UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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C.R. BARD, INC.
Petitioner

v.

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

_____

Case IPR _____
U.S. Patent No. 8,852,160
Issue Date: October 7, 2014

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

_____

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,852,160 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

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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 requested for claims 1-22 of U.S. Patent No. 8,852,160 B2 ("the '160 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 '160 patent or its parent, U.S. Patent No. 8,257,325; however, filed concurrently herewith is a Petition For *Inter Partes* Review Of U.S. Patent No. 8,257,325.

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:

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Petitioner consents to electronic service by email.

II. PAYMENT OF FEES

Payment of $26,200.00 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 '160 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 '160 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 1-22 of the '160 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 '160 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 1-22 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 1-22 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 1-22 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 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 also 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 X-ray viewable indicia on a flange created by voids in the form of alphanumeric characters as a power port identifier, rendering the challenged claims of the '160 patent obvious. The tertiary references emphasize the obviousness of voids/cutouts in the form of alphanumeric characters, which is taught by PowerPort (alphanumeric character shaped voids 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, 3:19-20. 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, 3:33-35. "[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, 3:33-44. Thus, as used in the '160 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, 3:33-38. The reservoir 22 is defined as "a well 30 having a bottom floor 32 and side walls 34." Ex. 1001, 3:35-38. 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, 3:40-44, 4:5-6. 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, 4:6. 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, 2:19-26.

Void: The '160 patent discloses "suture openings 38 and holes 40 through base flange 36." Ex. 1001, 3:41-44, 4:5-6, Figs. 10, 11, 12. The '160 patent additionally recites "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, 4:65-67. As recited in the claims, the term "void" should be construed as an empty space. Ex.1015.

All claim terms, including the above terms, should be afforded their ordinary and customary meanings. Ex.1009, ¶¶ 38-47.

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

Explanations of how claims 1-22 are unpatentable under the grounds identified in Section III.B.2 are provided in Sections 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 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 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/radiolucent 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 '160 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 ports. Ex.1009, ¶¶ 18-26.

IV. SUMMARY OF THE '160 PATENT

A. Description Of The Alleged Invention Of The '160 Patent

The '160 patent is entitled "Venous Access Port With Molded And/Or Radiopaque Indicia." One of the embodiments disclosed in the '160 patent is a "venous access port assembly having a housing base, a flange, and a septum. The housing base defines an interior reservoir. The flange includes integrally molded X-ray discernable indicia identifying that the assembly is rated for power injection. The X-ray discernable indicia may extend through a height of the flange from a top surface to a bottom surface of the flange. According to one aspect, the flange may be formed from X-ray discernable material, and the X-ray discernable indicia may be formed from the X-ray discernable material of the flange, or they may be formed by voids in the X-ray discernable material." Ex. 1001, Abstract; Ex.1009, ¶¶27-32. The general structures of the ports are depicted in Figs. 1-4 of the '160 patent, reproduced below:

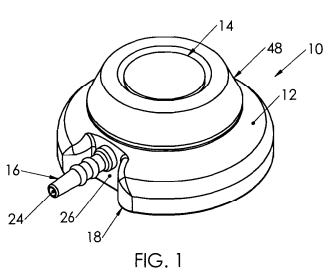


FIG. 1

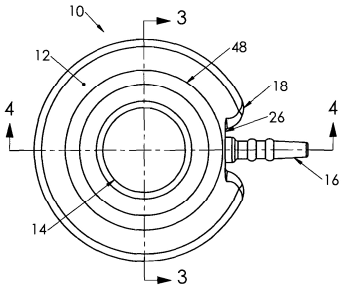


FIG. 2

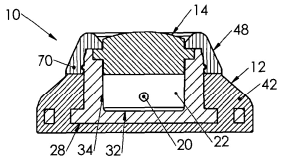


FIG. 3

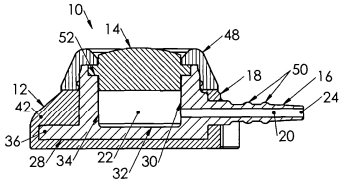


FIG. 4

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, 3:45-49, Figs. 3, 4; Ex.1009, ¶¶33-34.

Figure 5 (reproduced below) is an isometric view of the base of the access port of Fig. 1. Ex. 1001, 2:43-44; Ex.1009, ¶35.

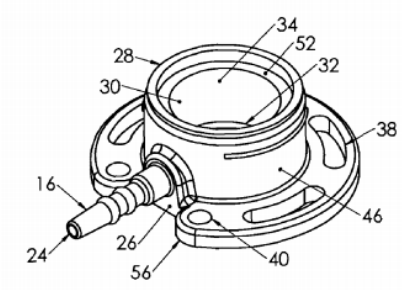
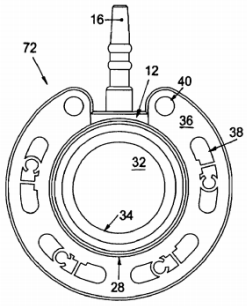


FIG. 5



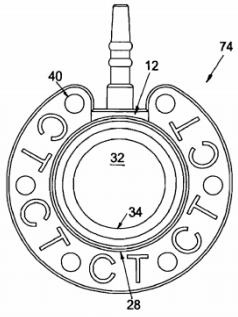


Fig. 11

Fig. 11 (reproduced above) shows top views of two alternative embodiments of the housing base showing integrally molded alphanumeric characters, *i.e.*, "CT" markings. Ex. 1001, 2:55-58; Ex.1009, ¶37.

B. Summary Of The Prosecution Of The '160 Patent

The '160 patent is a continuation of Application No. 12/143,377, filed June 20, 2008, issued as U.S. Patent No. 8,257,325 ("the '325 patent"), which 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 '160 patent is June 20, 2007.

All claims presented for examination were rejected for obviousness. To obtain allowance of the claims, Applicant agreed to an examiner's amendment whereby each of the three independent claims was amended to recite, "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 discernible indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection."

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

> The subject matter of the prior art of record does not teach or render obvious a venous access port assembly for implantation into a patient, comprising a housing comprising a flange adjacent at least one

reservoir and the flange comprising an X-ray discernible material and one or more voids extending through the X-ray discernible material of the flange from a top surface to a bottom surface of the flange and the one or more voids are X-ray discernible in combination with all the claim limitations.

Notice Of Allowability, pp. 4-5, June 4, 2014.

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 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 Titanium Implanted Port, including the flange, comprises titanium. Ex. 1002.

6. Titanium is an X-ray discernable material.

7. The flange of 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 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 Titanium Implanted Port has a biocompatible silicone skirt overmolded about the flange. The silicone skirt is radiotransparent/radiolucent. Ex.1002.

10. The housing base of Titanium Implanted Port is substantially the same as the housing base depicted in Fig. 5 of the ‘160 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 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 Titanium Implanted Port are capable of receiving sutures there through. Ex.1002.

13. "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.

14. 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, front page and 1:7-9.

18. Powers' effective date as a prior art reference with respect to the claims of the '160 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 septum is in communication with the housing. Ex.1003, 4:29-45, Figs. 1A, 1B; Ex.1016, p.8/65 (¶[0038]), Figs. 1A, 1B; Ex.1009, ¶¶135-137.

24. The base 16 forms a reservoir 36 having a bottom floor and side walls beneath septum 18. Ex.1003, 4:43-45, Fig. 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 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, 9:19-23; 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. The radiopaque identifier utilized in the PowerPort*- M.R.I.* Device is made from an X-ray discernable material.

33. 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.

34. 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.

35. 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.

36. 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.

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

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

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

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

41. 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.

42. 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.

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

44. 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.

45. 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.

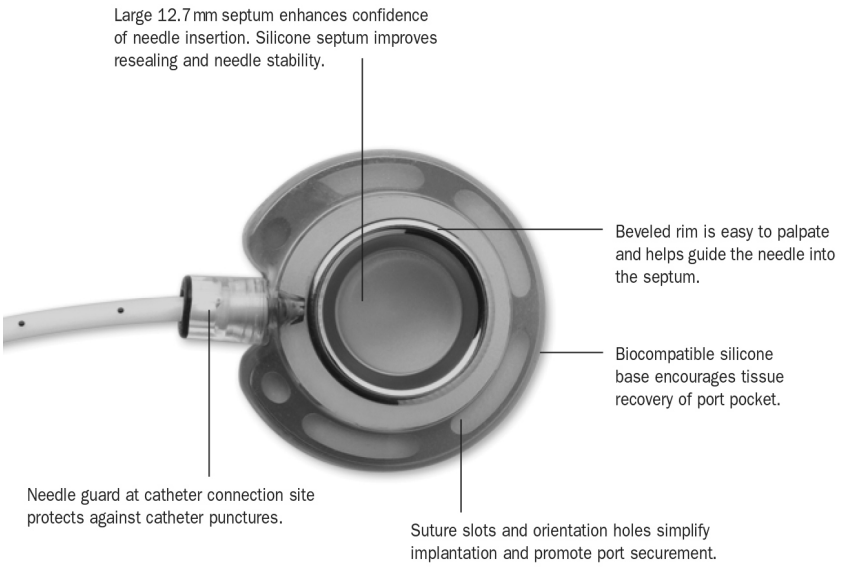
VI. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '160 PATENT IS UNPATENTABLE

A. Identification Of The References As Prior Art

1. **PORTS (Ex.1002):** The PORTS brochure disclosing the Titanium Implanted Port has been publicly available since 2003. Ex. 1019, ¶¶8-18. PORTS is prior art to the '160 patent under pre-AIA 35 U.S.C. §102(b). The configuration of the Titanium Implanted Port depicted in PORTS has been well known and in

use since before 1991. Ex. 1009, ¶16, 48-71. Titanium Implanted Port is a venous access port for implantation into a patient.

Titanium Implanted Port comprises a housing, a housing base, a discharge port, a needle-penetrable septum, and a reservoir. The housing base is made of titanium, which is an X-ray discernable material. The base includes a flange portion with 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 through the flange from the top surface of the flange to the bottom surface of the flange. Ex.1002, pp. 10, 16; Ex.1009, ¶¶48-71.



PORTS (Ex.1002), p. 10

Titanium Implanted Port has a flange that extends outwardly from and is adjacent to the reservoir. Titanium Implanted Port has a flange that extends outwardly from the base about a perimeter of the at least one reservoir. The

housing of the Titanium Implanted Port has a flange that includes a radiotransparent silicone skirt overmolded about at least a portion of the base flange. Ex. 1002, p. 10; Ex.1009, ¶¶ 48-71.

2. **Powers (Ex.1003):** Powers issued from Application No. 11/368,954, filed March 6, 2006, and is prior art to the '160 Patent under pre-AIA 35 U.S.C. §102(e) for its March 6, 2006 filing date. 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 '160 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.

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. *See generally* Ex.1009, ¶¶78-88.

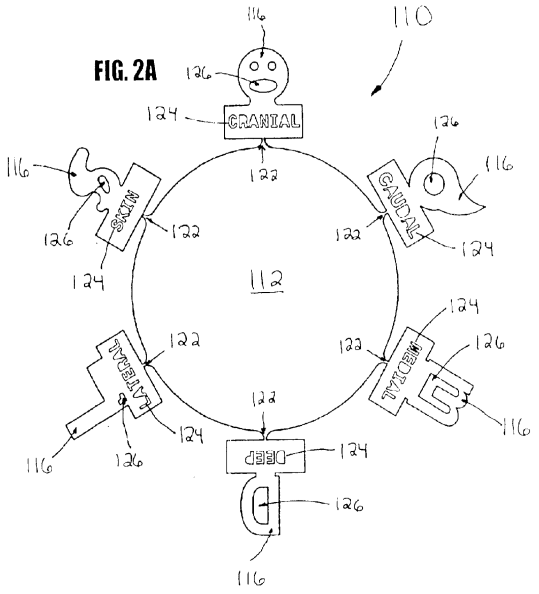
3. **PowerPort (Ex.1004):** PowerPort is a printed publication which was publicly available at least as early as February 2007. Ex.1018, ¶¶9-26. PowerPort

is prior art to the '160 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. 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, ¶¶89-97.

4. **Sayre (Ex.1007):** Sayre, issued November 30, 2004, is prior art to the '160 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, ¶¶98-105.



Sayre Fig. 2A

Sayre discloses cutouts (voids) extending through the X-ray discernable material. 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, ¶¶ 104-105.

5. **Meyer (Exs.1005 & 1006):** Meyer is a French patent that issued December 4, 1967, and is prior art to the '160 Patent under pre-AIA 35 U.S.C. §102(b). Ex.1005. 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 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 are formed in whole or part by creating voids. 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, ¶¶106-115.

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 the Titanium Implanted Port disclosed in Ex.1002, p.10; Ex.1009, ¶72. Hickman confirms that the Titanium Implanted Port has a base defining a reservoir, *i.e.,* a well comprising a bottom floor and side walls defining a reservoir. Ex.1009, ¶¶73-77.

B. Summary Of Invalidity Arguments

Titanium Implanted Port is a venous access port substantially similar to the access ports depicted and claimed in the '160 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, *e.g.,* 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. Powers discloses power injectable ports adapted to withstand higher pressures and flow rates used for power injection including 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 each 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 1-22 of the '160 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.

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 1-22 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 1-22 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, ¶¶ 116-205.

1. PORTS, Powers, PowerPort And Hickman Disclose All Elements Of Claim 1

PORTS and Powers teach all of the elements of claim 1. Ex.1009, ¶ 117. 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 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 at least one reservoir; and

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, ¶120; 1016, 1017. Hickman confirms that the base inside the Titanium Implanted Port defines a reservoir. Ex.1017.

b. 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, ¶¶121-123.

c. the flange comprising an X-ray discernable material,

The base of Titanium Implanted Port includes a flange portion which is made from titanium, which is an X-ray discernable material. Ex.1002, p.10; Ex.1009, ¶124.

d. 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,

Titanium Implanted Port has suture slots and orientation holes which extend through the flange from the top surface of the flange to the bottom surface of the

flange. Ex.1002, p.10; Ex.1009, ¶125. The suture slots and orientation holes in the X-ray discernable material of the flange (titanium) are voids. Ex.1009, ¶126.

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, ¶127.

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, ¶128.

e. 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

Powers discloses a power injectable port adapted to withstand higher pressures and flow rates used for power injection and 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, an alphanumeric message, under X-ray examination, indicates that the assembly is rated for power injection. *Id.*; Ex.1009, ¶¶129-131. 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.1009, ¶127.

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. The PowerPort*- M.R.I.* Device disclosed in PowerPort has a radiopaque identifier depicted below:

The radiopaque identifier with the characters "C" and "T" indicate, under X-ray examination, that the PowerPort*- M.R.I.* Device is rated for power injection. Ex.1009, ¶¶132-134.

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

Titanium Implanted Port includes a needle-penetrable septum in communication with the housing. Ex.1002, p. 10; Ex.1009, ¶135. 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, ¶¶135-137.

2. Independent Claim 1 Is Unpatentable As Obvious

A POSA at the time of invention would have understood that PORTS discloses all of the elements of claim 1 other than that Titanium Implanted Port was power injectable and the indicia indicating "that the assembly is rated for power injection." Ex.1009, ¶138. 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, ¶¶ 139-140. To identify the Titanium Implanted Port as a power injectable port, at the time of the invention, it would have been obvious to a POSA to provide 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. Ex.1009, ¶141.

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, ¶142. Powers, like the Titanium Implanted Port, is a venous access port comprising a cap, a base, a septum and a reservoir. Ex.1003, 4:29-45, Fig. 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 1B; Ex.1009, ¶81. Powers specifically discloses an alphanumeric message discernable using X-

rays to identify the port as power-injectable. Ex.1003, 11:41-12:2; Ex.1016, [0034], [0037], [0069]-[0070], p.48/65 (Nos. 5-7); Ex.1009, ¶83. 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, ¶¶143-144. 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; Ex.1016, p.16/65 (¶[0067]), Ex.1009, ¶¶87, 127.

PowerPort discloses a power injectable port where voids in the shape of "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 ¶145.

Titanium Implanted Port includes voids (orientation holes) in the flange which, under X-ray examination, function as indicia of orientation. 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 as in Powers, under X-ray examination, that the assembly is rated for power injection. The flange of the Titanium Implanted Port is already known as a location for X-ray discernable indicia created by voids. 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. 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, ¶¶146-151.

As shown in the claim chart below, all of the elements of claim 1 are taught by the prior art, such that 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, ¶¶153-154.

Claim 1	**PORTS in view of Powers and in further view of PowerPort and Hickman**
1. A venous access port assembly for implantation into a patient, comprising:	Titanium Implanted Port is a venous access port for implantation into a patient. Ex.1002, p. 10. Powers discloses a venous access port for implantation into a patient. Ex.1003, 1:62-66;

	Ex.1016, p.5/65 (¶[0007]). PowerPort discloses a venous access port for implantation into a patient. Ex.1004.
a housing comprising:	Titanium Implanted Port has a housing. Ex.1002, p. 10. Powers discloses a housing 20. Ex.1003, 4:34-36, Fig. 1A; Ex.1016, p.8/65 (¶[0038]), Fig. 1A. PowerPort discloses a housing. Ex. 1004.
a base defining at least one reservoir;	Titanium Implanted Port has a base defining a reservoir, located below the septum. Ex. 1002. Hickman illustrates the cross-sectional structure of a base defining a bottom wall of a reservoir of a port similar to the Titanium Implanted Port. Ex. 1017. Powers discloses a base 16 defining at least one cavity (reservoir) 36. Ex.1003, 4:43-45, Fig. 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 1B.
and 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" adjacent to the reservoir. Ex.1003, 9:18-22; Ex.1016, p.15/65 (¶[0061]).
the flange comprising an X-ray discernable material,	Titanium Implanted Port has a flange made of titanium. Ex.1002, p. 10, 16.
a top surface, a bottom surface, and one or more voids extending through the X-ray discernable material	Titanium Implanted Port has suture slots and orientation holes extending through a top surface and bottom surface of the titanium flange.

of the flange from the top surface of the flange to the bottom surface of 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. 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.
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	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, 3:43-47, 11:41-12:2; Ex.1016, [0034], [0037], [0069]-[0070], p.48/65 (Nos. 5-7). PowerPort discloses one or more voids are X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection. Ex.1004.
a needle-penetrable septum communicating with the housing.	Titanium Implanted Port has a needle-penetrable septum in communication with the housing. Ex.1002, p. 10. Powers discloses 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. PowerPort discloses a needle-penetrable septum communicating with the housing. Ex.1004.

Accordingly, claim 1 is unpatentable as obvious over PORTS in view of Powers and in further view of PowerPort and Hickman.

3. Independent Claim 9 Is Unpatentable As Obvious

Claim 9 differs from claim 1 only in the last element regarding the recitation of a septum. Claim 1 recites "a needle-penetrable septum *communicating with* the housing" and claim 9 recites "a needle-penetrable septum *secured to* the housing." (Emphasis added). Titanium Implanted Port has a needle-penetrable septum secured to the housing. Ex.1002, p. 10. Thus, claim 9 would have been obvious to a POSA at the time of invention for the same reasons claim 1 would have been obvious to a POSA at the time of invention. Ex.1009, ¶¶155-158.

Powers also discloses a needle-penetrable septum secured to the housing. Ex.1003, 4:29-45, Figs. 1A, 1B; Ex.1016, p.8/65 (¶[0038]), Figs. 1A, 1B; Ex.1009, ¶159. If for any reason PORTS is not found to expressly disclose a septum secured to the housing, claim 9 would still have been obvious to a POSA, as shown by Powers and Hickman, as it is necessary for the septum to be secured to the housing to be sufficiently attached to the housing to function as an access port, especially for power injection. Ex.1009, ¶¶158-162.

Accordingly, claim 9 is unpatentable as obvious over PORTS in view of Powers and further in view of PowerPort and Hickman.

4. Independent Claim 16 Is Unpatentable As Obvious

Claim 16 differs from claim 1 in that claim 16 further defines the housing as "comprising a well comprising a bottom floor and side walls, the bottom floor and side walls defining at least one reservoir" and also "a cap securing the needle-penetrable septum to the housing." Ex.1009, ¶163.

Although not shown in cross-section, as confirmed by Hickman, the Titanium Implanted Port has a housing base comprising a well comprising a bottom floor and side walls, the bottom floor and side walls defining at least one reservoir. Ex.1002; Ex.1017; Ex.1009, ¶164. Titanium Implanted Port also has a cap that secures the septum to the housing. Ex.1002, p. 10; Ex.1009, ¶165.

Accordingly, claim 16 would have been obvious to a POSA at the time of invention for the same reasons claim 1 would have been obvious to a POSA at the time of invention. Ex.1009, ¶166.

Likewise, Powers discloses a housing base comprising a well comprising a bottom floor and side walls, the bottom floor and side walls defining at least one reservoir. Ex.1003, 4:43-45, Fig. 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 1B; Ex.1009, ¶167. Powers also discloses a cap securing the septum to the housing base. Ex.1003, 4:29-45, Fig. 1B; Ex.1016, [0038], Fig. 1B. Ex.1009, ¶168.

If for any reason PORTS is not found to expressly disclose the recited well and/or cap, claim 16 would still have been obvious because a POSA would have

constructed the Titanium Implanted Port with a well and cap as taught by Powers. Ex.1009, ¶169.

Thus, claim 16 is unpatentable as obvious over PORTS in view of Powers and in further view of PowerPort and Hickman.

5. Claims 2, 10 and 17 Are Unpatentable As Obvious

Claims 2, 10 and 17 depend from independent claims 1, 9 and 16, respectively, and recite: "wherein at least a portion of the X-ray discernable material is disposed within the one or more voids." The PowerPort*- M.R.I.* Device (Ex.1004) is a power injectable port with a radiopaque identifier. The radiopaque identifier includes alphanumeric characters "C" and "T" formed by voids which extend through the X-ray discernable material. The radiopaque identifier indicates, under X-ray examination, that the PowerPort*- M.R.I.* Device is rated for power injection. The alphanumeric character "C" is formed by a portion of the X-ray discernable material extending into an oval void to create the "C". Ex.1009, ¶¶ 89-97, 170-178.

Titanium Implanted Port has suture slots and orientation holes that extend through the X-ray discernable material of the flange from the top surface of the flange to the bottom surface of the flange. Ex.1002, p.10. It would have been obvious to a POSA at the time of invention that the X-ray discernable indicia of the Titanium Implanted Port modified by Powers and PowerPort would have been

structured in view of the PowerPort*- M.R.I.* Device 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 of Titanium Implanted Port. For example, the void with a portion of the titanium flange extending into or disposed therein could have an alphanumeric form, such as the "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 the voids could have any desired shape that would provide an indication that the port is power injectable. Thus, claims 2, 10 and 17 are unpatentable as obvious over PORTS in view of Powers and further in view of PowerPort and Hickman. Ex.1009, ¶¶179-181.

6. Claims 3, 4, 11, 12, 18 And 19 Are Unpatentable As Obvious

Claims 3, 4, 11, 12, 18 and 19 directly depend from independent claims 1, 9 and 16, and recite: "wherein the flange extends outwardly from" either (i) "the at least one reservoir" (claims 3, 11); (ii) from the well (claim 18); or (iii) "from the base about a perimeter of the at least one reservoir" (claims 4, 12, 19). Titanium Implanted Port has a metal base including a metal flange that extends outwardly

from the reservoir, the well, and the base about a perimeter of the reservoir. Ex.1002; Ex.1009, ¶¶182-183.

A POSA would have known that openings in the flange of the Titanium Implanted Port made it easier to secure an access port to the patient using sutures. Ex.1009, ¶¶ 184-186. Additionally, the orientation holes of the Titanium Implanted Port extend from the top surface of the flange to the bottom surface of the flange, and that such holes would be discernable using X-rays. Ex.1009, ¶187.

Thus, PORTS includes all of the features recited in these dependent claims, and therefore, claims 3, 4, 11, 12, 18 and 19 are unpatentable as obvious over PORTS in view of Powers and further in view of PowerPort and Hickman. Ex.1009, ¶¶ 188-189.

7. Claims 5, 6, 7, 13, 14, 20 And 21 Are Unpatentable As Obvious

Claims 5, 13 and 20 depend from independent claims 1, 9 and 16, respectively, and recite: a "skirt overmolded about at least a portion of the base." Claims 6, 14 and 21 depend from dependent claims 5, 13 and 20, respectively, and recite that the "skirt is further overmolded about the flange." Claims 7, 13 and 20 additionally recite that the skirt is "radiotransparent or radiolucent." Ex.1009, ¶¶190-192. Titanium Implanted Port has a silicone skirt overmolded about the base, including the flange. The silicone skirt of Titanium Implanted Port is radiotransparent. Ex.1002, p.10; Ex.1009, ¶¶ 193-194.

A POSA at the time of invention would have known that the silicone skirt of the Titanium Implanted Port could be overmolded about the base and flange as shown in PORTS. Ex.1002, p.10. A POSA at the time of invention would also have known that the silicone used to make the skirt of the Titanium Implanted Port would be radiotransparent. Biocompatible silicone skirts such as shown in PORTS would encourage tissue recovery, and more importantly, prevent unwanted tissue growth in the suture slots and orientation holes (voids), thereby making it easier to later remove the port. Ex.1009, ¶¶195-197.

Thus, PORTS includes all of the features recited in these dependent claims, and therefore, claims 5, 6, 7, 13, 14, 20 and 21 are unpatentable as obvious over PORTS in view of Powers and further in view of PowerPort and Hickman. Ex.1009, ¶¶ 198-199.

8. Claims 8, 15 And 22 Are Unpatentable As Obvious

Claims 8, 15 and 22 depend from independent claims 1, 9 and 16, respectively, and recite: "wherein the X-ray discernable indicia further indicate, under X-ray examination, that the assembly is adapted to withstand high pressures used for 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 high pressures used for injection of contrast fluid. Ex.1009, ¶¶200-201.

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 high pressures used for injection of contrast fluid. Ex. 1004; Ex.1009, ¶202.

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. Thus, claims 8, 15 and 22 are unpatentable as obvious over PORTS in view of Powers and further in view of PowerPort and Hickman. Ex.1009, ¶¶203-205.

B. Ground 2: Claims 1-22 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.

Sayre discloses X-ray discernable indicia, such as alphanumeric characters, defined by apertures (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, ¶¶206-207. Thus, for substantially the same reasons that claims 1-22

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, claims 1-22 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. Ex.1009, ¶¶208, 209. In particular, a POSA would have understood that 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, ¶210. A POSA would have known that the Titanium Implanted Port could be constructed to handle power injection. Ex.1009, ¶210. 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 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, ¶211. The 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, ¶¶62-63.

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, ¶212. Powers, like the Titanium Implanted Port, is a

venous access port comprising a cap, a base, a septum and a reservoir. Ex.1003, 4:29-45, Fig. 1B; Ex.1016, [0038], Fig. 1B; Ex.1009, ¶213. 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); Ex.1009, ¶214. Under X-ray examination, the port disclosed in Powers can be identified as power-injectable. *Id.;* Ex.1009, ¶215. 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; s*ee* Ex.1009, ¶¶87, 127.

Titanium Implanted Port includes holes (voids) in the flange which, under X-ray examination, function as indicia of orientation. Ex.1002; Ex.1009, ¶216. 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 voids extending through the flange from the top to the bottom surface of the Titanium Implanted Port to indicate, under X-ray examination, that the assembly is rated for power injection. 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 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. Ex.1009, ¶¶ 98-105, 206, 217-219. Additionally, indicia in the form of apertures in a flange made 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, ¶¶ 220-221.

1. Independent Claim 1 Is Unpatentable As Obvious

As shown in the claim chart below, all of the elements of claim 1 are disclosed by the prior art, such that 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, ¶¶ 222-223.

Claim 1	**PORTS in view of Powers and in further view of Sayre and Hickman**
1. A venous access port assembly for implantation into a patient, comprising:	Titanium Implanted Port is a venous access port for implantation into a patient. Ex.1002, p. 10. Powers discloses a venous access port for implantation into a patient. Ex.1003, 1:62-66; Ex.1016, p.5/65 (¶[0007]).
a housing comprising:	Titanium Implanted Port has a housing. Ex.1002,

	p. 10. Powers discloses a housing 20. Ex.1003, 4:34-36, Fig. 1A; Ex.1016, p.8/65 (¶[0038]), Fig.1A.
a base defining at least one reservoir;	Titanium Implanted Port has a base defining a reservoir, located below the septum. Ex.1002. Hickman illustrates the cross-sectional structure of a base defining a reservoir of a port similar to the Titanium Implanted Port. Ex. 1017. Powers discloses a base 16 defining at least one cavity (reservoir) 36. Ex.1003, 4:43-45, Fig. 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 1B.
and 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" adjacent to the reservoir. Ex.1003, 9:18-22; Ex.1016, p.15/65 (¶[0061]).
the flange comprising an X-ray discernable material,	Titanium Implanted Port has a flange made of titanium. Ex.1002, pp. 10, 16.
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,	Titanium Implanted Port has suture slots and orientation holes extending through a top surface and bottom surface of the titanium 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. Sayre discloses the X-ray indicia aid in indicating the orientation of each marker. Exhibit 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 in which the indicia 124 are letters defined by one or more apertures formed through the respective marker 116 to provide unique identifying information. Ex.1007, 4:11-31, Fig. 2A. Apertures of Sayre can define letters that can receive sutures used to secure the markers. Ex.1004, 4:41-57, Figs. 2A-2C. 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. Exhibit 1007, 4:8-31, 4:53-57, Fig. 2A, claim 6.
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	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, 3:43-47, 11:41-12:2; Ex.1016, [0034], [0037], [0069]-[0070], p.48/65 (Nos. 5-7).
a needle-penetrable septum communicating with the housing.	Titanium Implanted Port has a needle-penetrable septum in communication with the housing. Ex.1002, p. 10. Powers discloses 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.

Accordingly, claim 1 is unpatentable as obvious over PORTS in view of Powers and in further view of Sayre and Hickman.

2. Independent Claim 9 Is Unpatentable As Obvious

Claim 9 differs from claim 1 only in the last element regarding the recitation of a septum. Claim 1 recites "a needle-penetrable septum *communicating with* the housing" and claim 9 recites "a needle-penetrable septum *secured to* the housing." (Emphasis added). Titanium Implanted Port has a needle-penetrable septum secured to the housing. Ex.1002, p. 10. Thus, claim 9 would have been obvious to a POSA at the time of invention for the same reasons claim 1 would have been obvious to a POSA at the time of invention. Ex.1009, ¶224.

Powers also discloses a needle-penetrable septum secured to the housing. Ex.1003, 4:29-45, Figs. 1A, 1B; Ex.1016, [0038], Figs. 1A, 1B. If for any reason PORTS is not found to expressly disclose a septum secured to the housing, claim 9 would still have been obvious to a POSA, as shown by Powers and Hickman, as it is necessary for the septum of the Titanium Implanted Port to be secured to the housing to be sufficiently attached to the housing to function as an access port, especially for power injection.

Accordingly, claim 9 is unpatentable as obvious over PORTS in view of Powers and in further view of Sayre and Hickman. Ex.1009, ¶224.

3. Independent Claim 16 Is Unpatentable As Obvious

Claim 16 differs from claim 1 in that claim 16 further defines the housing as "comprising a well comprising a bottom floor and side walls, the bottom floor and side walls defining at least one reservoir" and also "a cap securing the needle-penetrable septum to the housing."

Although not shown in cross-section, as confirmed by Hickman, the Titanium Implanted Port has a housing base comprising a well comprising a bottom floor and side walls, the bottom floor and side walls defining at least one reservoir. Ex.1002; Ex.1017; Ex. 1009, ¶164. Titanium Implanted Port also has a cap that secures the septum to the housing. Ex.1002, p. 10.

Accordingly, claim 16 is unpatentable as obvious for the same reasons claim 1 would have been obvious to a POSA at the time of invention. Ex.1009, ¶224.

Likewise, Powers discloses a housing base comprising a well comprising a bottom floor and side walls, the bottom floor and side walls defining at least one reservoir. Ex.1003, 4:43-45; Ex.1016, p.8/65 (¶[0038]). Powers also discloses a cap securing the septum to the housing base. Ex.1003, 4:29-45, Fig. 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 1B; Ex.1009, ¶¶167-168.

If for any reason PORTS is not found to expressly disclose the recited well and/or cap, claim 16 would still have been obvious because a POSA would have

constructed the Titanium Implanted Port with a well and cap as taught by Powers. Ex.1009, ¶169.

Thus, claim 16 is unpatentable as obvious over PORTS in view of Powers and in further view of Sayre and Hickman. Ex.1009, ¶224.

4. Claims 2, 10 and 17 Are Unpatentable As Obvious

Claims 2, 10 and 17 recite: "wherein at least a portion of the X-ray discernable material is disposed within the one or more voids." Sayre discloses indicia 124, such as letters, 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 formed through the respective marker 116 to provide unique identifying information. Ex.1007, 4:11-31, Fig. 2A, claim 6. Sayre shows that it was known to include indicia in the form of apertures within an X-ray discernable material to provide X-ray readable identification indicia that can also aid in indicating orientation.

Titanium Implanted Port has suture slots and orientation holes that extend through the X-ray discernable material of the flange from the top surface to the bottom surface of the flange. It would have been obvious to a POSA at the time of invention to modify Titanium Implanted Port (Ex.1002) in view of Powers (Ex.1003) and Sayre (Ex.1007) such that a portion of the titanium flange ("X-ray discernable material") of the Titanium Implanted Port extends into and is disposed

in the suture slots and/or the orientation holes to provide a void in the form of various alphanumeric characters, such as a "C", thereby providing the X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection.

Accordingly, claims 2, 10 and 17 are unpatentable as obvious over PORTS in view of Powers and in further view of Sayre and Hickman. Ex.1009, ¶¶225-226

5. Claims 3, 4, 11, 12, 18 And 19 Are Unpatentable As Obvious

Claims 3, 4, 11, 12, 18 and 19 recite: "wherein the flange extends outwardly from" either (i) "the at least one reservoir" (claims 3, 11); (ii) from the well (claim 18); or (iii) "from the base about a perimeter of the at least one reservoir" (claims 4, 12, 19). Such flanges are taught by PORTS, and thus, these claims would have been obvious to a POSA at the time of invention for the same reasons set forth in Section VII.A.6. Ex.1009, ¶226.

6. Claims 5, 6, 7, 13, 14, 20 And 21 Are Unpatentable As Obvious

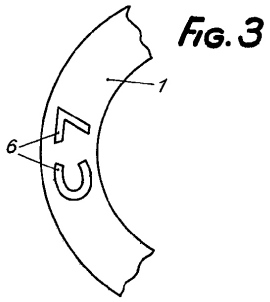
Claims 5, 13 and 20 recite: a "skirt overmolded about at least a portion of the base." Claims 6, 14 and 21 recite that the "skirt is further overmolded about the flange." Claims 7, 13 and 20 additionally recite that the skirt is "radiotransparent or radiolucent." Such silicone skirts are taught by PORTS, and thus, these claims would have been obvious to a POSA at the time of invention for the same reasons set forth in Section VII.A.7. Ex.1009, ¶226.

7. Claims 8, 15 And 22 Are Unpatentable As Obvious

Claims 8, 15 and 22 recite: "wherein the X-ray discernable indicia further indicate, under X-ray examination, that the assembly is adapted to withstand high pressures used for injection of contrast fluid." Such indicia are taught by Powers, and thus, these claims would have been obvious to a POSA at the time of invention for the same reasons set forth in Section VII.A.8. Ex.1009, ¶226.

C. Ground 3: Claims 1-22 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 1-22 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. Meyer does not disclose an access port. Rather, Meyer discloses a container (reservoir) with a flange 1 about the container, and alphanumeric characters in the flange formed in whole or part by voids. The alphanumeric characters shown in Fig. 3 are formed by cutouts 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 in the flange, even though the flange is plastic,

the cutouts (voids) would be discernable under X-ray examination. Ex.1006; Ex.1009, ¶¶ 227-231.

Thus, for substantially the same reasons that claims 1-22 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, claims 1-22 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. Ex.1009, ¶232. A POSA at the time of invention would have understood that PORTS 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." Ex.1009, ¶233. 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, ¶234. To identify the Titanium Implanted Port as a power injectable port, 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. Ex.1009, ¶235. 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, ¶¶62-63.

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, ¶236. Powers, like the Titanium Implanted Port, is a venous access port comprising a cap, a base, a septum and a reservoir. Ex.1003, 4:29-45, Fig. 1B; Ex.1016, [0038], Fig. 1B; Ex.1009, ¶237. 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); Ex.1009, ¶238. Under X-ray examination, the Powers port can be identified as power-injectable. *Id.*; Ex.1009, ¶239. 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, ¶¶87, 127.

Titanium Implanted Port includes holes (voids) in the flange which, under X-ray examination, function as indicia of orientation. Ex.1002; Ex.1009, ¶¶146, 240. 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 voids

extending through the flange from the top to the bottom surface of the Titanium Implanted Port to indicate, under X-ray examination, that the assembly is rated for power injection. 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 Meyer's disclosure of indicia in the form of alphanumeric voids in a flange adjacent to a container. Ex.1009, ¶¶241-243. Additionally, voids in the shape of letters in a flange made of titanium would be expected to provide high contrast so that the letters would be readily observable, under X-ray examination, after implantation. Ex.1009, ¶244.

1. Independent Claim 1 Is Unpatentable As Obvious

As shown in the claim chart below, all of the elements of claim 1 are disclosed by the prior art, such that 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, ¶¶ 245-246.

Claim 1	**PORTS in view of Powers and in further view of Meyer and Hickman**
1. A venous access port assembly for implantation	Titanium Implanted Port is a venous access port for implantation into a patient. Ex.1002, p. 10.

into a patient, comprising:	Powers discloses a venous access port for implantation into a patient. Ex.1003, 1:62-66; Ex.1016, p.5/65 (¶[0007]).
a housing comprising:	Titanium Implanted Port has a housing. Ex.1002, p. 10. Powers discloses a housing 20. Ex.1003, 4:34-36, Fig. 1A; Ex.1016, p.8/65 (¶[0038]), Fig. 1A.
a base defining at least one reservoir;	Titanium Implanted Port has a base defining a reservoir, located below the septum. Exhibit 1002. Hickman illustrates the cross-sectional structure of a base defining a reservoir of a port similar to the Titanium Implanted Port. Ex. 1017. Powers discloses a base 16 defining at least one cavity (reservoir) 36. Ex.1003, 4:43-45, Fig. 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 1B.
and 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" adjacent to the reservoir. Ex.1003, 9:18-22; Ex.1016, p.15/65 (¶[0061]). Meyers discloses a container (reservoir) and a flange 1. Ex.1006, Fig. 1.
the flange comprising an X-ray discernable material,	Titanium Implanted Port has a flange made of titanium. Ex.1002, pp. 10, 16.
a top surface, a bottom surface, and one or more voids extending through the	Titanium Implanted Port has suture slots and orientation holes extending through a top surface and bottom surface of the titanium flange.

X-ray discernable material of the flange from the top surface of the flange to the bottom surface of 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. In Meyer, the characters shown in Figs. 2, 3 and 4 are formed in whole or part by creating voids. The alphanumeric characters shown in Fig. 3 are formed by cutouts in the flange (collar 1) and would be discernable under X-ray examination. Ex. 1006.
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	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, 3:43-47, 11:41-12:2; Ex.1016, [0034], [0037], [0069]-[0070], p.48/65 (Nos. 5-7).
a needle-penetrable septum communicating with the housing.	Titanium Implanted Port has a needle-penetrable septum in communication with the housing. Ex.1002, p. 10. Powers discloses 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.

Accordingly, claim 1 is unpatentable as obvious over PORTS in view of Powers and in further view of Meyer and Hickman.

2. Independent Claim 9 Is Unpatentable As Obvious

Claim 9 differs from claim 1 only in the last element regarding the recitation of a septum. Claim 1 recites "a needle-penetrable septum *communicating with* the housing" and claim 9 recites "a needle-penetrable septum *secured to* the housing." (Emphasis added). Titanium Implanted Port has a needle-penetrable septum secured to the housing. Ex.1002, p. 10. Thus, claim 9 would have been obvious to a POSA at the time of invention for the same reasons claim 1 would have been obvious to a POSA at the time of invention. Ex.1009, ¶249.

Powers also discloses a needle-penetrable septum secured to the housing. Ex.1003, 4:29-45, Figs. 1A, 1B; Ex.1016, p.8/65 (¶[0038]), Figs. 1A, 1B. If for any reason PORTS is not found to expressly disclose a septum secured to the housing, claim 9 would still have been obvious to a POSA, as shown by Powers and Hickman, as it is necessary for the septum of the Titanium Implanted Port to be secured to the housing to be sufficiently attached to the housing to function as an access port, especially for power injection.

Accordingly, claim 9 is unpatentable as obvious over PORTS in view of Powers and in further view of Meyer and Hickman. Ex.1009, ¶¶ 249, 251.

3. Independent Claim 16 Is Unpatentable As Obvious

Claim 16 differs from claim 1 in that claim 16 further defines the housing as "comprising a well comprising a bottom floor and side walls, the bottom floor and

side walls defining at least one reservoir" and also "a cap securing the needle-penetrable septum to the housing."

Although not shown in cross-section, as confirmed by Hickman, the Titanium Implanted Port has a housing base comprising a well comprising a bottom floor and side walls, the bottom floor and side walls defining at least one reservoir. Ex.1002; Ex.1009, ¶164, Ex.1017. The Titanium Implanted Port also has a cap that secures the septum to the housing. Ex.1002, p. 10; Ex.1009, ¶165.

Accordingly, claim 16 would have been obvious to a POSA at the time of invention for the same reasons claim 1 would have been obvious to a POSA at the time of invention. Likewise, Powers discloses a housing base comprising a well comprising a bottom floor and side walls, the bottom floor and side walls defining at least one reservoir. Ex.1003, 4:43-45; Ex.1016, p.8/65 (¶[0038]). Powers also discloses a cap securing the septum to the housing base. Ex.1003, 4:29-45, Fig. 1B; Ex.1016, p.8/65 (¶[0038]), Fig. 1B.

If for any reason PORTS is not found to expressly disclose the recited well and/or cap, claim 16 would still have been obvious because a POSA would have constructed the Titanium Implanted Port with a well and cap as taught by Powers.

Thus, claim 16 is unpatentable as obvious over PORTS in view of Powers and in further view of Meyer and Hickman. Ex.1009, ¶¶ 249, 251.

4. Claims 2, 10 and 17 Are Unpatentable As Obvious

Claims 2, 10 and 17 recite: "wherein at least a portion of the X-ray discernable material is disposed within the one or more voids." Meyer (Exs.1005 & 1006) discloses an embodiment shown in Fig. 2, wherein alphanumeric characters 5 are formed by molding or cutting. Ex.1006, p. 3/4, left column, lines 25-32, Fig. 2. Meyer further discloses an embodiment shown in Fig. 3, wherein characters 6 are formed by cutouts provided in the flange (collar 1). Ex.1006 p.3/4, left column, lines 43-47, Fig. 3.

Meyer discloses that the flange (collar 1) has a top surface and a bottom surface through which the cutout characters (voids) extend. Ex.1006, p.3/4, Fig. 3. Meyer also discloses a flange 1 provided on its periphery with four character sets, manufactured, for example by molding or cutting. Ex.1006, p.3/4, right column, line 6-12, Fig. 4. The character sets shown in Meyer Fig. 4 are A7, B7, C7 and D7. Ex.1006, Fig. 4. The characters A, B, and D are formed in part by creating voids, which are molded or cut out. Ex.1006, Fig. 4; Ex.1009, ¶247.

Titanium Implanted Port has suture slots and orientation holes that extend through the X-ray discernable material of the flange from the top surface of the flange to the bottom surface of the flange. It would have been obvious to a POSA at the time of invention to modify the Titanium Implanted Port in PORTS in view of Powers (Ex. 1003) and in further view of Meyer (Ex.1006) such that a portion of

the titanium flange ("X-ray discernable material") extends into and is disposed in the suture slots and/or the orientation holes of the Titanium Implanted Port to provide a void in the form of various alphanumeric characters, such as a "C", thereby providing the X-ray discernable indicia configured to indicate, under X-ray examination, that the assembly is rated for power injection. Ex.1009, ¶248.

Accordingly, claims 2, 10 and 17 are unpatentable as obvious over PORTS in view of Powers and in further view of Meyer and Hickman. Ex.1009,¶¶250-251.

5. Claims 3, 4, 11, 12, 18 And 19 Are Unpatentable As Obvious

Claims 3, 4, 11, 12, 18 and 19 recite: "wherein the flange extends outwardly from" either (i) "the at least one reservoir" (claims 3, 11); (ii) from the well (claim 18); or (iii) "from the base about a perimeter of the at least one reservoir" (claims 4, 12, 19). Such flanges are taught by PORTS, and thus, these claims would have been obvious to a POSA at the time of invention for the same reasons set forth in Sections VII.A.6 and B.5. Ex.1009, ¶¶ 250-251.

6. Claims 5, 6, 7, 13, 14, 20 And 21 Are Unpatentable As Obvious

Claims 5, 13 and 20 recite: a "skirt overmolded about at least a portion of the base." Claims 6, 14 and 21 recite that the "skirt is further overmolded about the flange." Claims 7, 13 and 20 additionally recite that the skirt is "radiotransparent or radiolucent." Such silicone skirts are taught by PORTS, and thus, these claims

would have been obvious to a POSA at the time of invention for the same reasons set forth in Sections VII.A.7 and B.6. Ex.1009, ¶¶250-251.

7. Claims 8, 15 And 22 Are Unpatentable As Obvious

Claims 8, 15 and 22 recite: "wherein the X-ray discernable indicia further indicate, under X-ray examination, that the assembly is adapted to withstand high pressures used for injection of contrast fluid." Such indicia are taught by Powers, and thus, these claims would have been obvious to a POSA at the time of invention for the same reasons set forth in Sections VII.A.8 and B.7. Ex.1009, ¶¶250-251.

VIII. CONCLUSION

For the reasons described above, there is a reasonable likelihood that Petitioner will prevail as to each of claims 1-22 of the '160 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 1-22 of the '160 patent is respectfully requested.

Dated: July 31, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the attached Petition For *Inter Partes* Review Of U.S. Patent No. 8,852,160 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. 8,852,160:

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