material, aid in indicating orientation of each marker 116." Ex.1007, 4:8-10. Sayre further discloses indicia 124 photoetched from radiopaque material or formed in radiopaque markers 116 by stamping, laser cutting, or by other means and in which the indicia 124 are defined by one or more apertures formed through the respective marker 116 to provide unique identifying information when viewed by X-ray. Ex.1007, 4:11-31, Fig. 2A, claim 6; Ex.1009, ¶¶102-103.



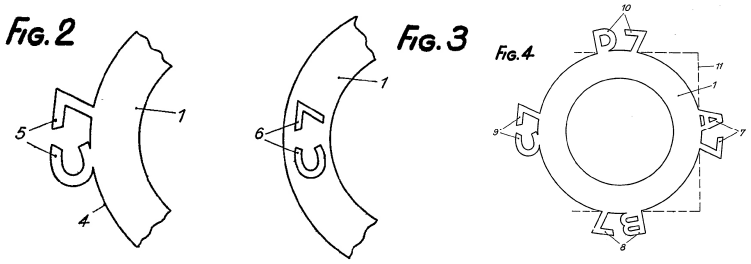
Sayre Fig. 2A

Sayre disclose cutouts (voids) extending through the X-ray discernable material, from top to bottom, that are visually discernable to a naked eye from both the top and the bottom. The radiopaque markers of Sayre can be made from metal,

such as titanium. Ex.1007, 5:6-15. The apertures of Sayre can define letters that can receive sutures used to secure the markers. Ex.1007, 4:41-57, Figs. 2A-2C; Ex.1009, ¶¶ 104-109.

5. **Meyer (Exs.1005 & 1006):** Meyer is a French patent that issued December 4, 1967, and is prior art to the '325 Patent under pre-AIA 35 U.S.C. §102(b). An English translation of Meyer with certification is provided. Ex.1006. Meyer Figs. 2, 3 and 4 depict alphanumeric characters formed by molding or cutting. Meyer Fig. 3 shows characters 6 which are formed by cutouts (voids) provided in the flange (collar 1). Ex.1006 p.3/4, left column, last paragraph; Fig. 3. The flange (collar 1) has a top surface and a bottom surface through which the cutout characters (voids) extend. Ex.1006, Fig. 3.

The alphanumeric characters shown in Figs. 2, 3 and 4 of Meyer (reproduced below), are formed in whole or part by creating voids.



Meyer Figs. 2, 3 and 4

Although not radiopaque like metal, plastic is expected to be discernable under X-ray examination as compared to voids in the plastic, and the voids in the

plastic would be expected to be discernable under X-ray examination. Ex.1009, ¶¶110-119.

Meyer further discloses a flange 1 comprising a height extending from a top surface of the flange to a bottom surface of the flange, the cutouts (voids) in the flange extend through the height of the flange from the top surface of the flange to the bottom surface of the flange, and the cutouts (voids) are visually discernable to a naked eye from both the top surface of the flange and the bottom surface of the flange. Ex.1009, ¶¶ 120, 121.

6. **Hickman (Ex.1017):** Hickman is a printed publication which was publicly available at least as early as 1992. Ex. 1019, ¶¶ 19-22. Hickman depicts a cutaway of a port, which is the same as the non-illustrated inside of Titanium Implanted Port disclosed in Ex.1002, p.10; Ex.1009, ¶ 76. Hickman confirms that the Titanium Implanted Port has a base defining a reservoir, and a well comprising a bottom floor and side walls defining a reservoir. Ex. 1009, ¶¶ 77-81.

B. Summary Of Invalidity Arguments

Titanium Implanted Port is an access port substantially similar to the access ports depicted and claimed in the '325 patent. *E.g., see* Ex.1001, Figs. 1, 5. Titanium Implanted Port has a flange with voids that are X-ray discernable indicia under X-ray examination, *i.e.,* orientation holes; however, PORTS does not

disclose that the Titanium Implanted Port is a power injectable port that includes voids configured to indicate that the assembly is rated for power injection.

Powers discloses X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection. For example, Powers discloses power injectable ports with radiopaque alphanumeric characters that convey to a practitioner that the venous access port assembly is power injectable when an X-ray is taken after implantation. Ex.1003, 3:43-47, 11:41-12:2; Ex.1016, [0034], [0037], [0069]-[0070], p.48/65 (Nos. 5-7). Powers also discloses that suture apertures may be positioned so as to identify the access port after subcutaneous implantation. Ex.1003, 10:16-18, Fig. 20; Ex.1016, p.16/65 (¶[0067]), Fig. 20.

PORTS in view of Powers teaches all of the recited elements of the challenged claims, including the access port being adapted to withstand higher pressures and flow rates used for power injection and indicia in the form of voids on a flange and X-ray viewable indicia in the form of alphanumeric characters as a power port identifier, rendering obvious the inclusion of X-ray discernable indicia in the form of voids extending through the flange of the Titanium Implanted Port to indicate that the port assembly is rated for power injection. The tertiary references emphasize the obviousness of voids in the form of alphanumeric characters; PowerPort (alphanumeric characters voids in X-ray discernable

material)(Ex.1004), Sayre (alphanumeric characters cutout in X-ray discernable material that can be used for suturing)(Ex.1007), and Meyer (alphanumeric characters cutout in a flange) (Exs.1005 & 1006). PowerPort, Sayre and Meyer disclose using cutouts (voids) of alphanumeric characters as identification indicia. PowerPort and Sayre expressly disclose using cutouts (voids) as X-ray identification indicia. Sayre also discloses that the X-ray indicia aid in indicating orientation. Ex.1007, 2:41-44; 4:8-10.

Hickman (Ex.1017) confirms that the Titanium Implanted Port has a base defining a reservoir and a housing comprising a well comprising a bottom floor and side walls defining a reservoir.

The subject matter disclosed in claims 1-2, 5-13, 15-19 and 21-22 of the '325 patent would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of PowerPort, Sayre or Meyer, and Hickman. Ex.1009, ¶¶307-310.

VII. DETAILED EXPLANATION UNDER 37 C.F.R. § 42.104(b)

In accordance with 37 C.F.R. § 42.104(b) an explanation of each proposed ground of unpatentability is provided.

A. Ground 1: Claims 1-2, 5-13, 15-19 And 21-22 Are Unpatentable As Obvious Under 35 U.S.C. §103(a) Over PORTS In View Of Powers And In Further View Of PowerPort And Hickman.

Claims 1-2, 5-13, 15-19 and 21-22 would have been obvious to a POSA over PORTS (Ex.1002) in view of Powers (Ex.1003) and in further view of PowerPort (Ex.1004) and Hickman (Ex.1017). Ex.1009, ¶¶ 122-125, 307, 308.

1. Independent Claim 1 Is Unpatentable As Obvious

PORTS and Powers teach all of the elements of claim 1. Ex.1009, ¶ 123. PowerPort emphasizes the obviousness of the X-ray discernable indicia in a power injectable port being in the form of alphanumeric character shaped voids. Hickman confirms that the Titanium Implanted Port disclosed in PORTS has a base defining a reservoir. The elements of claim 1 are addressed below.

a. A venous access port assembly for implantation into a patient, comprising: a housing comprising a base defining a bottom wall of at least one reservoir,

PORTS (Ex.1002) and Powers (Ex.1003) disclose a venous access port assembly for implantation into a patient comprising a housing including a base defining a bottom wall of a reservoir. Exs. 1002; 1003; 1009 ¶126; 1016; 1017.

Hickman confirms that the base inside the Titanium Implanted Port defines a reservoir. Ex. 1017.

b. a discharge port extending from the at least one reservoir, and

Titanium Implanted Port has a discharge port extending from the reservoir. Ex.1002, p.10; Ex.1009, ¶127. Powers similarly discloses an outlet stem 31 (discharge port) extending from the reservoir. Ex. 1003, 4:43-45, Figs. 1A, 1B; Ex.1009, ¶128; Ex. 1016, Figs. 1A, 1B.

c. a flange adjacent to the at least one reservoir,

Titanium Implanted Port has a flange adjacent to the reservoir. Ex.1002, p. 10. Powers discloses a flange that "extends about at least a portion of the periphery of the access port 10" and is adjacent to the reservoir. Ex.1003, 9:18-22; Ex. 1016, p.15/65 (¶[0061]); Ex.1009, ¶¶129-131.

d. the flange comprising a height extending from a top surface of the flange to a bottom surface of the flange,

The flange of the Titanium Implanted Port comprises a height extending from a top surface of the flange to a bottom surface of the flange. Ex.1002; Ex.1009, ¶132.

e. the flange further comprising X-ray discernable indicia

The flange of the Titanium Implanted Port is made of titanium, an X-ray discernable material. Ex.1002; Ex.1009, ¶133.

f. configured to indicate, under X-ray examination, that the port assembly is rated for power injection,

Powers discloses a power injectable port which has X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection. "For example, the instant disclosure contemplates that at least one feature of an access port may be observable through interaction with an imaging technology such as x-ray…" Ex.1003, 11:44-47; Ex.1016, p. 17/65 (¶[0069]). Specifically, in Powers, an alphanumeric message indicates, under X-ray examination, that the assembly is rated for power injection. *Id.*; Ex.1009, ¶¶134-136. Powers discloses that suture apertures 66 may be positioned so as to identify the access port 10 after subcutaneous implantation. Ex.1003, 10:16-18, Fig. 20; Ex.1016, p.16/65 (¶[0067]), Fig. 20; Ex.1009, ¶137.

PowerPort also discloses a power injectable port which has X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection. Ex.1004; Ex.1009, ¶138. The PowerPort*-M.R.I.* Device disclosed in PowerPort has a radiopaque identifier depicted below:

The radiopaque identifier with voids comprising the alphanumeric characters "C" and "T" indicate, under X-ray examination, that the PowerPort*- M.R.I.* Device is rated for power injection. Ex.1009, ¶¶138-139.

g. the X-ray discernable indicia located in the flange and extending through the height of the flange from the top surface of the flange to the bottom surface of the flange

Titanium Implanted Port has suture slots and orientation holes which extend through the height of the flange from the top surface of the flange to the bottom surface of the flange. Ex.1002, p.10; Ex.1009, ¶140.

PowerPort discloses X-ray discernable material with a top surface, a bottom surface, and one or more voids extending through the X-ray discernable material from the top surface to the bottom surface. Ex.1004; Ex.1009, ¶141.

h. so that the X-ray discernable indicia are visually discernable to a naked eye from both the top surface of the flange and the bottom surface of the flange prior to implantation of the port assembly; and

Titanium Implanted Port has suture slots and orientation holes that are visually discernable to a naked eye from both the top surface of the flange and the bottom surface of the flange prior to implantation of the port assembly. Ex.1002; Ex.1009, ¶142.

i. a needle-penetrable septum communicating with the housing.

Titanium Implanted Port includes a needle-penetrable septum in communication with the housing. Exs.1002, p.10; Ex.1009, ¶143. Powers and

PowerPort also disclose a needle-penetrable septum in communication with the housing. Ex.1003, 4:29-45, Figs. 1A, 1B; Ex.1016, p.8/65 (¶[0038]), Figs. 1A, 1B; Ex.1004; Ex.1009, ¶¶144-145.

As demonstrated above, PORTS, Powers, PowerPort and Hickman disclose all of the elements of claim 1 and for the reasons discussed herein, claim 1 is unpatentable for obviousness. Ex.1009, ¶146.

A POSA at the time of invention would have understood that PORTS, as evidenced by Hickman, discloses all of the elements of claim 1 other than that the Titanium Implanted Port was power injectable and the indicia indicating "that the assembly is rated for power injection." A POSA would have known that the Titanium Implanted Port in view of Powers could be constructed to handle power injection. Specifically, Titanium Implanted Port would be modified in view of Powers to handle the higher pressures and flow rates associated with power injection for injecting contrast media, *e.g.,* for a CT scan. Ex.1009, ¶¶147-148. To identify the Titanium Implanted Port in view of Powers as a power injectable port, at the time of the invention, it would have been obvious to a POSA in view of Powers to provide the Titanium Implanted Port with X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection. Ex.1009, ¶149. Titanium Implanted Port already has indicia

extending through the height of the flange of the port which, under X-ray examination, indicate the orientation of the port. Ex.1009, ¶150.

In particular, regarding indicia indicating under X-ray examination that a port is rated for power injection, Powers discloses a power injectable port with "X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection." Ex. 1003; Ex.1016; Ex.1009, ¶151. Powers, like the Titanium Implanted Port, is a venous access port comprising a cap, a base, a discharge port, a septum and a reservoir. Ex.1003, 4:29-45, Fig. 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 1B; Ex.1009, ¶152. Powers specifically discloses an alphanumeric message visible using X-rays to identify the port as power-injectable. Under X-ray examination, the Powers port can be identified as power-injectable Ex.1003, 11:41-12:2; Ex.1016, [0034], [0037], [0069]-[0070], p.48/65 (Nos. 5-7); Ex.1009, ¶¶153-154. Powers discloses that suture apertures 66 may be positioned so as to identify the access port 10 after subcutaneous implantation.Ex.1003,10:16-18, Fig.20; Ex.1016, p.16/65 (¶[0067], Fig. 20; Ex.1009, ¶155.

PowerPort discloses a power injectable port where the voids "C" and "T" are X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection. Ex.1004; Ex.1009, ¶156.

Titanium Implanted Port includes holes (voids) in the flange which, under X-ray examination, function as indicia of orientation. Ex.1002; Ex.1009, ¶157.

Powers discloses X-ray discernable indicia indicating that a port is power-injectable as well as that suture apertures can identify the port. Ex.1009, ¶158. As such, it would have been obvious for a POSA in light of PORTS in view of Powers to include X-ray discernable indicia comprising alphanumeric characters in the form of voids extending through the height of the flange of the Titanium Implanted Port to indicate, under X-ray examination, that the assembly is rated for power injection, because, for example, the flange of the Titanium Implanted Port is already known as a location for X-ray discernable indicia created by voids extending from the top of the flange to the bottom of the flange. The obviousness of including X-ray identifiable indicia in the form of voids in the flange of the Titanium Implanted Port in view of Powers to indicate that the assembly is rated for power injection is emphasized by PowerPort's disclosure of X-ray discernable indicia comprising alphanumeric characters in the form of voids indicating that a port is power injectable. Indicia in the form of voids in the flange of the Titanium Implanted Port would be expected to provide high contrast so that the alphanumeric characters would be readily discernable, under X-ray examination, after implantation. Ex.1009, ¶¶159-162. Moreover, the indicia in the flange of the Titanium Implanted Port are already structured and arranged so as to be visually discernable prior to implantation of the port as well as to be X-ray discernable after implantation. Ex.1009, ¶163. Accordingly, the same expected result would be

understood to be obtained with respect to indicia indicating that the assembly is rated for power injection extending from the top to the bottom surface of the flange of the modified Titanium Implanted Port as for the indicia already included in the flange of the Titanium Implanted Port. Ex.1009, ¶164.

In view of the above, and the supporting expert testimony (Ex.1009, ¶¶ 122-165), claim 1 would have been obvious to a POSA over PORTS in view of Powers and in further view of PowerPort and Hickman. Ex.1009, ¶166.

2. Dependent Claim 2 Is Unpatentable As Obvious

Claim 2 recites: "The assembly of claim 1, wherein the X-ray discernable indicia comprise radiopaque markings." Ex. 1001; Ex.1009, ¶167.

The '325 patent discloses with respect to the embodiments illustrated in Figs. 12 and 13 that if the base flange "is comprised of metal (particularly the letters "CT"), those portions would naturally be visible by X-ray examination without application of the radiopaque agent." Ex. 1001, 4:65-5:3. Thus, the voids in the '325 patent discernable by X-ray are radiopaque markings. Similarly, PORTS modified by Powers and PowerPort includes X-ray discernible indicia extending through the height of the flange indicating that the port is power injectable. These indicia obviously comprise radiopaque markings in the titanium metal flange of the modified Titanium Implanted Port. Ex.1009, ¶¶168-171.

Accordingly, claim 2 would have been obvious to a POSA over PORTS in view of Powers and in further view of PowerPort and Hickman for the reasons set forth with respect to claim 1.

3. Dependent Claim 5 Is Unpatentable As Obvious

Claim 5 recites: "The assembly of claim 1, wherein the flange is comprised of a metal material, whereby the indicia are visible by X-ray examination when the assembly is subcutaneously implanted in a patient." As noted with respect to claim 1, the flange of the Titanium Implanted Port is made of the metal titanium. Ex.1002. Therefore, claim 5 would have been obvious to a POSA over PORTS in view of Powers and in further view of PowerPort and Hickman for the reasons set forth with respect to claim 1. Ex.1009, ¶¶172-174.

4. Dependent Claim 6 Is Unpatentable As Obvious

Claim 6 recites: "The assembly of claim 1, wherein the flange extends outwardly from the base about a perimeter of the at least one reservoir." The flange of the Titanium Implanted Port extends outwardly from the base about a perimeter of the reservoir. Ex.1002. Accordingly, claim 6 would have been obvious to a POSA over PORTS in view of Powers and in further view of PowerPort and Hickman for the reasons set forth with respect to claim 1. Ex.1009, ¶¶175-177.

5. Dependent Claim 7 Is Unpatentable As Obvious

Claim 7 recites: "The assembly of claim 1, wherein the flange further includes suture openings, and the indicia are located within predetermined suture openings." Titanium Implanted Port has suture slots in the flange. Ex.1002. Powers discloses that suture apertures 66 may be positioned so as to identify the access port 10 after subcutaneous implantation. Ex.1003, 10:16-18, Fig. 20; Ex.1016, p.16/65 (¶[0067]), Fig. 20. Also, the orientation openings can be used for suturing. Ex.1009, ¶¶178-181.

As noted with respect to claim 1, it would have been obvious to a POSA at the time of the invention to modify the flange of the Titanium Implanted Port to include X-ray identifiable indicia as disclosed by Powers and PowerPort to indicate that the assembly is rated for power injection. The flange would be an expected location on the port for X-ray identifiable indicia as the flange already includes X-ray identifiable indicia, *e.g.,* orientation holes, as well as suture slots that are X-ray identifiable and can be used for suturing the port in position. Thus, cutouts (voids) having dual functionality as suture openings and indicia are known. It would have been obvious to a POSA that the indicia be various alphanumeric characters, such as disclosed by Powers and PowerPort, by having a portion of the titanium flange ("X-ray discernable material") of the Titanium Implanted Port extending into or disposed in the suture slots and/or the orientation holes. For example, a void with

a portion of the titanium flange extending into or disposed therein in the form of the alphanumeric letter "C" would have the recited intended dual functionality for receiving sutures and the indicia being located within predetermined suture openings. Ex.1009, ¶¶182-186. Accordingly, claim 7 is unpatentable as obvious.

6. Dependent Claim 8 Is Unpatentable As Obvious

Claim 8 recites: "The assembly of claim 1, wherein the indicia comprise flange material." Ex.1009, ¶187. As noted with respect to claim 1, it would have been obvious for a POSA to include X-ray discernable indicia in the form of alphanumeric characters in the form of voids configured to indicate, under X-ray examination, that the assembly is rated for power injection on the flange of the Titanium Implanted Port disclosed in PORTS in view of Powers and PowerPort. Accordingly, the indicia in the form of voids in the flange material obviously comprise flange material. Ex.1009, ¶¶188-189. Accordingly, claim 8 is unpatentable as obvious.

7. Dependent Claim 9 Is Unpatentable As Obvious

Claim 9 recites: "The assembly of claim 1, wherein the indicia are voids in the flange." Ex.1009, ¶190. For the reasons already set forth with respect to claim 1, it would have been obvious to a POSA at the time of the invention to include indicia in the form of voids in the flange of the modified Titanium Implanted Port of PORTS in view of Powers and PowerPort and Hickman, especially when the

Titanium Implanted Port includes voids, *i.e.,* suture slots and orientation holes, in the flange that are X-ray discernable indicia under X-ray examination. Ex. 1002; Ex.1009, ¶191. Accordingly, claim 9 is unpatentable as obvious.

8. Dependent Claim 10 Is Unpatentable As Obvious

Claim 10 recites: "The assembly of claim 1, wherein the assembly is at least partially comprised of radiotransparent material." Ex.1009, ¶192. Titanium Implanted Port has a silicone skirt that is radiotransparent. Ex. 1002. Accordingly, claim 10 would have been obvious to a POSA over PORTS in view of Powers and in further view of PowerPort and Hickman. Ex.1009, ¶¶193-194.

9. Dependent Claim 11 Is Unpatentable As Obvious

Claim 11 recites: "The assembly of claim 1, wherein the indicia indicate, under X-ray examination, that the assembly is adapted to withstand high pressures used for injection of contrast fluid." Ex.1009, ¶195.

Powers discloses a power injectable port with X-ray discernable indicia (alphanumeric characters) on the port, which indicates, under X-ray examination, that the assembly is power injectable, *i.e.,* adapted to withstand high pressures used for injection of contrast fluid. Ex. 1003, 3:42-59, 11:56-12:2; Ex.1016, p.7/65 (¶[0034]), p.17/65 (¶[¶[0069]-[0070]), p.48/65 (Nos. 5-7). A power injectable port is a port adapted to withstand high pressures used for injection of contrast fluid. Ex.1009, ¶¶196-197.

PowerPort also discloses a power injectable port with X-ray discernable indicia (alphanumeric characters), which indicates, under X-ray examination, that the assembly is power injectable, *i.e.,* adapted to withstand higher pressures and increased flow rates used for injection of contrast fluid. Ex. 1004; Ex.1009, ¶198.

It would have been obvious to a POSA at the time of invention, in view of Powers and PowerPort, to provide the Titanium Implanted Port with alphanumeric X-ray discernable indicia, such as "CT" or "C" and "T", which indicates, under X-ray examination, that the power injectable port is adapted to withstand higher pressures and increased flow rates used for injection of contrast fluid. Ex.1009, ¶199. Accordingly, claim 11 would have been obvious to a POSA over PORTS in view of Powers and in further view of PowerPort and Hickman. Ex.1009, ¶200.

10. Independent Claim 12 Is Unpatentable As Obvious

Claim 12 recites: "An implantable venous access port assembly comprising: a needle-penetrable septum; a housing securing the needle-penetrable septum, the housing comprising a housing base defining at least one reservoir, and a flange extending radially from the housing base, the flange comprising: X-ray discernable material; a height extending from a top surface of the flange to a bottom surface of the flange; and one or more cutouts extending entirely through the height of the flange from the top surface of the flange to the bottom surface of the flange, the one or more cutouts comprising one or more voids in the X-ray discernable

material, the one or more cutouts configured to indicate, under X-ray examination, that the port assembly is rated for power injection, the one or more cutouts further configured to be visually discernable to a naked eye from both the top surface of the flange and the bottom surface of the flange prior to implantation of the port assembly; and a discharge port extending from the housing." Ex.1009, ¶201.

Titanium Implanted Port is an implantable venous access port with a needle-penetrable septum secured by the housing. The housing comprises a base which defines a reservoir, and has a discharge port extending from the housing. Titanium Implanted Port has a flange extending radially from the base, and is made of titanium, an X-ray discernable material. Titanium Implanted Port has cutouts (voids), *i.e.,* suture slots and orientation holes, which extend entirely through the height of the flange from the top surface of the flange to the bottom surface of the flange. In the Titanium Implanted Port, the suture slots and orientation holes are visually discernable to a naked eye from both the top surface of the flange and the bottom surface of the flange prior to implantation of the port assembly. Ex.1002. Hickman ports, such as the Titanium Implanted Port disclosed in PORTS, include a base defining a reservoir. Ex.1017; Ex.1009, ¶¶202-203.

Powers discloses a power injectable port with "X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection." Ex. 1003; Ex.1016. Powers, like the Titanium Implanted Port, is

a venous access port comprising a cap, a base, a discharge port, a septum and a reservoir. Ex.1003, 4:29-45, Fig. 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 1B. Powers specifically discloses an alphanumeric message visible using X-rays to identify the port as power-injectable. Ex.1003, 3:43-47, 11:41-12:2; Ex.1016, [0034], [0037], [0069]-[0070], p.48/65 (Nos. 5-7); Ex.1009, ¶¶204-206. Under X-ray examination, the Powers port can be identified as power-injectable. Ex.1003, 3:43-47, 11:41-12:2, 12:64-67 (claim 1); Ex.1016, [0034], [0037], [0069]-[0070], p.48/65 (Nos. 5-7); Ex.1009, ¶207. Powers discloses that suture apertures 66 may be positioned so as to identify the access port 10 after subcutaneous implantation. Ex.1003, 10:16-18, Fig. 20; Ex.1016, p.16/65 (¶[0067], Fig. 20; Ex.1009, ¶208.

PowerPort discloses a power injectable port where the voids "C" and "T" are X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection. Ex.1004; Ex.1009 ¶209.

Titanium Implanted Port includes holes (cutouts/voids) in the flange which, under X-ray examination, function as indicia of orientation. Ex.1002; Ex.1009, ¶210.

A POSA would understand that PORTS, as evidenced by Hickman, discloses all of the elements of claim 12 other than that the Titanium Implanted Port is power injectable and the indicia indicating "that the assembly is rated for power injection." A POSA would have understood that Titanium Implanted Port,

in view of Powers, could be constructed to handle power injection. At the time of the invention, it would have been obvious to a POSA to provide the Titanium Implanted Port, modified in view of Powers, with X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection. Titanium Implanted Port already has indicia extending through the height of the flange of the port which, under X-ray examination, indicate the orientation of the port. Ex.1009, ¶¶211-214.

It would have been obvious over PORTS in view of Powers to include X-ray discernable indicia comprising alphanumeric characters in the form of cutouts (voids) extending through the height of the flange of the Titanium Implanted Port to indicate, under X-ray examination, that the assembly is rated for power injection, because, for example, the flange of the Titanium Implanted Port is already known as a location for X-ray discernable indicia created by voids extending from the top of the flange to the bottom of the flange. Ex.1009, ¶215.

The obviousness of including X-ray identifiable indicia in the form of cutouts (voids) in the flange of the Titanium Implanted Port disclosed in PORTS in view of Powers to indicate that the assembly is rated for power injection is emphasized by PowerPort's disclosure of X-ray discernable indicia comprising alphanumeric characters in the form of cutouts (voids) indicating that a port is power injectable. Indicia in the form of cutouts (voids) in the flange of the

Titanium Implanted Port would be expected to provide high contrast so that the alphanumeric characters would be readily discernable, under X-ray examination, after implantation. Moreover, the indicia in the flange of the Titanium Implanted Port are already structured and arranged so as to be visually discernable prior to implantation of the port as well as to be X-ray discernable after implantation. Accordingly, the same expected result would be understood to be obtained with respect to indicia indicating that the assembly is rated for power injection extending from the top to the bottom surface of the flange of the modified Titanium Implanted Port as for the indicia already included in the flange of the Titanium Implanted Port. Ex.1009, ¶¶216-219.

In view of the above, and the supporting expert testimony (Ex.1009), claim 12 would have been obvious to a POSA over PORTS in view of Powers and in further view of PowerPort and Hickman. Ex.1009, ¶¶201-221.

11. Dependent Claim 13 Is Unpatentable As Obvious

Claim 13 recites: "The port assembly of claim 12, wherein the flange comprises the X-ray discernable material and the one or more cutouts extend entirely through the X-ray discernable material from the top surface of the flange to the bottom surface of the flange." This feature is already recited in claim 12, and is obvious for the same reasons as claim 12. Ex.1009, ¶¶222-223.

12. Dependent Claim 15 Is Unpatentable As Obvious

Claim 15 recites: "The port assembly of claim 12, wherein the one or more cutouts are further configured to indicate, under X-ray examination, that the port assembly is rated to be used for power injection of contrast fluid."

Powers discloses a power injectable port with X-ray discernable indicia (alphanumeric characters) on the port, which indicates, under X-ray examination, that the assembly is power injectable, *i.e.,* adapted to withstand high pressures used for injection of contrast fluid. Ex. 1003, 3:42-59, 11:56-12:2; Ex.1016, p.7/65 (¶[0034]), p.17/65 (¶[¶[0069]-[0070]), p.48/65 (Nos. 5-7). A power injectable port is a port adapted to withstand higher pressures and increased flow rates used for injection of contrast fluid. Ex.1009, ¶¶224-226.

PowerPort also discloses a power injectable port with X-ray discernable indicia (alphanumeric characters), which indicates, under X-ray examination, that the assembly is power injectable, *i.e.,* adapted to withstand higher pressures and increased flow rates used for injection of contrast fluid. Ex. 1004; Ex.1009, ¶227.

It would have been obvious to a POSA at the time of invention, in view of Powers and PowerPort, to provide the Titanium Implanted Port with alphanumeric X-ray discernable indicia, *e.g.,* cutouts (voids), such as "CT" or "C" and "T", which indicate, under X-ray examination, that the power injectable port is rated to be used for power injection of contrast fluid. Accordingly, claim 15 would have

been obvious to a POSA over PORTS in view of Powers and in further view of PowerPort and Hickman. Ex.1009, ¶¶228-229.

13.Dependent Claim 16 Is Unpatentable As Obvious

Claim 16 recites: "The port assembly of claim 12, wherein the one or more cutouts are further configured to indicate, under X-ray examination, that the port assembly is adapted to withstand high pressures used for injection of contrast fluid." Ex.1009, ¶230.

For the same reasons set forth with respect to claim 15, it would have been obvious to a POSA at the time of invention, in view of Powers and PowerPort, to provide the Titanium Implanted Port with cutouts (voids), such as "C" and "T", which indicate, under X-ray examination, that the power injectable port is adapted to withstand high pressures used for injection of contrast fluid. Accordingly, claim 16 would have been obvious to a POSA over PORTS in view of Powers and in further view of PowerPort and Hickman. Ex.1009, ¶¶231-232.

14. Independent Claim 17 Is Unpatentable As Obvious

Claim 17 recites: "An implantable venous access port assembly comprising: a needle-penetrable septum; a housing securing the needle-penetrable septum, the housing comprising a housing base defining at least one reservoir, and a flange extending radially from the housing base, the flange comprising: a height extending from a top surface of the flange to a bottom surface of the flange; one or

more X-ray discernable indicia formed in the flange and extending through the height of the flange from the top surface of the flange to the bottom surface of the flange, the one or more X-ray discernable indicia configured to indicate, under X-ray examination, that the port assembly is rated for power injection, the one or more X-ray discernable indicia further configured to be visually discernable to a naked eye from both the top surface of the flange and the bottom surface of the flange prior to implantation of the port assembly; and a discharge port extending from the housing." Ex.1009, ¶233.

Claim 17 is substantially similar to claim 12, the primary difference being that where claim 12 recites "cutouts," claim 17 recites "X-ray discernable indicia." Both the cutouts of claim 12 and the X-ray discernable indicia of claim 17 are described as extending through the height of the flange, and configured to be visually discernable to a naked eye from both the top surface of the flange and the bottom surface of the flange prior to implantation of the port assembly. Thus, claim 17 would have been obvious to a POSA for the same reasons claim 12 would have been obvious to a POSA. Ex.1009, ¶¶234-236.

15. Dependent Claim 18 Is Unpatentable As Obvious

Claim 18 recites: "The port assembly of claim 17, wherein the flange further comprises one or more cutouts disposed about peripheries of the one or more X-ray discernable indicia." The flange of the Titanium Implanted Port has cutouts

(voids). The radiopaque identifier in PowerPort has alphanumeric characters formed by voids. The alphanumeric character "C" is formed by a portion of the X-ray discernable material extending into an oval void to create the "C".

It would have been obvious to a POSA at the time of invention that the X-ray discernable indicia of the Titanium Implanted Port disclosed in PORTS (Ex.1002) modified by Powers (Ex.1003) and PowerPort (Ex.1004) as evidenced by Hickman (Ex.1017) would have been structured in view of Powers and PowerPort to have various alphanumeric characters by having a portion of the titanium flange ("X-ray discernable material") extending into or disposed in the suture slots and/or the orientation holes. For example, the void with a portion of the titanium flange extending into or disposed therein could have an alphanumeric form, such as the disclosed cutout "C" of PowerPort (which is in the form of a void with X-ray discernible material disposed), thereby providing the X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection. It would have been obvious to a POSA that voids of any shape would provide an indication that the port is power injectable. Accordingly, claim 18 would have been obvious to a POSA over PORTS in view of Powers and in further view of PowerPort and Hickman. Ex.1009, ¶¶ 237-243.

16. Dependent Claim 19 Is Unpatentable As Obvious

Claim 19 recites: "The port assembly of claim 18, wherein: the flange comprises X-ray discernable material extending entirely through the height of the flange from the top surface of the flange to the bottom surface of the flange, the one or more X-ray discernable indicia extend entirely through the X-ray discernable material from the top surface of the flange to the bottom surface of the flange, and the one or more cutouts extend entirely through the X-ray discernable material from the top surface of the flange to the bottom surface of the flange."

The features of claim 19 have already been addressed with respect to claim 18. Accordingly, claim 19 is unpatentable for the same reasons as claim 18. Ex.1009, ¶¶ 244-245.

17. Dependent Claim 21 Is Unpatentable As Obvious

Claim 21 recites: "The port assembly of claim 17, wherein the one or more X-ray discernable indicia are further configured to indicate, under X-ray examination, that the port assembly is rated to be used for power injection of contrast fluid." Ex.1009, ¶246.

Powers discloses a power injectable port with X-ray discernable indicia (alphanumeric characters) on the port, which indicates, under X-ray examination, that the assembly is power injectable. Ex. 1003, 3:42-59, 11:56-12:2; Ex.1016, p.7/65 (¶[0034]), p.17/65 (¶[¶[0069]-[0070]), p.48/65 (Nos. 5-7). Ex.1009, ¶247.

PowerPort also discloses a power injectable port with X-ray discernable cutouts (voids), which indicate, under X-ray examination, that the assembly is power injectable. Ex. 1004; Ex.1009, ¶248.

It would have been obvious to a POSA at the time of invention, in view of Powers and PowerPort, to provide the Titanium Implanted Port with alphanumeric X-ray discernable indicia, *e.g.,* cutouts (voids), such as "CT" or "C" and "T", which indicate, under X-ray examination, that the power injectable port is rated to be used for power injection of contrast fluid. Accordingly, claim 21 would have been obvious to a POSA over PORTS in view of Powers and in further view of PowerPort and Hickman. Ex.1009, ¶¶ 249-250.

18. Dependent Claim 22 Is Unpatentable As Obvious

Claim 22 recites: "The port assembly of claim 17, wherein the one or more X-ray discernable indicia are further configured to indicate, under X-ray examination, that the port assembly is adapted to withstand high pressures used for injection of contrast fluid." Ex.1009, ¶251.

For the same reasons set forth with respect to claim 21, it would have been obvious to a POSA at the time of invention, in view of Powers and PowerPort and Hickman, to provide the Titanium Implanted Port disclosed in PORTS with cutouts (voids), such as "C" and "T", which indicate, under X-ray examination, that the power injectable port is adapted to withstand high pressures used for injection of

contrast fluid. Accordingly, claim 22 would have been obvious to a POSA over PORTS in view of Powers and in further view of PowerPort and Hickman. Ex.1009, ¶¶252-253.

B. Ground 2: Claims 1-2, 5-13, 15-19 And 21-22 Are Unpatentable As Obvious Under 35 U.S.C. §103(a) Over PORTS In View Of Powers And In Further View Of Sayre And Hickman.

Claims 1-2, 5-13, 15-19 and 21-22 would have been obvious to a POSA over PORTS (Ex.1002) in view of Powers (Ex.1003) and in further view of Sayre (Ex.1007) and Hickman (Ex.1017). Sayre discloses X-ray discernable indicia, such as alphanumeric characters, defined by apertures (cutouts/voids) in radiopaque material that can also aid in indicating orientation as well as receive sutures. Ex.1007, 4:8-31, 53-57, Fig. 2A, claim 6. Ex.1009, ¶¶254-255. Thus, claims 1-2, 5-13, 15-19 and 21-22 would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of Sayre and Hickman for the same reasons these claims would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of PowerPort an Hickman because Sayre, like PowerPort, teaches indicia in the form of alphanumeric character cutouts (voids). Ex.1009, ¶¶ 256, 307, 309.

1. Independent Claim 1 Is Unpatentable As Obvious

A POSA at the time of invention would have understood that PORTS, as evidenced by Hickman, discloses all of the elements of claim 1 other than that the

Titanium Implanted Port was power injectable and the indicia indicating "that the assembly is rated for power injection." A POSA would have known that the Titanium Implanted Port in view of Powers could be constructed to handle power injection. At the time of the invention, it would have been obvious to a POSA to provide the Titanium Implanted Port in view of Powers with X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection. Titanium Implanted Port already has indicia extending through the height of the flange of the port which, under X-ray examination, indicate the orientation of the port. Ex.1009, ¶¶257-260.

In particular, regarding indicia indicating, under X-ray examination that a port is rated for power injection, Powers discloses a power injectable port with "X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection." Ex.1009, ¶261. Powers, like the Titanium Implanted Port, is a venous access port comprising a cap, a base, a septum, a discharge port and a reservoir. Ex.1003, 4:31-49, Fig 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 1B. Ex.1009, ¶262. Powers specifically discloses alphanumeric characters visible using X-rays to identify the port as power-injectable. Ex.1003, 3:43-47, 11:41-12:2; Ex.1016, [0034], [0037], [0069]-[0070], p.48/65 (Nos. 5-7). Under X-ray examination, the Powers port can be identified as power-injectable. *Id.*; Ex.1009, ¶¶263-264. Powers also discloses that suture apertures may be

positioned so as to identify the access port after subcutaneous implantation. Ex.1003, 10:16-18, Fig. 20; Ex.1016, p.16/65 (¶[0067]), Fig. 20; Ex.1009, ¶265.

Titanium Implanted Port includes holes (voids) in the flange which, under X-ray examination, function as indicia of orientation. Ex.1002; Ex.1009, ¶266. Powers discloses X-ray discernable indicia indicating that a port is power-injectable as well as that suture apertures can identify the port. Ex.1003; Ex. 1016; Ex.1009, ¶267. As such, it would have been obvious for a POSA in light of PORTS in view of Powers to include X-ray discernable indicia comprising alphanumeric characters in the form of cutouts (voids) extending through the height of the flange of the Titanium Implanted Port to indicate, under X-ray examination, that the assembly is rated for power injection, because, for example, the flange of the Titanium Implanted Port is already known as a location for X-ray discernable indicia created by voids extending from the top of the flange to the bottom of the flange. Ex.1002; Ex.1009, ¶268. The obviousness of including X-ray identifiable indicia in the form of cutouts (voids) in the flange of the Titanium Implanted Port in view of Powers to indicate that the assembly is rated for power injection is emphasized by Sayre's disclosure of X-ray discernable indicia, such as alphanumeric characters, defined by apertures (cutouts/voids) in radiopaque material that can also aid in indicating orientation and receive sutures. Additionally, indicia in the form of apertures in a flange formed of titanium would

be expected to provide high contrast so that the indicia would be readily observable, under X-ray examination, after implantation. Ex.1009, ¶269.

In view of the above, and the supporting expert testimony, claim 1 would have been obvious to a POSA over PORTS in view of Powers and in further view of Sayre and Hickman. Ex.1009, ¶¶257-271.

2. Independent Claims 12 And 17 Are Unpatentable As Obvious

Claims 12 and 17 would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of Sayre and Hickman for the same reasons that claims 12 and 17 would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of PowerPort and Hickman. Sections VII.A.10 and 14. In other words, PORTS in view of Powers teaches the recited elements of the challenged claims, including indicia in the form of cutouts (voids) on a flange and X-ray viewable indicia in the form of alphanumeric characters as a power port identifier. Sayre emphasizes the obviousness of cutouts (voids) in the form of alphanumeric characters as does PowerPort. Ex.1009, ¶¶272-273.

3. Dependent Claims 2, 5-11, 13, 15, 16, 18, 19 And 21-22 Are Also Unpatentable As Obvious

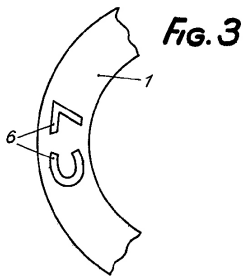
Dependent claims 2, 5-11, 13, 15, 16, 18, 19 and 21-22 would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of Sayre and Hickman for the same reasons that these claims would

have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of PowerPort (Section VII.A.).

Specifically, PORTS in view of Powers teaches the recited elements of the dependent claims, including indicia in the form of cutouts (voids) on a flange and X-ray viewable indicia in the form of alphanumeric characters as a power port identifier. Sayre, like PowerPort, teaches cutouts (voids) in the form of alphanumeric characters. Sayre, like PowerPort, emphasizes obviousness of the alphanumeric characters of Powers located in the flange of the Titanium Implanted Port in the form of cutouts (voids). Ex.1009, ¶¶274-277.

C. Ground 3: Claims 1-2, 5-13, 15-19 And 21-22 Are Unpatentable As Obvious Under 35 U.S.C. §103(a) Over PORTS In View Of Powers And In Further View Of Meyer And Hickman.

Claims 1-2, 5-13, 15-19 and 21-22 would have been obvious to a POSA over PORTS (Ex.1002) in view of Powers (Ex.1003) and in further view of Meyer (Ex.1006) and Hickman (Ex.1017). Meyer discloses a container (reservoir) with a flange 1 about the container, and alphanumeric characters in the flange formed in whole or part by cutouts (voids). The alphanumeric characters shown in Meyer Fig. 3 (reproduced below) are formed by cutouts (voids) in the flange (collar 1). Ex. 1006.



Meyer thus teaches using a flange with indicia created by voids. Ex.1006. As the alphanumeric characters are cutouts (voids) in the flange, even though the flange is plastic, the cutouts (voids) would be discernable under X-ray examination. Ex.1006; Ex.1009, ¶¶278-284.

Thus, claims 1-2, 5-13, 15-19 and 21-22 would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of Meyer and Hickman for the same reasons these claims would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of PowerPort and Hickman, and for the same reasons that these claims would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of Sayre and Hickman, because Meyer, like PowerPort and Sayre, teaches indicia in the form of alphanumeric character cutouts (voids). Ex.1009, ¶¶285, 307, 310.

1. Independent Claim 1 Is Unpatentable As Obvious

A POSA at the time of invention would have understood that PORTS, as evidenced by Hickman, discloses all of the elements of claim 1 other than that the

Titanium Implanted Port was power injectable and the indicia indicating "that the assembly is rated for power injection." A POSA would have known that the Titanium Implanted Port in view of Powers could be constructed to handle power injection. At the time of the invention, it would have been obvious to a POSA to provide the Titanium Implanted Port in view of Powers with X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection. Titanium Implanted Port already has indicia extending through the height of the flange of the port which, under X-ray examination, indicate the orientation of the port. Ex.1009, ¶¶286-289.

In particular, Powers discloses a power injectable port with "X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection." Ex.1009, ¶290. Powers, like the Titanium Implanted Port, is a venous access port comprising a cap, a base, a septum, a discharge port and a reservoir. Ex.1003, 4:31-49, Fig. 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 1B; Ex.1009, ¶291. Powers specifically discloses alphanumeric characters visible using X-rays to identify the port as power-injectable. Ex.1003, 3:43-47, 11:41-12:2; Ex.1016, [0034], [0037], [0069]-[0070], p.48/65 (Nos. 5-7). Under X-ray examination, the Powers port can be identified as power-injectable. Ex.1003, 3:43-47, 11:41-12:2; Ex.1016, [0034], [0037], [0069]-[0070], p.48/65 (Nos. 5-7); Ex.1009, ¶¶292-293. Powers also discloses that suture apertures may

be positioned so as to identify the access port after subcutaneous implantation. Ex.1003, 10:16-18, Fig. 20; Ex.1016, p.16/65 (¶[0067]), Fig. 20; Ex.1009, ¶294.

Titanium Implanted Port includes holes in the flange which, under X-ray examination, function as indicia of orientation. Ex.1002; Ex.1009 ¶295. Powers discloses X-ray discernable indicia indicating that a port is power-injectable as well as that suture apertures can identify the port. As such, it would have been obvious for a POSA in light of PORTS in view of Powers to include X-ray discernable indicia comprising alphanumeric characters in the form of cutouts (voids) extending through the height of the flange of the Titanium Implanted Port to indicate, under X-ray examination, that the assembly is rated for power injection, because, for example, the flange of the Titanium Implanted Port is already known as a location for X-ray discernable indicia created by voids extending from the top of the flange to the bottom of the flange. The obviousness of including X-ray identifiable indicia in the form of cutouts (voids) in the flange of the Titanium Implanted Port in view of Powers to indicate that the assembly is rated for power injection is emphasized by Meyer in its disclosure of indicia in the form of alphanumeric cutouts (voids) in a flange adjacent to a container. Ex.1009, ¶¶296-297.

In view of the above, and the supporting expert testimony, claim 1 would have been obvious to a POSA over PORTS in view of Powers and in further view of Meyer and Hickman. Ex.1009, ¶¶286-299.

2. Independent Claims 12 And 17 Are Unpatentable As Obvious

Claims 12 and 17 would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of Meyer and Hickman for the same reasons that claims 12 and 17 would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of PowerPort and Hickman, and for the same reasons that these claims would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of Sayre and Hickman. Sections VII.A.10 and 14, VII.B.2 and VII.C.1. In other words, PORTS in view of Powers teaches the recited elements of the challenged claims, including indicia in the form of cutouts (voids) on a flange and X-ray viewable indicia in the form of alphanumeric characters as a power port identifier. Meyer emphasizes the obviousness of cutouts (voids) in the form of alphanumeric characters as does PowerPort, and Meyer teaches that the cutouts (voids) are in the flange. Ex.1009, ¶¶300-302.

3. Dependent Claims 2, 5-11, 13, 15, 16, 18, 19 And 21-22 Are Also Unpatentable As Obvious

Dependent claims 2, 5-11, 13, 15, 16, 18, 19 and 21-22 would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in

further view of Meyer and Hickman for the same reasons that these claims would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of PowerPort and Hickman (Section VII.A.), and for the same reasons that these claims would have been obvious to a POSA at the time of invention over PORTS in view of Powers and in further view of Sayre and Hickman. (Section VII.B.) Specifically, PORTS in view of Powers teaches the recited elements of the dependent claims, including indicia in the form of cutouts (voids) on a flange and X-ray viewable indicia in the form of alphanumeric characters as a power port identifier. Meyer, like PowerPort, teaches cutouts (voids) in the form of alphanumeric characters. Meyer teaches locating the alphanumeric character cutouts (voids) in a flange and like PowerPort emphasizes obviousness of the alphanumeric characters of Powers located in the flange of the Titanium Implanted Port in the form of cutouts (voids). Ex.1009, ¶¶303-306.

VIII. CONCLUSION

For the reasons described above, there is a reasonable likelihood that Petitioner will prevail as to each of claims 1-2, 5-13, 15-19 and 21-22 of the '325 patent and a reasonable likelihood that at least one of the claims challenged in the

petition is unpatentable. 37 C.F.R. § 42.108(c). Accordingly, *inter partes* review of claims 1-2, 5-13, 15-19 and 21-22 of the '325 patent is respectfully requested.

Dated: July 31, 2015

Respectfully submitted,

/Michael J. Fink/
_____
Michael J. Fink
Registration No. 31,827
Greenblum & Bernstein, P.L.C.
Email: MFink@gbpatent.com

/Arnold Turk/
_____
Arnold Turk
Registration No. 33,094
Greenblum & Bernstein, P.L.C.
Email: ATurk@gbpatent.com

Attorneys for Petitioner
C.R. Bard, Inc.

CERTIFICATE OF SERVICE

I hereby certify that the attached Petition For *Inter Partes* Review Of U.S. Patent No. 8,852,325 Under 35 U.S.C. §§ 311-319 And 37 C.F.R. § 42.100 et seq. and supporting materials were served as of the below date by Federal Express on the Patent Owners at the correspondence address indicated for U.S. Patent No. 8,852,325:

BLANK ROME LLP
Kristin M. Lawson
ONE LOGAN SQUARE
PHILADELPHIA PA 19103.

Dated: July 31, 2015

/Michael J. Fink/
_____
Michael J. Fink
Registration No. 31,827