Paper No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NIPRO CORPORATION
Petitioner

v.

NXSTAGE MEDICAL, INC.
Patent Owner

Patent No. 8,092,414
Issue Date: January 10, 2012
Title: DIAPHRAGM PRESSURE POD FOR MEDICAL FLUIDS

Inter Partes Review No. Unassigned

PETITION FOR *INTER PARTES* REVIEW
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *ET. SEQ.*

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EXHIBIT LIST

1001	U.S. Pat. No. 8,092,414 ("the '414 patent")
1002	Declaration of Mr. Charles E. Clemens
1003	Dobrin N. Paskalev, MD, PhD, *Georg Haas (1886–1971): The Forgotten Hemodialysis Pioneer*, 30 Dialysis and Transplantation 828 (December 2001).
1004	W.J. Kolff et al., *The Artificial Kidney: a dialyser with a great area*, 8 J. Am. Soc. Nephrology 1959 (1959) (reprinted from CXVII Acta. Med. Scand. 124 (1944)).
1005	U.S. Patent No. 5,693,008 ("Brugger").
1006	U.S. Patent No. 4,077,882 ("Gangemi").
1007	Non-Final Office Action in U.S. Appl. No. 11/270,080 (June 30, 2010).
1008	First Amendment in U.S. Appl. No. 11/270,080 (December 20, 2010).
1009	Final Office Action in U.S. Appl. No. 11/270,080 (February 4, 2011).
1010	Second Amendment in U.S. Appl. No. 11/270,080 (June 6, 2011).
1011	U.S. Patent No. 6,526,357 ("Soussan").
1012	Japanese Patent Publication No. 1986-143069 ("Minami")
1013	English Translation of Japanese Patent Publication No. 1986-143069 ("Minami")
1014	U.S. Patent No. 4,226,124 ("Kersten")
1015	U.S. Patent No. 4,412,916 ("Kell")
1016	Japanese Patent Publication No. 1997-24026 ("Onishi")
1017	English Translation of Japanese Patent Publication No. 1997-24026 ("Onishi")
1018	Merriam-Webster's Collegiate Dictionary (10th ed., Merriam-Webster, Inc. 1998).
1019	Random House Webster's Unabridged Dictionary (2nd ed., Random House, Inc. 2001) ("Random House")
1020	Japanese Patent Publication No. S64-29267 ("Sato")
1021	English Translation of Japanese Patent Publication No. S64-29267 ("Sato")
1022	NOT USED

1023	NOT USED
1024	U.S. Patent No. 6,039,078 (“Tamari”)
1025	Chinese Patent Publication No. 2522849Y (“He”)
1026	English Translation of Chinese Patent Publication No. 2522849Y (“He”)
1027	Japanese Patent Publication No. S62-5172Y2 (“Kirita”)
1028	English Translation of Japanese Patent Publication No. S62-5172Y2 (“Kirita”)
1029	Japanese Patent Publication No. 2001-353215 (“Isou”)
1030	English Translation of Japanese Patent Publication No. 2001-353215 (“Isou”)
1031	French Patent Publication No. 2346238 (“Calzia”)
1032	English Translation of French Patent Publication No. 2346238 (“Calzia”)
1033	U.S. Patent Publication No. 2002/0007137 (“Utterberg”)

NOTICE OF LEAD AND BACKUP COUNSEL

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NOTICE OF EACH REAL-PARTY-IN-INTEREST (RPI)

The RPI's for this Petition are Nipro Corp. and Nipro Medical Corp.

NOTICE OF RELATED MATTERS

U.S. Patent No. 8,491,518 issued from U.S. Appl. No. 13/299,868, which claims the benefit of U.S. Appl. No. 11/270,080 ("the '080 application"), which is the application from which the '414 patent issued.

Pending U.S. Appl. No. 13/928,454 claims the benefit of the '080 application.

NOTICE OF SERVICE INFORMATION

Please address all correspondence to the lead counsel at the address shown above. Petitioner consents to electronic service by email at: mkaminski@foley.com, smaebius@foley.com, and cbrill@foley.com.

GROUNDS FOR STANDING

Petitioner hereby certifies that the patent for which review is sought is available for *inter partes* review and that the Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in the petition. The Commissioner is hereby authorized to charge any

additional fees which may be required regarding this Petition under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741.

STATEMENT OF PRECISE RELIEF REQUESTED

Petitioner requests that claims 1-9, 12-16, 19-26, and 28 of the '414 patent be cancelled based on the following grounds of unpatentability explained in detail below. The anticipation rejection is under 35 U.S.C. § 102(b). The obvious rejections are under 35 U.S.C. § 103(a).

Ground 1. Claims 1, 2, and 7 are anticipated by Minami.

Ground 2. Claims 3 and 9 are obvious based on Minami and Kirita.

Ground 3. Claim 4 is obvious based on Minami, Kirita and Isou.

Ground 4. Claims 5 and 6 are obvious based on Minami and Tamari.

Ground 5. Claims 8 is obvious based on Minami and Brugger.

Ground 6. Claims 12, 13, 16, 19, 22, 23, and 26 are obvious based on Minami and He, as evidenced by Gangemi, Onishi, Kersten, Calzia, and Kell ("the Dome References")

Ground 7. Claim 14 is obvious based on Minami and He, as evidenced by the Dome References and Utterberg.

Ground 8. Claims 15 and 25 are obvious based on Minami, He, and Kirita, as evidenced by the Dome References.

Ground 9. Claims 20, 21, and 28 are obvious based on Minami, He, and

Kersten, as evidenced by the Dome References, and Sato.

Ground 10. Claim 24 is obvious based on Minami and He, as evidenced by the Dome References and Utterberg.

THRESHOLD REQUIREMENT FOR *INTER PARTES* REVIEW

A petition for *inter partes* review must demonstrate "a reasonable likelihood that the Petitioner would prevail with respect to at least one of the claims challenged in the petition." 35 U.S.C. § 314(a). The Petition meets this threshold. All elements of claims 1-9, 12-16, 19-26, and 28 of the '414 patent are taught in the prior art as explained below in the proposed grounds of unpatentability, and reasons to combine are established for each ground under 35 U.S.C. § 103.

STATEMENT OF REASONS FOR RELIEF REQUESTED

I. Level of Ordinary Skill In Art in the Relevant Timeframe

As supported by Petitioner's expert, in 2004-2005, a person of ordinary skill in the art would have had any one of the following: (i) a Bachelor degree in Mechanical Engineering, Biomedical Engineering, or a related field, and about 3 years of practical experience in the field of blood handling systems; or (ii) 7 years of practical experience in the field of blood handling systems. Ex. 1002, ¶ 11. These descriptions are approximate, and a higher level of education or skill might make up for less experience, and vice-versa. *Id.*

II. Technical Introduction

The following technical introduction is supported by the Declaration of Mr.

Charles E. Clemens, Ex. 1002.

A. Background on Blow Flow Sets and Pressure Monitoring

The ‘414 patent describes blood flow sets used for extracorporeal (outside the body) blood handling (*e.g.*, during dialysis), and parenteral solution sets used to administer parenteral solutions (*e.g.*, saline and heparin solutions). *See, e.g.*, Ex. 1001 at 1:6-10.

As admitted in the ‘414 patent, one advancement in blood flow sets prior to 2004-2005 was the use of pressure monitoring devices to monitor blood pressure. Ex. 1001 at 1:6-54. When the pressure of blood exceeds a certain value (about 500 mmHg) or falls below a certain value (about -400 mmHg), the blood can be damaged (these numbers may vary slightly depending on the flow rate, which causes sheer stress on the blood). Ex. 1033 at ¶¶ [0007]-[0008]. Thus, measuring pressure is an important aspect of a dialysis systems. Pressure monitoring devices are located either upstream or downstream of blood pump(s), and are typically configured to measure either positive pressure (downstream of a pump) or negative pressure (upstream of a pump). *See, e.g.*, Ex. 1014 at 2:52-3:2. In the 2004-2005 timeframe, there were two basic setups: (1) setups in which a blood-air interface exists, and (2) setups in which no blood-air interface exists. Ex. 1002, ¶15.

B. Setups with a Blood-Air Interface (Drip Chamber Type)

1. Drip Chamber Alone

Many pressure monitoring systems simply included a pressure transducer that

was coupled directly to air in a drip chamber (also called a "bubble trap" or "air trap"). Examples are shown in Figs. 9 and 10 of Minami (Ex. 1012, Eng. Trans. in Ex. 1013), and described in its background section. *See* Ex. 1013 at ¶¶ [0003]-[0005]. This system includes two drip chambers 6a, 6b. Drip chamber 6a is located upstream of a dialyzer 3, while drip chamber 6b is located downstream of the dialyzer 3. Blood *c* enters drip chamber 6a, 6b from a tube connected at a top of the drip chamber, and exits drip chamber 6a, 6b from a tube 5 connected at a bottom of the drip chamber. A pressure gauge 7a, 7b is in communication with air d above the blood *c*. The pressure of the air d is essentially the same as the pressure of the blood *c*. Thus, the pressure of the blood *c* can be determined by measuring the pressure of the air *d* with the pressure gauge 7a, 7b. *See* Ex. 1013 at ¶¶ [0003]-[0005]. Ex. 1002, ¶¶ 16-17.

Systems with drip chambers suffer from several drawbacks, as is recognized in Minami. Problem 1 is that, if the blood level in the drip chamber becomes too high, damage to pressure gauge can result and blood can become contaminated; and if the blood level becomes too low, air can potentially enter the patient, which can be life threatening. Problem 2 is that use of the drip chamber causes decreased handleabilty , because the drip chamber must be kept in an upright position; Problem 3 is that a blood-air interface accelerates coagulation of blood, which can clog the dialyzer. *See* Ex. 1013 at ¶¶ [0003]-[0005], [0012], and [0020]; *see also*

Ex. 1006 at 1:42-52. Ex. 1002, ¶ 18.

2. Drip Chamber with Pressure Transmitting Device

To address Problem 1 above, some pressure monitoring systems utilized a pressure transmitting device to prevent direct contact with between the blood and the pressure gauge. These pressure transmitting devices typically included a housing having two separate chambers, with a diaphragm isolating a first chamber on a blood side of the device from a second chamber operatively connected to a pressure transducer. The diaphragm prevents the blood from damaging the pressure gauge, and prevents contaminants from the pressure gauge from entering the blood. Ex. 1002, ¶ 19.

For example, Kersten (Ex. 1014) describes a pressure transmitting device for use with a drip chamber, as illustrated in Figs. 3 and 4. The Kersten device 34 includes a pressure chamber 38 having an inlet portion 40 and an outlet portion 42 separated by a membrane 66. The inlet portion 40 is connected by a tube 62 to a drip chamber (bubble trap 14, 24 (not illustrated)). The outlet portion 42 is connected by a tube 64 to a pressure monitor 32. Ex. 1014 at 2:61-3:15. The Kersten system addresses the possibility of blood damaging the pressure gauge and becoming contaminated with bacteria and other foreign material from the pressure gauge. However, because the Kersten system includes a drip chamber, it does not address the coagulation and handleability issues (Problems 2 and 3) associated

with drip chambers. Ex. 1002, ¶¶ 20-21.

C. Setups with No Blood-Air Interface (Pressure Pod Type)

As an alternative, systems having no drip chamber, and thus no blood-air interface, have been used. In these devices, a pressure-transmitting device (often termed a "pressure pod") is used without a drip chamber, and blood, or saline in contact with the blood, enters the pressure transmitting device via either a single blood port or two blood ports. These systems address all of Problems 1-3 above. Ex. 1002, ¶ 22.

1. Pressure Pods with a Single Blood Port

An example of a single blood port system is disclosed in Gangemi (Ex. 1006). Gangemi teaches a "blood isolation and pressure transferring means" 22 that includes a pressure chamber 24. A first housing segment 40 of the pressure chamber 24 includes an outlet portion 30 connected by a tube 32 to a pressure transducer 18. A second housing segment 42 includes an inlet portion 26 connected by a tube 28 to a pumping and purifying portion 12. A thin, flexible blood isolating and pressure transmitting membrane 60 is disposed within the pressure chamber, isolating the inlet portion 26 from the outlet portion 30. Thus, pressure of blood in the pumping and purifying portion 12 can be sensed by the transducer 18, via the tube 28, second housing segment 42, membrane 60 (i.e., a diaphragm), first housing segment 40, and tube 32. Ex. 1006 at 3:48-4:27, 4:49-

57, Fig. 1. Ex. 1002, ¶¶ 23-24.

2. Pressure Pods with Two Blood Ports

Unlike pressure pods with a single blood port, pressure pods with two blood ports allow blood to flow through a chamber in the pressure pod. Ex. 1002, ¶ 25.

a. Pressure Pod Mounted to Dialysis Machine

Brugger (Ex. 1005) described in the '414 patent, teaches one such pressure pod with two blood ports. In the Brugger system, shown for example in Fig. 3, a pressure pod 150 is mounted directly to a dialysis apparatus 20 using a mounting assembly 206. Ex. 1005 at 5: 4-54, 6:41-50. Ex. 1002, ¶¶ 26-28.

As recognized in the '414 patent, it can be disadvantageous for a pressure pod to be mounted directly to a pressure transducer on a dialysis machine, as in Brugger. According to the '414 patent, this is a problem because the blood tubing must be long enough for the pressure pod to reach the dialysis machine, and that a long length of blood flow tubing is expensive and increases the clottable surface area of blood in the tubing. Ex. 1001 at 1:55-67. What the '414 patent fails to mention is that there were many other known pressure monitoring systems in which, rather than being mounted directly to a pressure transducer on a dialysis machine, a pressure pod was instead connected to a pressure transducer via an elongated pressure tube. Ex. 1002, ¶ 29.

a. Pressure Pod Connected to Pressure Transducer via Pressure Tube

One system in which a pressure pod is connected to a pressure transducer via a pressure tube is described in Minami, the primary reference in the grounds of unpatentability below. The Minami measuring device 26 includes a "pressure converter" (*i.e.*, a pressure pod) 25, which includes a container 11 and an elastic diaphragm 12. The container 11 has a first container member 11a defining an air chamber *b* and a second container member 11b defining a blood chamber *a*. The diaphragm 12 separates the blood chamber *a* from the air chamber *b*. Blood flows into and out of the blood chamber *a* via inlet 15, outlet 15, and associated blood tubing 18, 19. Ex. 1013 at ¶¶ [0009]-[0011]. However, unlike in Brugger, the measuring device 26 of Minami is not mounted to a dialysis machine. Rather, the air chamber *b* is in communication with a pressure gauge 22 via a pressure tube 20, so that the pressure pod 25 can be located remote from the pressure gauge 22—and therefore remote from the dialysis system if the pressure gauge 22 is in the dialysis system. Ex. 1013 at ¶¶ [0009]-[0011]. Ex. 1002, ¶ 30-33.

III. The Specification of the '414 Patent

A. Embodiments Described in the '414 Patent

The focus of the '414 patent is on pressure pod type devices like those discussed directly above. *See, e.g.*, Ex. 1001, 2:12-15, 3:3-7:23. The '414 specification describes three primary embodiments of a pressure pod. The first is best shown in Figs. 2-5, the second in Figs. 8 and 9, and the third in Figs. 18 and

19. The remaining figures show systems utilizing the various embodiments of the pressure pods, or specific components of the pressure pods. Ex. 1002, ¶ 34.

As seen in Fig. 2 of the '414 patent, the pressure pod 12 of the first embodiment includes a lower compartment-defining portion 22, an upper compartment-defining portion 24, and a flexible diaphragm 26. The diaphragm 26 has a central portion 24 that bulges into the upper compartment of the portion 24. The lower compartment-defining portion 22 includes a blood inlet port 30 and a blood outlet port 32, for connection with blood tubing, and an access port 34 for connection with tubing 35 to allow for administration of parenteral solution, heparin, etc. The upper compartment-defining portion 24 includes a connection port 40 for connection to pressure tubing 42. The pressure tubing is connectable at its other end to a pressure measurement equipment connector 41, which communicates with a pressure transducer 43, as shown in Fig. 1 of the '414 patent. Thus, when a pressure is applied to the diaphragm 26 by the blood, the diaphragm 26 moves until pressures on both sides of the diaphragm 26 are balanced, thereby allowing the pressure of the blood to be measured by the pressure transducer 43. Ex. 1001 at 8:31-9:25. Ex. 1002, ¶¶ 35-36.

The second embodiment of the '414 patent pressure pod, best shown in Figs. 8 and 9, differs from the first embodiment in that the diaphragm 26a of the second embodiment is "of slightly different design" than that of the first embodiment, and

in that the upper compartment 92 has a port 112 for testing and a connection port 116 with a breakable partition 120. Ex. 1001 at 11:1-24. Ex. 1002, ¶¶ 37-38.

The third embodiment of the '414 patent pressure pod, best shown in Figs. 17 and 18, differs from the first and second embodiments in that the pod 150 and diaphragm 154 of the third embodiment are elongated. The pod 150 of the third embodiment includes a port 160 having a breakable partition, like the second embodiment, but does not include the testing port of the second embodiment. Ex. 1001 at 13:55-14:15. Ex. 1002, ¶¶ 39-40.

B. Problems Purportedly Addressed by '414 Patent Devices

The '414 patent alleges to address three problems of previous devices, when those problems were actually solved well before the application leading to the '414 patent was filed. Ex. 1002, ¶ 41.

First, the '414 patent allegedly addresses a disadvantage that "sets which fit the great majority of the world's dialysis machines . . . have drip chambers . . . ." Ex. 1001 at 2:7-11, 20-25. However, as discussed above, the problems with drip chambers were known well before the 2004-2005 time frame and solved by using blood flow-through devices without drip chambers, such as that described in Minami. *See* Ex. 1013 at ¶¶ [0003]-[0005]. Ex. 1002, ¶ 42.

Second, the '414 patent allegedly addresses a supposed disadvantage of pressure pod type devices mounted on a dialysis machine (as in Brugger), that

because the pressure pod is mounted on the dialysis machine, "[f]low-through blood tubing must convey blood to and from [a pressure pod] mounted on the face of the machine." Ex. 1001, 1:39-67. The suggestion is that the '414 patent solves the alleged disadvantage of the prior art by allowing pressure pod to be located remote from the pressure measurement machine—that is, the machine that contains the actual pressure transducer used to measure blood pressure via the pressure pod, such as the dialysis machine. This allegation was repeated by the Patent Owner during prosecution of the application leading to the '414 patent, where the Patent Owner argued that the claims were distinguishable from the cited prior art on this basis. *See, e.g.*, Ex. 1008 at 4, 9-13; Ex. 1010 at 9. However, contrary to these allegations, by the 2004-2005 timeframe, there were many publications teaching extracorporeal blood handling systems that used pressure pods that were remote from the dialysis machine, including that described in Minami. Ex. 1002, ¶ 43.

Further, the '414 patent allegedly addresses a disadvantage that "the non-sterile side of the diaphragm is open to atmosphere prior to being brought into sealing relation with the equipment's pressure port, and therefore may be displaced prior to use." Ex. 1001 at 2:1-6. The '414 purports to address this disadvantage by including the breakable partition 120 in the pressure connections ports 116, 160. *See, e.g.*, Ex. 1001 at 11:16-64. However, the independent claims of the '414 patent do not recite this feature, and the dependent claims that do (claims 10, 17,

18, and 27) are not at issue in this proceeding. Ex. 1002, ¶ 44.

IV. Claims Subject to Review

A. Independent Claims

The '414 patent includes three independent claims: 1, 13, and 23. The primary difference between the claims is that claims 13 and 23, unlike claim 1, recite that the diaphragm is "dome-shaped." There are some other, minor differences between the claims, but they are largely insignificant. For example, claims 1 and 23 require that the diaphragm be capable of bowing outwardly in two opposing directions, while claim 13 does not. And the precise language relating to the flexible positioning of the pressure pod relative to the "pressure sensing machine" or "blood treatment machine" varies slightly among the claims. Ex. 1002, ¶¶ 46-47.

B. Claim Construction

In accordance with the Trial Practice Guide, Petitioner hereby provides "a simple statement that the claim terms are to be given their broadest reasonable interpretation, as understood by one of ordinary skill in the art and consistent with the disclosure" (77 Fed. Reg. 48764), except as discussed below. The following constructions should not be construed as any admission as to constructions that would be properly adopted by a district court, which may apply a different standard than that applied in an IPR proceeding.

1. "pressure sensing pod" (claim 1)

The term "pressure ***sensing*** pod" in claim 1 is a misnomer, because the pod

itself does not ***sense*** pressure, but rather only ***transmits*** pressure from a blood circuit. In all embodiments disclosed in the '414 patent, the actual pressure sensor 43 is not in the pod itself. *See, e.g.*, Ex. 1001 at 9:20-25 and Fig. 1; And in fact, claims 13 and 23 recite a "pressure transmitting pod" rather than a "pressure sensing pod." For these reasons, it is clear from the specification and the context of the claims that the term "pressure sensing pod" is intended to mean "pressure transmitting pod." Ex. 1002, ¶ 49.

2. "said diaphragm being moveable between first and second positions, the diaphragm in said first position bowing outwardly to substantially maximize volume in said chamber that communicates with said blood flow tubing , the diaphragm in said second position bowing inwardly to substantially minimize but not eliminate the blood volume in said chamber that is inside of said diaphragm" (claim 1)

Generally, this limitation refers to the ability of the diaphragm to move between a first position, where the diaphragm is at its maximum displacement toward to the pressure tubing side of the pod, and a second position, where the diaphragm is at its maximum displacement toward the blood tubing side of the pod. For example, Fig. 19 of the '414 patent shows a pod 150 with its diaphragm 154 in the first position, while Fig. 4 of the '414 patent shows a pod 12 with its diaphragm 26a in the second position. Ex. 1002, ¶¶ 50-51.

This limitation refers to maximizing "volume in said chamber that communications with said blood flow tubing." However, claim 1 previously recites "a pressure sensing pod defining a chamber" and recites "a length of

pressure tubing connected at one end with said chamber." In other words, the "chamber" of claim 1 includes both an air chamber section and a blood chamber section. When the diaphragm is in its first position, only the volume in the blood chamber section of the pod is maximized. And when the diaphragm is in its second position, only the volume in the blood chamber section of the pod is minimized. Ex. 1002, ¶ 52.

Further, this limitation refers to minimizing, but not eliminating, "the blood volume in said chamber that is inside of said diaphragm." The term "inside of said diaphragm" is not entirely clear, but in the context of claim 1, it would be understood by one of skill in the art to refer to the blood chamber section of the pod, because the claim refers to the diaphragm bowing "inwardly" to its second position, towards the blood tubing side of the pod. Ex. 1002, ¶ 53.

Thus, for clarity, this limitation should be construed as follows: "said diaphragm being moveable between first and second positions, the diaphragm in said first position bowing outwardly to substantially maximize volume in a portion of said chamber that communicates with said blood flow tubing , the diaphragm in said second position bowing inwardly to substantially minimize but not eliminate the blood volume in said portion of said chamber that communicates with said blood flow tubing." Ex. 1002, ¶ 54.

3. "wherein the pressure tubing is flexible and elongate and integrally attached to the chamber" (claim 1); "which tubing is integral

with said pod" (claim 13); "the pressure tubing being integral with said pod" (claim 23)

Claim 1 recites that the pressure tubing is "integrally attached to the chamber." Claims 13 and 23 recite that the pressure tubing is "integral with said pod." The plain meaning of the term "integral" is "formed as a unit with another part," as is defined in Merriam-Webster's Collegiate Dictionary. Ex. 1018 at 607. The meaning of "integral" in the context of claims 1, 13, and 23, requires clarification.

As to claim 1, it suggests that the pressure tubing and the ***chamber*** are formed as a single unit. However, the chamber is not a physical entity, but rather a space defined by the pod, and it is nonsensical for a length of tubing and a space to be attached to one another, much less formed as a single unit. Ex. 1002, ¶ 56.

Further, with respect to all of claims 1, 13, and 23, it makes little sense for the pressure tubing and the pod to be formed as a single unit, because they are typically made of different materials, the pressure tubing typically being flexible, while the pod is typically rigid. *See, e.g.*, Ex. 1001 at claim 1 (reciting that the pressure tubing is "flexible and elongate"), 8:47-52 (stating that the pod components are made typically of conventional thermoplastic and/or thermoset materials). Ex. 1002, ¶ 57.

Additionally, dependent claim 16, which depends from claim 13, recites that "said pressure tubing is capable of disconnection from the connection port of the pod." Thus, the term "integral" in claim 13—and presumably, claims 1 and 23 as

well—cannot mean that the pressure tubing is permanently attached to the pod. Ex. 1002, ¶ 58; *see George Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1333 (Fed. Cir. 1999) ("Unless the patent otherwise provides, a claim term cannot be given a different meaning in the various claims of the same patent.").

Thus, the only reasonable interpretation of these limitations is that they require that the pressure tubing be directly attached to the pod. This is consistent with the embodiments shown in the '414 patent, such as Fig. 4 showing that the tubing 42 is directly attached to the pod 12. Ex. 1002, ¶ 59.

For these reasons, the limitation "wherein the pressure tubing is flexible and elongate and integrally attached to the chamber" in claim 1 should be construed as "wherein the pressure tubing is flexible and elongate and directly attached to the pod." The phrase "which tubing is integral with said pod" in claim 13 should be construed as "which tubing is directly attached to said pod." And the phrase "the pressure tubing being integral with said pod" in claim 23 should be construed as "the pressure tubing being directly attached to said pod." Ex. 1002, ¶¶ 60-61.

4. "said diaphragm is dome shaped" (claim 12); "said diaphragm having a dome shape" (claims 13 and 23)

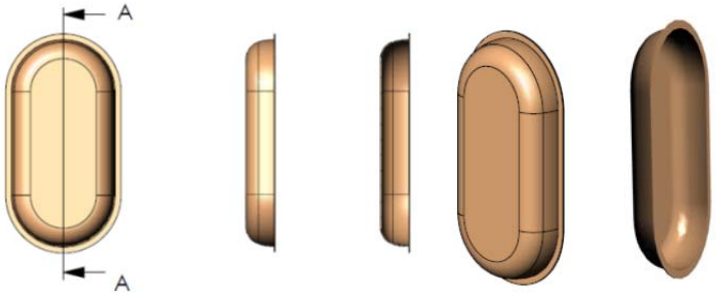
The term "dome" has many possible definitions, none of which comport with the use of the term in the '414 patent. For example, the closest definition provided in Merriam-Webster's Collegiate Dictionary is "a large hemispherical roof or ceiling." Ex. 1018 at 344. The closest definitions provided in Random House

Webster's Unabridged Dictionary are "a vault having a circular plan and usually in the form of a portion of a sphere, so constructed as to exert an equal thrust in all directions," "a domical roof or ceiling," "any covering thought to resemble the hemispherical vault of a building or room," and "anything shaped like a hemisphere." Ex. 1019 at 581. However, the '414 patent describes dome-shaped diaphragms that do not fit within any of these ordinary definitions. Ex. 1002, ¶62.

As discussed above in Section III(A), there are three primary embodiments described in the '414 patent, the first having a dome 26 best shown in Figs. 2-5, the second having a dome 26a best shown in Figs. 8 and 9, and the third having a dome 154 best shown in Figs. 18 and 19. The '414 patent specifically refers to the diaphragms 26a and 154 of the second and third embodiments as having a dome. For example, with respect to the second embodiment, the '414 patent states that "[t]he pressure sensing diaphragm in pod 80 defines a dome 28 *a* . . . ." Ex. 1001 at 11:25-26. As to the third embodiment, the '414 patent states that "[r]eferring to FIGS. 18 and 19, a pod 150, defining a chamber 152 and a flexible diaphragm 154, defining a dome in a manner similar to those of previous embodiments such as diaphragm 26, is disclosed." Ex. 1001 at 31:55-58; *see also* Ex. 1001 at 14:6-7. The '414 patent suggests that the diaphragm 26 of the first embodiment has a dome as well. Ex. 1001 at 14:6-7, 13:55-58;. Ex. 1002, ¶ 63.

Given that the diaphragm 154 of the third embodiment is referred to as

defining a dome, the term "dome" in claims 12, 13, and 23 cannot be limited to a shape having a circular plan, or a shape of a hemisphere, because the diaphragm 154 of the third embodiment neither has a circular plan, nor has a hemispherical shape. Rather, as shown in Figs. 18 and 19, the diaphragm 154 of the third embodiment has a general ovular or stadium plan and a flat top. The below images show the shape of the diaphragm 154, as would be understood based on Figs. 18 and 19 and their corresponding description in the '414 patent. Ex. 1002, ¶ 64.



The diaphragm 154 is certainly not hemispherical, and thus does not match the ordinary definition of the term "dome." Ex. 1002, ¶ 65.

The term "dome" is not explicitly defined in the '414 patent. However, the '414 patent does appear to use the terms "dome" and "bulge" interchangeably, stating that "[d]iaphragm 26a is generally of similar design to diaphragm 26, having a ***bulge 28a*** of slightly different design," and then stating that "[t]he pressure sensing diaphragm in pod 80 defines a ***dome 28a***." Ex. 1001 at 11:8-9, 25-26. Further, the '414 patent states that "FIG. 2 shows an exploded view of pressure pod 12, comprising . . . a flexible diaphragm 26, which defines a convex,

central portion 28 shown to be bulging outwardly from the blood flow portion of the chamber." Ex. 1001 at 8:31-36 (emphasis added). However, merely defining a dome as a bulge would not adequately capture the idea that a dome is typically hollow. Nor would it capture the fact that the bulge is only in the central portion of the diaphragms 26, 26a, and 154, and that there may be a flange extending outward from an edge of the bulge so that the diaphragms 26, 26a, and 154 can be held within the pod, as shown in Figs. 2, 8, and 19. Ex. 1002, ¶ 66. To take these two points into account, the phrases "said diaphragm is dome shaped" and "said diaphragm having a dome shape" should be construed to mean that "said diaphragm has a hollow, bulging central portion." Ex. 1002, ¶ 66.

5. "outwardly in either of two opposed directions" (claim 12)

This limitation required some clarification because claim 12 depends from claim 1, which already recites that "said diaphragm being moveable between first and second positions, the diaphragm in said first position ***bowing outwardly*** to substantially maximize volume in said chamber that communicates with said blood flow tubing , the diaphragm in said second position ***bowing inwardly*** to substantially minimize but not eliminate the blood volume in said chamber that is inside of said diaphragm." Claim 12 refers to both positions as positions at which the diaphragm bows "outwardly." Ex. 1002, ¶¶ 67-68.

Thus, for consistency, the Board should construe the phrase "outwardly in

either of two opposed directions" as "outwardly and inwardly in either of two opposing directions." Ex. 1002, ¶ 68.

V. Claim-By-Claim Explanation Of Grounds For Unpatentability

A. Claims 1, 2, and 7 are anticipated by Minami (Ground 1)

Minami was published on June 30, 1986, and is prior art under § 102(b).

1. Claim 1

The disclosure of Minami is correlated to elements 1[a] and 1[b] of independent claim 1 in the claim chart below. Ex. 1002, ¶¶ 69-70.

Claim Element	Disclosure of Minami
1[a]: "A tubular blood flow set which comprises a pressure sensing pod defining a chamber, said pod being connected in flow-through relation to blood flow tubing of said set"	"tubular blood flow set" – Fig. 1 (tubes 18 and 19) "pressure sensing pod" – Fig. 1 (container 11 having blood chamber *a* and air chamber *b*) Container 11 is connected in a flow-through relation to blood flow tubes 18 and 19. *See* Ex. 1013 at ¶¶ [0009]-[0010].
1[b]: "said set defining a length of pressure tubing connected at one end with said chamber, for connection at the other pressure tubing end with a pressure measuring equipment connector with said pod being spaced from said connector"	"length of pressure tubing connect at one end with said chamber" – Figs. 1-3 (tube 20 connected one end to a chamber *b* of container, and at the other end to pressure gauges 22, 22a and 22b (Fig. 3)) Ex. 1013 at ¶¶ [0009]-[0011] Gauges 22, 22a, or 22b may each be a Bourdon pressure gauge, a liquid column pressure gauge, or a strain gauge, or a combination of a semiconductor sensor and a suitable

	display device. Ex. 1013 at ¶ [0015].

a. Element 1[c]: "a flexible diaphragm sealingly mounted within said pod between connections of said blood flow tubing and said pressure tubing , said diaphragm being moveable between first and second positions, the diaphragm in said first position bowing outwardly to substantially maximize volume in said chamber that communicates with said blood flow tubing, the diaphragm in said second position bowing inwardly to substantially minimize but not eliminate the blood volume in said chamber that is inside of said diaphragm, said diaphragm in use being in contact on one side thereof with flowing blood"

Minami teaches a flexible diaphragm 12 that is sealingly mounted with the container 11 between connections of the blood flow tubes 18 and 19 the pressure tube 20. Ex. 1013 at ¶¶ [0009]-[0011]. The diaphragm is capable of taking the claimed first and second positions. Figure 1 of Minami shows the diaphragm 12 bowing outwardly such that the volume in the blood chamber *a* is increased. And while Minami does not provide an image of the diaphragm 12 in a position at which the volume in the blood chamber *a* is "maximized" or "minimized but not eliminated," the diaphragm 12 of Minami, being flexible, is certainly capable of moving to such positions. In fact, paragraph [0013] of Minami discusses the ability of the diaphragm 12 to take a position at which it minimizes blood flow in the blood chamber *a*, describing a position at which "***diaphragm 12 illustrated in Fig. 1 is pushed against the side inner wall of container 11 closer to blood chamber a***." Ex. 1013 at ¶ [0013]. Ex. 1002, ¶ 71.

If the diaphragm 12 is capable of moving to a position at which the diaphragm

12 abuts the wall of the blood chamber *a* (the bottom wall of the container 11 in Fig. 1 of Minami), it is also capable of moving to a position at which the diaphragm 12 is close to, but does not touch the inner wall of the blood chamber *a* (so as to minimize, but not eliminate blood flow through the blood chamber *a*), as the diaphragm 12 necessarily passes such a position as it moves to the inner wall of the blood chamber a. Additionally, because the diaphragm 12 is capable of moving to a position at which it abuts the inner wall of the blood chamber a, it is also capable of moving to a position at which it abuts the inner wall of the air chamber *b* (the top wall of the container 11 in Fig. 1 of Minami). Ex. 1002, ¶ 72.

b. Element 1[d] - "wherein the pressure tubing is flexible and elongate and integrally attached to the chamber to permit the pod to be positioned remotely from the pressure measuring equipment connector and to permit the pod and blood flow tubing set to be connected to blood treatment machines with pressure measuring equipment connectors in various locations of the blood treatment machines"

Minami discloses that the tube 20 is elongate, as is indicated by the double lines dividing the top and bottom portions of the tube 20 in Fig. 1, and as is also shown in Fig. 3. Minami also shows that the tube 20 is flexible. For example, Minami states that the pressure converters 25a and 25b can be used "in an arbitrary position," which indicates that the location of the pressure converters can be freely adjusted. This would only be possible if the pressure tube 20 is flexible. Ex. 1013 at ¶ [0012]. The flexibility of the tube 20 is demonstrated in Fig. 3 of Minami,

which shows a system having two pressure transmitting devices 25a and 25b, each including a container 11 and a diaphragm 12. *See* Ex. 1013 at ¶ [0010]. The tube between the pressure transmitting device 25a and the pressure gauge 22a is shown to be straight, while the tube between the pressure transmitting device 25b and the pressure gauge 22b is shown to be bent. Additionally, Minami describes an embodiment in which both the pressure gauge 22 and an injector 23 are connected to a single connection port of the container 11 via a single branching tube, and further indicates that the tube to the injector 23 can be blocked by clamping it with a clamp 24. *See* Ex. 1013 at ¶ [0009]. If the tube to the injector 23 is capable of being clamped, it must be flexible. And if the tube to the injector 23 is formed as a single branching tube with the tube to the pressure gauge 22, then the tube to the pressure gauge 22 must be flexible as well. Ex. 1002, ¶ 73.

Further, pressure tubing used in extracorporeal blood handling sets in the 2004-2005 time frame was (and is today) almost always flexible. In fact, the '414 patent admits as much in its Background section, stating that drip chambers "generally have a permanently connected, branching, hollow-bore, ***flexible, branch line*** communicating with said air space ***for an air pressure line which connects via a reversible connector at its remote end to an equipment pressure port*** on the permanent equipment, ***which in turn communicates with a pressure monitor transducer for measuring air-pressure in the chamber as a surrogate for blood-***

pressure." Ex. 1001, 1:10-18. It would be nonsensical to make the tube 20 of Minami of a non-flexible material, as such a construction would render the Minami device entirely impractical to use. Ex. 1002, ¶ 74.

The limitation that the pressure tubing is "integrally attached" to the chamber should be construed to mean that the pressure tubing is "directly attached to the pod." *See* Section (IV)(B)(3). The pressure tube 20 of Minami is directly attached to first connection port 16 of the container 11. Ex. 1002, ¶ 75.

2. Claim 2

Minami implicitly teaches the limitation of claim 2. As can be seen in Fig. 1 of Minami, the diaphragm 12 would take the second position if the blood in the tubes 18 and 19 were negatively pressurized. In other words, if the blood in the tubes 18 and 19 were negatively pressurized, the diaphragm would move toward an inner wall of the blood chamber *a*, and if the pressure were negative enough, would become pushed against the wall of the blood chamber *a* (the bottom wall of the container 11 in Fig. 1 of Minami). Given the configuration of the diaphragm 12, container 11, and blood tubes 18, 19, the Minami device could not work in any other way. Ex. 1002, ¶ 76.

3. Claim 7

Minami discloses that the chamber within the container 11 of the pressure converter 25a connects to pump segment tubing. For example, Fig. 3 of Minami

shows that the pressure converter 25a is connected to a segment of blood tubing through which a flow of blood is generated by the pump 2. *See also* Ex. 1013 at paragraph [0011] ("During the dialysis performed with blood pump 2 being rotated, blood is circulated in respective blood chambers *a*."). Ex. 1002, ¶ 88.

B. Claims 3 and 9 are obvious based on Minami and Kirita (Ground 2)

Kirita (Ex. 1027, Eng. Trans. in Ex. 1028) was published on February 5, 1987, and is prior art under § 102(b).

Minami teaches that its pressure tube 20 is attached at one end to the container 11, which corresponds to the pressure sensing pod of claim 1. Minami does not explicitly disclose that the other end of the pressure tube 20 carries "a connector for sequential connection with (1) a pressure sensing device and (2) a device to apply positive pressure through said outlet port to said chamber, to drive said diaphragm to the second position." However, the use of connectors to attach pressure tubes to various devices was standard practice in the 2004-2005 time frame. For example, Kirita teaches a pressure transmitting device with a pressure tube that includes a connector for connection with a pressure gauge. This device is shown in Figs. 5 and 6 of Kirita. Ex. 1002, ¶¶ 77, 91.

The pressure transmitting device of Kirita is for an extracorporeal blood circuit without a blood-air interface, like the Minami device. *See*, *e.g.*, Ex. 1028 at ¶ [0006]. Ex. 1002, ¶¶ 78, 91.

As shown in Fig. 5 of Kirita, a connector is located at an end of the pressure tube 19, to allow the pressure tube 19 to be connected to the pressure gauge 20. A person of ordinary skill would have been motivated to include a connector on the pressure tube 20 of Minami to allow for easy connection between the pressure tube 20 and the pressure gauge 22. Ex. 1002, ¶¶ 79, 91.

Regarding the limitation in claim 3 that the connector be "for sequential connection with (1) a pressure sensing device and (2) a device to apply positive pressure through said outlet port to said chamber, to drive said diaphragm to the second position" (*see* corresponding description in Ex. 1001 at 4:51-5:3), this limitation merely recites an intended use of the claimed connector, and has no effect on the structure of the connector itself. *See, e.g., Hewlett-Packard Co.v.Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990) ("[A]pparatus claims cover what a device *is*, not what a device *does*."); *Ex parte Masham*, 2 USPQ2d 1647 (BPAI 1987) ("A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim."). Claim 3 does not describe any structural details of the connector, and the '414 specification does not

describe this connector in any more detail than is recited in claim 3.[1] The connector of Kirita, when added to the pressure tube 20 of Minami, would certainly be capable of sequential connection with a pressure sensing device and a device to apply positive pressure. At the time of the Kirita filing (1981), the 2004-2005 time frame, and today, a common example of a connector that would be used on a pressure tube would be a luer lock connector having threads so that the connector can simply be rotated to attach the connector to a corresponding connector of the pressure gauge. Ex. 1002, ¶¶ 80, 91.

C. Claim 4 is obvious based on Minami, Kirita, and Isou (Ground 3)

Isou (Ex. 1029, Eng. Trans. in Ex. 1030) was published on December 25, 2001, and is prior art under § 102(b).

Minami teaches that the pressure tube 20 is flexible, as discussed above with respect to claim 1. Minami discloses that a clamp 24 is used to block a tube 21, which is a tube leading to a an injector 23 used to adjust an air content in the air

[1] The '414 patent does describe structural details of a male luer connector 106 to be located on the ***pod*** side of a pressure tube, which is specifically configured to rupture a portion 98 sealing an air chamber of a pressure pod. However, the '414 patent does not describe any structural details of a connector on a ***non-pod*** side of a pressure tube, which is the connector referred to in claim 3.

chamber *b* of Minami's pressure transmitting device. Minami does not explicitly disclose that the pressure tube 20 carries a clamp. However, the use of clamps to block a pressure tube was well known in the 2004-2005 time frame. For example, Japanese Patent Publication No. 2001-353215 ("Isou") (Ex. 1029, Eng. Translation at Ex. 1030) teaches a clamp for use with "[an] extracorporeal circulation circuit or an auxiliary circuit, an infusion line, an anticoagulant supply line, a level adjustment line, a ***pressure monitor line***, or the like." Ex. 1030 at ¶ [0037] (emphasis added). Ex. 1002, ¶ 81.

The claim language indicating that the clamp is "to retain said positive pressure at said diaphragm" is merely an intended use of the clamp, and has no effect on its structure. But regardless, it would have been obvious to use the clamp to retain positive pressure at the diaphragm for the following reasons. Ex. 1002, ¶ 82.

Minami differs from the '414 patent systems in that, rather than a pressure pod having a single pressure tube, Minami teaches (i) a pressure pod having two connection ports 16 and 17, the port 16 being attached to a pressure gauge 22 via a pressure tube 20, and the port 17 being attached to a syringe 23 via a pressure tube 21 (Ex. 1013 at ¶ [0009]), or (ii) a pressure pod with a single connection port having a branched tube connected thereto (Ex. 1013 at ¶ [0015]). Ex. 1002, ¶ 83.

However, the use of a single pressure tube connected to a pressure transmitting device, rather than dual or branching tubes, was a known variation of the

configurations disclosed in Minami. For example, the Kirita system utilizes only a single pressure tube 19 with a connector at its end. *See* Ex. 1028 at ¶ [0006]. In such a configuration, the pressure tube 19 would need to be disconnected from the pressure gauge 20 in order to attach a syringe to the pressure tube. Under these circumstances, a person of ordinary skill would have been motivated to use a clamp on the tube leading to the syringe to retain a positive pressure at a diaphragm. Ex. 1030 at ¶ [0037]. For example, Minami teaches applying positive pressure to the air chamber by injecting air from a syringe 23a and 23b in a case where a blood pressure is high. *See* Ex. 1013 at ¶ [0011]. Further, it is common that incomplete attachment of the connector at the end of a pressure tube (like the connector of Kirita) is found after a dialysis procedure starts. In such a situation, the diaphragm would be moved to its uppermost position because the pressure of blood is applied to the diaphragm while air leaks from the connector portion. To address this, a syringe must be connected to the pressure tube to apply a positive pressure to move back the diaphragm to its correct position. After using the syringe to move the diaphragm, the pressure tube would need to be clamped to retain the diaphragm in its correct position while the pressure tube is reconnected to the pressure gauge. Ex. 1002, ¶ 84.

To summarize, a configuration using a single pressure tube was a known variation of the Minami device as demonstrated by Kirita. And it would have been

necessary to include the clamp of Isou on the pressure tube, which is explicitly suggested in Isou to be a use of its clamp, to maintain positive pressure on the diaphragm while the pressure tube is disconnected from a syringe and reconnected to a pressure gauge, which was known to be necessary following adjustment of the diaphragm position using the syringe. Thus, a person of ordinary skill would have been highly motivated to include a clamp on the pressure tube when using the known single pressure tube configuration. Ex. 1002, ¶ 85.

D. Claims 5 and 6 are obvious based on Minami and Tamari (Ground 4)

Tamari (Ex. 1023, Eng. Trans. in Ex. 1024) was published on March 21, 2000, and is prior art under § 102(b).

1. Claim 5

Minami does not teach that a bottom wall of the container 11 defines a transverse channel having a wall of U or V-shaped cross-section, whereby the diaphragm in the second position does not block flow through the channel. However, Tamari discloses a pressure transmitting device having a pod with a bottom wall that defines a transverse channel. Specifically, in Figs. 21a and 21b, Tamari discloses a device that includes a tube 2191 that is divided into a blood path 2174 and an interluminal space 2134 by a flexible thin wall section 2191a (a type of flexible diaphragm). A bottom wall of the tube 2191 defines a transverse bleed channel 2191g having a U-shaped cross-section, as can be seen in Fig. 21b of

Tamari. The channel 2191g of Tamari is configured such that, even when in a position at which the volume in the blood path 2174 is minimized (a position corresponding to the second position of the '414 patent), the thin wall section 2191a does not block the channel 2191g. *See* Ex. 1024 at 27:13-49. Thus, the purpose of the bleed channel 2191g is the same as the purpose of the channel of claim 5—to prevent the thin wall section 2191a from entirely blocking a flow of blood through a pressure transmitting device. In fact, while Tamari states that the device of Fig. 21 is for use as a pressure relief valve, Tamari states that its devices may also be used for noninvasive pressure monitoring. *See, e.g.*, Ex. 1024 at 6:12-22. A person of ordinary skill would have been motivated to include a transverse channel having a U-shaped cross section, like the channel 2191g of Tamari, in the bottom wall of the container 11, so that blood would be able to flow through the blood chamber *a*—and dialysis could continue—even if diaphragm 12 were to contact the bottom wall of container 11. Ex. 1002, ¶ 86.

2. Claim 6

Tamari also teaches that a wall of the channel 2191g is substantially contiguous with a wall portion of blood flow tubes 1175 and 1176, as can be seen in Fig. 21a of Tamari. As discussed above, a person of ordinary skill in the art would have been motivated to include a transverse channel having a U-shaped cross section, like the channel 2191g of Tamari, in the bottom wall of the container 11, so that

blood would be able to flow through the blood chamber *a*—and dialysis could continue—even if the diaphragm 12 were to contact the bottom wall of the container 11. Additionally, a person of ordinary skill would have been motivated to make the channel in the bottom wall of the container substantially contiguous to the blood flow tubes 14, 15 to promote efficient flow from the blood flow tube 18 to the channel, and from the channel to the blood flow tube 19. Ex. 1002, ¶ 87.

E. Claim 8 is obvious based on Minami and Brugger (Ground 5)

Brugger was published on December 2, 1997, and is prior art under § 102(b).

Minami does not disclose that an "access port is provided to communicate with the chamber interior at a side of said diaphragm opposed to said pressure tubing." The '414 patent explains that the purpose of the access port is "to provide parenteral solution, heparin, or other medicaments to the blood or for withdrawing blood or air or saline from the flowpath." Ex. 1001 at 6:23-25. Minami does not disclose an access port to the blood chamber *a* for such a purpose. However, Brugger discloses a pressure pod 58 having an access port—termed "secondary outlet" 62—precisely for this purpose. Ex. 1005 at 4:1-8. Ex. 1002, ¶ 89.

A person of ordinary skill in the art would have been motivated to include an access port like the secondary outlet 62 of Brugger in the Minami device, to allow for introduction of saline solution and other fluids into the blood within the Minami blood set. Ex. 1002, ¶ 90.

F. Claims 12, 13, 19, 22, 23, and 26 are obvious based on Minami and He, as evidenced by Gangemi, Onishi, Kersten, Calzia, and Kell ("the Dome References") (Ground 6)

He (Ex. 1025, Eng. Trans. in Ex. 1026) was published on Nov. 27, 2002. Gangemi was published on Mar. 7, 1978. Onishi (Ex. 1016, Eng. Trans. in Ex. 1017) was published on Jan. 28, 1997. Kersten was published on Oct. 7, 1980. Calzia (Ex. 1031, Eng. Trans. in Ex. 1032) was published on Oct. 28, 1977. Kell (Ex. 1015) was published on Nov. 1, 1983. All are prior art under § 102(b).

1. Claim 12

Minami does not teach that its diaphragm 12 is dome-shaped. The '414 patent alleges that the benefits of using a "dome-shaped" diaphragm are (i) minimizing stretching of an elastomeric diaphragm and (ii) enabling a usage of non-elastomeric material for a diaphragm. Ex. 1001 at 14:29-34. However, these benefits of dome-shaped diaphragms were already well known in the art. Ex. 1002, ¶¶ 92-93.

As discussed above, the limitation that "said diaphragm is dome shaped" should be construed to mean that "said diaphragm has a hollow, bulging central portion." But regardless of whether the term dome is given this or a narrower construction (for example, requiring a partially or entirely rounded shape), He teaches a pressure pod that includes a dome-shaped diaphragm. Ex. 1002, ¶ 94.

Specifically, He teaches a pressure transmitting device for protecting pressure

instruments, termed an "overpressure protector," which is the same as those used commonly used in blood circuits, as discussed above in Sections II(B)(2) and (II)(C). The He device includes a lower connection body 1 having an opening leading to the air or liquid whose pressure is to be measured, an upper connection body 3 having an opening leading to a pressure measuring instrument, and a dome-shaped membrane 2 clamped between the lower connection body 1 and the upper connection body 3. The membrane 2 begins in a position shown in Fig. 4 of He, where the membrane contacts an inner surface of the lower connection body. An increase in the pressure of air or liquid in the lower connection body 1 causes the diaphragm to move toward the upper connection body 3, compressing air or a liquid working medium in the upper connection body 3, as shown in Fig. 5 of He. Thus, the pressure of the air or liquid in the lower connection body 1 can be measured by the pressure measuring instrument via the dome-shaped membrane 2, and the air or liquid in the upper connecting body. Ex. 1026 at ¶¶ [0022]-[0025]. Ex. 1002, ¶¶ 95-96 .

He suggests that its device is appropriate for use in chemical production processes using harmful gases or liquids (Ex. 1026 at ¶ [0002]), but this is merely an example, and the devices of He are certainly not limited to such uses. And while He is not in the field of extracorporeal blood handling sets, this reference is highly pertinent to one of the problems that the '414 patent purports to address—

that is, accurately measuring the pressure of a fluid while preventing contact between the fluid and the pressure gauge. For example, He states that its membrane "isolates the direct connection between a detected medium and a pressure instrument, thereby providing anti-corrosion protection to the pressure instrument." Ex. 1026 at [0009]. Blood, like other liquids, can cause corrosion to a pressure instrument. In fact, blood is corrosive to metal (a typical material for pressure measurement instruments) due to the electrolytes it contains. A person of ordinary skill designing a pressure pod certainly would have looked outside the field of extracorporeal blood handling sets, to references more generally describing pressure pods. Ex. 1002, ¶ 97.

The membrane 2 of He moves between the two states in Figs. 4 and 5 without stretching**.** For example, He explains that "[b]efore the pressure is introduced, the functional membrane 2 ***falls naturally***" to conform with an inner surface of the lower compartment body as shown in in the "zero pressure" state of Fig. 4. Ex. 1026 at ¶¶ [0016] and [0025]. When a pressure is increased, the membrane 2 moves upwardly to contact an inner surface of the upper compartment body, which has the same shape as the lower compartment body. *Id*. at ¶ [0025]. Of course, if the membrane 2 "falls naturally" when in the position in Fig. 4, the membrane is not stretched in this position. And the membrane 2 must take the position in Fig. 5 without stretch because the shape of the membrane 2 in this position is identical

with that in the position of Fig. 4. It is clear that any intermediate state between these two states also occurs without stretching. Ex. 1002, ¶ 98.

Gangemi, Onishi, Kersten, and Calzia provide evidence that a person of ordinary skill in the art at the time of the invention would have been highly motivated to replace the diaphragm 12 of Minami with a hollow, bulging diaphragm like that of He, for the reasons explained below. Ex. 1002, ¶ 99.

All of the below motivations relate to one basic feature of flat diaphragms—namely, that they must stretch during use. Ex. 1002, ¶ 100.

a. Explicit Motivation 1: Avoiding Damage to the Diaphragm

A flat diaphragm, such as the diaphragm 12 of Minami, must stretch when it is caused to move by increased or decreased blood pressure in the blood chamber *a*. When the blood pressure in the blood chamber *a* is positive, the diaphragm 12 must stretch as it bulges into the air chamber *b*, as shown in Fig. 1 of Minami. Similarly, when the blood pressure in the blood chamber *a* is negative, the diaphragm 12 would stretch as it bulges into the blood chamber *a*. One reason this stretching is disadvantageous is because stretching can lead to failure of the diaphragm. This is recognized in, for example, Gangemi, which states that "diaphragms [of the prior art], whose action depends upon ***stretching***, are generally unsatisfactory because they prove to eventually crack in use and have not sufficient membrane memory to return to their original state . . . ." Ex. 1006 at 1:65-2:1.

Gangemi indicates, that, by using its non-stretching diaphragms rather than a flat diaphragm, "the membrane 60 is generally more resistant to cracking or breaking than a conventional diaphragm which must stretch to operate." Ex. 1006 at 2:60-63, 5:40-45. Of course, the same is true of any dome-shaped diaphragm, including the diaphragm of He, which moves without stretching. Thus, a person of ordinary skill would have been motivated to replace the flat diaphragm 12 of Minami with the dome-shaped diaphragm of He, to avoid cracking or breaking of the diaphragm. Ex. 1002, ¶ 101.

b. Explicit Motivation 2: Avoiding Non-Linearity and Hysteresis

A flat, stretching diaphragm, such as the diaphragm 12 of Minami, is also disadvantageous because it results in the pressure in the air chamber *b* not representing the pressure in the blood chamber *a* in an entirely accurate manner. First, a stretching diaphragm leads to non-linearity in a relationship between pressure in the blood chamber *b* and pressure in the air chamber *a*. For example, here the pressure in the blood chamber *a* is positive, the pressure in the blood chamber *a* will always be at least slightly higher than the pressure in the air chamber *b*, because part of the increase in pressure in the blood chamber *a* goes toward stretching the diaphragm 12, rather than reducing the volume in the air chamber *b*. Similarly, where the pressure in the blood chamber *a* is negative, the pressure in the blood chamber *a* will always be at least slightly lower than the

pressure in the air chamber *b*, because part of the decrease in pressure in the blood chamber *a* goes toward stretching the diaphragm 12, rather than increasing the volume in the air chamber *b*. This effect is magnified as the diaphragm 12 continues to stretch, so that the pressure in the air chamber will increase and decrease non-linearly with respect to the pressure in the blood chamber, and the pressure in the air chamber may differ depending on whether the pressure in the blood chamber is increasing or decreasing. Compensating for this non-linearity would require secondary pressure calibration in the dialysis system, which would increase cost and complexity. Ex. 1002, ¶ 102.

Additionally, a flat, stretching diaphragm leads to a hysteresis effect. The stretching of a diaphragm is never perfectly elastic. Thus, when the diaphragm stretches, there is a tendency for the diaphragm to stay in its stretched position. This may cause a measured value of pressure to be different when the pressure is increasing, and the diaphragm is expanding, as opposed to when the pressure is decreasing, and the diaphragm is contracting, because when the pressure is decreasing, the diaphragm tends to stay in its expanded state. Compensating for the hysteresis effect would require yet additional secondary calibration, resulting in yet additional cost and complexity. Ex. 1002, ¶ 103.

Onishi describes these non-linearity and hysteresis problems associated with flat diaphragms, explicitly referring to Minami. Ex. 1017 at ¶¶ [0006]-[0007].

Onishi suggests replacing the Minami diaphragm with a diaphragm that does not stretch. One of the diaphragms suggested by Onishi to avoid the stretching problem is a stepped hollow, bulging diaphragm, shown in Fig. 10, which is described in Onishi as having a "terraced shape." Ex. 1017 at ¶ [0022]. This diaphragm is nearly identical to the stepped, hollow bulging diaphragm disclosed in Gangemi, and similar to the diaphragm in He in that it moves without stretching. Onishi's teaches provide additional motivation to replace the flat diaphragm of Minami with the dome-shaped diaphragm of He. Ex. 1002, ¶ 104.

c. Explicit Motivation 3: Maximizing Air Volume Displacement

In order to suppress problems caused by stretching of a flat diaphragm during pressure measurement (e.g., failure of diaphragm, non-linearity and hysteresis), the diaphragm could be used with only small diaphragm movement. However, small movement of a diaphragm causes another problem. Namely, because the pressure tubing of the Minami system is relatively long (due to the pressure pod 25 being located remote from the pressure gauge 22), the volume of air in the pressure tubing 20 is relatively large. Small movement of the diaphragm 12 would lead to only small variations in volume relative to the total volume in the pressure tubing 20 and in the first container member 11a. These relatively small variations in

volume can make it more difficult to detect pressure changes.[2] This problem was known in the art, and provides yet additional motivation to use hollow, bulging diaphragms, (i.e., dome-shaped diaphragms). Ex. 1002, ¶ 105.

For example, Kersten recognizes the problem that results when the displacement of the diaphragm and associated volume displacement in the pressure tubing is small. To address this problem Kersten, like Gangemi and Onishi, suggests using a hollow, bulging diaphragm similar to the diaphragm in He (Ex. 1014 at 1:50-57, 4:17-24), and states that its diaphragm with steps (like that of He) is superior to the stepped diaphragm of Gangemi (Ex. 1014 at 1:23-34). Further, a person of ordinary skill would have understood that a maximum air volume displacement in the Minami pod can be achieved by employing a dome-shaped diaphragm in the same manner as in He—that is, a diaphragm having a downward dome shape before a positive pressure is introduced (as in Fig. 4 of He) and an upward dome shape when a pressure is increased (as in Fig. 5 of He). Kersten's teachings provide yet additional motivation to replace the flat diaphragm of Minami with the dome-shaped diaphragm of He. Ex. 1002, ¶ 106-109.

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[2] Because of Boyle's law (PV=const), a small volume variation will lead to a small pressure variation, which is more difficult to detect with a pressure transducer. For more detail, please refer to Section V(G), below.

d. Explicit Motivation 4: Allowing Use of Non-Elastic Diaphragm Materials

As yet additional motivation to substitute the flat diaphragm of Minami with a dome-shaped diaphragm, Calzia teaches that, by employing a dome-shaped diaphragm, it is possible to make the diaphragm from a non-elastic material, which can avoid stretching problems altogether. *See* Ex. 1032 at 6:25-27. Of course, the same will be true of any flexible dome-shape diaphragm, including the dome-shaped diaphragm of He. Calzia demonstrates that this benefit of using dome-shaped diaphragms, described in the '414 patent (Ex. 1001 at 14:32-33), was known well before 2004-2005 time frame. Ex. 1002, ¶ 110.

Specifically, Calzia describes a blood storage container utilizing a dome-shaped diaphragm. The container 1 of Calzia includes a shell 2 consisting of two hemispherical elements 3, 4, which grip a deformable hemispherical membrane 7. The membrane 7 divides the space within the shell into two compartments 12, 13. Ex. 1032 at 2:26-3:2; Figs. 2 and 3. Ex. 1002, ¶ 111.

Initially, when the container 1 is empty, the membrane 7 contacts an internal surface of the element 4, so that compartment 12 occupies the entire space in the shell 2. Compartment 12 is in communication with an air supply tube 16 via a manifold 14. Compartment 13 is in communication with a tube 18 for transferring blood via a manifold 15. Pump 17 is connected to the air supply tube 16 via the manifold 14 to remove air from the compartment 12, which causes blood to enter

the compartment 13 via the manifold 15. To empty the container, the pump is used to supply air to the compartment 12 via the manifold 14, causing blood to exit the compartment 13 via the manifold 15. Ex. 1032 at 3:13-4:30. Ex. 1002, ¶ 112.

In one of the embodiments described in Calzia, shown in Fig. 8, the container 1 includes two tubes 34, 35 connected to the compartment 13, so that the blood can flow into the compartment 13 via the tube 34, and out of the compartment 13 via the blood 35. Ex. 1002, ¶ 113.

While Calzia does not indicate that its device is for pressure measurement, a person of ordinary skill would have understood that the devices of Calzia and Minami have interchangeable uses. For example, Minami states that, in addition to pressure measurement, its pressure transmitting devices can be used as a blood storage container (like the blood storage container of Calzia). Ex. 1013 at ¶ [0019]. Similarly, a person of ordinary skill in the art would have recognized that dome-shaped diaphragms for pressure transfer in a blood storage container (as in Calzia), would have similar benefits when used in a pressure transmitting device for pressure measurement (such as that in Minami). Ex. 1002, ¶ 114.

And as discussed above, Calzia indicates that its diaphragm may be made of a non-elastic material (Ex. 1032 at 6:25-27), which is one of the benefits of dome-shaped diaphragms mentioned in the ‘414 patent. Consequently, a person of ordinary skill would have been motivated to use such a dome-shaped diaphragm to

make it possible to use a diaphragm made of a non-elastomeric material, and thereby avoid stretching problems altogether. Ex. 1002, ¶ 115.

e. Summary of Explicit Motivation

Given the teachings of Gangemi, Onishi, Kersten, and Calzia, a person of ordinary skill would be highly motivated to replace the flat diaphragm 12 of Minami with the dome-shaped diaphragm like that of He. The reason is simple. The container 11 of Minami has a rounded dome-shape, as can be seen in Figs. 1, 2, 6A, and 6B of Minami. As discussed above, it was known that (i) it was desirable to use a hollow, bulging diaphragm to avoid the problems caused by a stretching diaphragm (*see* Ex. 1006 at 2:60-63, 5:40-45; Ex. 1017 at ¶¶ [0006]-[0007]), and (ii) it was desirable to ***maximize*** the air volume displacement caused by movement of the diaphragm (*see* Ex. 1014 at 1:23-34, 50-57). The optimal diaphragm shape to both (i) minimize stretching, and (ii) maximize air volume displacement in the air chamber *b* of Minami caused by movement of the diaphragm, would be a shape that conformed to an inner surface of the container 11 of Minami—i.e., a rounded dome-shape. Thus, a person of ordinary skill would have been motivated to replace the flat diaphragm of Minami with a rounded dome-shaped diaphragm, such as that described in He, and would have been particularly motivated to select such diaphragm so that its shape matches that of the container 11 (which would result in the diaphragm being capable of easily

taking the first and second positions recited in claim 1). Ex. 1002, ¶ 116.

f. Simple Substitution

Furthermore, even ignoring the explicit motivations discussed above, it would still have been obvious to replace the Minami diaphragm 12 with a dome-shaped diaphragm. Minami differs from the device of claim 12 only in that the diaphragm 12 of Minami is flat, rather than dome-shaped. However, pressure transmitting devices having dome-shaped diaphragms, and specifically rounded dome-shaped diaphragms, were known in the art. He discloses one such device. Ex. 1026 at Figs. 2, 4, and 5. Ex. 1002, ¶ 117.

Calzia provides evidence that pressure pods having dome-shaped diaphragms were known for use in extracorporeal blood handling sets, as discussed above in Section V(F)(1)(d). Ex. 1002, ¶ 118.

Kell provides additional evidence that pressure pods having flexible dome-shaped diaphragms were known for use in extracorporeal blood handling sets ***for the specific purpose of sensing pressure***, stating:

> Blood pressure sensing, or measuring device 34 is a gas tight receptacle formed of a generally hemispherical-shaped compressible, or flexible, diaphragm, or dome, member 54, . . . and a rigid, generally hemispherical-shaped dome 56, which . . . is provided with an integrally attached gas outlet port 58. . . . Outlet port 58 is adapted for connection to means for transmitting gas to a remotely located pressure gauge or pressure measuring means of convention type such

> as a pressure transducer . . . . Pressure sensing means 34 functions to reflect small changes in pressure of the blood flowing in housing 28 and the consequent deflection of the flexible convex dome 54 into cavity 70 as pressure increases, and vice versa. The gas that is thus displaced is transmitted to a previously calibrated pressure transducer . . . to provide a continuous pressure indication on a conventional indicator . . . ." (Ex. 1015, 6:46-7:29.) (Ex. 1002, ¶ 119.)

The function of dome-shaped diaphragms—allowing transmission of pressure from a first medium (such as blood) to a second medium (such as air), without contact between the two mediums—was also known in the art. Ex. 1026 at ¶¶ [0009] and [0025]. A person of ordinary skill could have easily substituted the flat diaphragm 12 of Minami with the dome-shaped diaphragm disclosed in He, which would have yielded the predictable result that pressure could be measured more reliably and more accurately than could be measured using the flat diaphragm 12 of Minami, as the problems caused by the stretching of the Minami diaphragm 12 would be avoided, while air volume displacement would be maximized. *See* discussion in Sections V(F)(1)(a) to V(F)(1)(c), above. Ex. 1002, ¶ 121.

When the flat diaphragm 12 of Minami is substituted with the dome-shaped diaphragm 2 of He, the diaphragm would be capable of bowing outwardly toward a wall of the first container member 11a, and inwardly toward a wall of the second container member 11b (as it does in Figs. 4 and 5 of He). Ex. 1002, ¶ 122.

2. Claim 13

The disclosure of Minami is correlated to elements 13[a]-13[c] of independent claim 13 in the claim chart below. Ex. 1002, ¶ 123-125.

Claim Element	Disclosure of Minami
13[a]: "A pressure transmitting pod defining a chamber, said pod being for connection in flow-through relation to fluid flow tubing of a fluid flow set"	"pressure sensing pod" – Fig. 1 (container 11 having blood chamber *a* and air chamber *b*) "flow tubing of a fluid flow set" – Fig. 1 (tubes 18 and 19) Container 11 is connected in a flow-through relation to blood flow tubes 18 and 19. *See* Ex. 1013 at ¶¶ [0009]-[0010].
13[b]: "said pod having a flexible, fluid impermeable diaphragm dividing the pod into separate compartments"	Fig. 1 – (diaphragm 12 dividing container 11 into a blood chamber *a* and an air chamber *b*)
13[c]: "a first of said compartments communicating with flow connectors for said fluid flow tubing"	"flow connectors for said fluid flow tubing" – Fig. 1 (inlet 14 connected to tube 18 and outlet 15 connected to tube 19)

a. Element 13[d] – "a second of said compartments communicating with a connection port for connection with a length of pressure tubing at one end thereof, which tubing is integral with said pod and is configured for sealed connection at its other end to a remote pressure connector of a pressure sensing machine, to transmit pressure from the second of said compartments through the pressure tubing to the pressure sensing machine for pressure monitoring, and to allow flexible positioning of said pod relative to the remote pressure sensing machine"

The air chamber b of Minami communicates with first connection port 16, which is for connection with pressure tube 20 at one end thereof. Ex. 1002, ¶¶ 126-127.

As to the limitation that the pressure tubing be "integral with said pod", this

limitation should be construed to mean that the pressure tubing is "directly attached to the pod." *See supra* Section IV(B)(3). The pressure tube 20 of Minami is directly attached to first connection port 16 of the container 11. Thus, Minami teaches this limitation of claim 13. Ex. 1002, ¶ 128.

Minami teaches that pressure tube 20 is configured for sealed connection at its other end to a remote connector of pressure gauge 22, 22a, 22b, as shown in Figs. 1 and 3. Ex. 1013 at ¶¶ [0009]-[0011]. Pressure tube 20 is configured to transmit pressure from air chamber *b* of container 11 through pressure tube 20 to pressure gauge 22, 22a, 22b for pressure monitoring. Ex. 1002, ¶ 129.

The pressure tube 20 allows flexible positioning of the container 11 relative to the pressure gauge 22, 22a, 22b. For example, Minami states that the pressure converters 25a and 25b can be used "in an arbitrary position," which indicates that the location of the pressure converters can be freely adjusted. Ex. 1013 at ¶ [0012]. Ex. 1002, ¶ 130.

b. Element 13[e] – "said diaphragm having a dome shape, and being sufficiently flexible to easily distort in a manner reflective of pressure changes, to vary the volumes of said one and other compartments"

Minami does not disclose that its diaphragm 12 has a dome shape. However, it would have been obvious to substitute the diaphragm 12 of Minami with the dome-shaped diaphragm of He, for the reasons discussed above with respect to claim 12. When the diaphragm 12 of Minami is substituted with the diaphragm 2 of He, the

diaphragm would still be sufficiently flexible to easily distort in a manner reflective of pressure changes, to vary the volumes of the two compartments separated by the diaphragm (as it does in Figs. 4 and 5 of He). Ex. 1002, ¶ 131.

3. Claim 16

Minami does not explicitly disclose that the pressure tube 20 is "capable of disconnection" from the first connection port 14. However, there are exactly two possibilities for attaching the pressure tube 20 of Minami to the first connection port 14. Either the pressure tube 20 is permanently attached to the first connection port (as recited in claim 15), or the pressure tube 20 is removably attached to the first connection port 14. It would have been obvious to implement either of these configurations. For example, one reason for the pressure tube 20 to be capable of disconnection from the first connection port 14 is to allow for the pressure tube 20 to be reused after a procedure. The pressure tube 20 is completely isolated from blood by the diaphragm 12 in the container 11, so it is possible for the pressure tube 20 to be reused, but it is not possible for the container 11 to be reused. Reusing the pressure tube 20 would allow for cost savings by eliminating the need to use a new pressure tube 20 for each medical procedure. Ex. 1002, ¶¶ 146-147.

4. Claim 19

The chamber defined by the container 11 of Minami has a length that is nearly exactly twice its width, as can be seen in Fig. 2 of Minami. Ex. 1002, ¶ 148.

Further, even ignoring the figures of Minami, it would have been obvious to select the container 11 of Minami such that its length is at least twice its width. As discussed above, the prior art recognized the importance of maximizing air volume displacement in a pressure pod, in order to allow use of the pressure pod with long pressure tubes. *See, e.g.*, Ex. 1014 at 1:50-57, 4:17-24. The volume of a pod can be defined by three dimensions: length, width, and depth. Among the three dimensions, length is an only factor that can be increased without increasing a risk of clotting. This is because a length is a dimension that is along a blood stream. On the other hand, both of the remaining two dimensions - width and depth - are dimensions that are lateral to a blood stream, and consequently may cause a stagnation and clotting of a blood by increasing their sizes. Thus, a person of ordinary skill in the art would have been motivated to use pressure pods defining longer chambers, including pressure pods defining chambers having a length at least twice their width, in order to increase the air volume displacement that can be achieved by the diaphragm in the pressure pod without increasing the risk of stagnation and clotting. Ex. 1002, ¶ 149.

5. Claim 22

As discussed above with respect to claim 1 in Section V(A)(1)(a), the diaphragm 12 of Minami is capable of bowing outwardly toward a wall of the first container member 11a, and inwardly toward a wall of the second container

member 11b. Ex. 1002, ¶ 153.

When the flat diaphragm 12 of Minami is substituted with the hollow, bulging diaphragm 2 of He, the diaphragm would still be capable of bowing outwardly toward a wall of the first container member 11a, and inwardly toward a wall of the second container member 11b (as it does in Figs. 4 and 5 of He). Ex. 1002, ¶ 156.

6. Claim 23

Elements [a]-[c] of claim 23 are identical to elements [a]-[c] of claim 13, and are disclosed in Minami as discussed above in Section V(F)(2) above. Ex. 1002, ¶¶155-157.

a. Element 23[d] – "a second of said compartments communicating with a connection port for connection to pressure tubing of a pressure sensing machine, the pressure tubing being integral with said pod and configured to allow attachment of said pod to pressure sensing ports of the pressure sensing machine and at least one other device having pressure sensing ports in a different location from the pressure sensing ports of the pressure sensing machine, to transmit pressure from the second of said compartments to the pressure sensing machine for pressure monitoring"

The air chamber *b* of Minami communicates with first connection port 16, which is for connection with pressure tube 20, the pressure tube 20 being configured to be connected to a pressure gauge 22, 22a, 22b. Minami states that the pressure gauge 22, 22a, 22b may be a Bourdon pressure gauge, a liquid column pressure gauge, or a strain gauge, or a combination of a semiconductor sensor and a suitable display device. Ex. 1013 at ¶ [0015]. Ex. 1002, ¶ 161.

As to the limitation that the pressure tubing be "integral with said pod", this limitation should be construed to mean that the pressure tubing is "directly attached to the pod." *See* Section IV(B)(3). The pressure tube 20 of Minami is directly attached to first connection port 16 of the container 11. Thus, Minami teaches this limitation of claim 23. Ex. 1002, ¶ 162.

The pressure tube 20 is configured for sealed connection at its other end to a remote connector of pressure gauge 22, 22a, 22b, as shown in Figs. 1 and 3. Ex. 1013 at ¶¶ [0009]-[0011]. The pressure tube 20 is configured to transmit pressure from the air chamber *b* of the container 11 through the pressure tube 20 to the pressure gauge 22, 22a, 22b for pressure monitoring. Ex. 1002, ¶ 163.

As to the limitation that the pressure tubing be "configured to allow attachment of said pod to pressure sensing ports of the pressure sensing machine and at least one other device having pressure sensing ports in a different location from the pressure sensing ports of the pressure sensing machine," the pressure tube 20 of Minami is capable of such use. The pressure tube 20 allows flexible positioning of the container 11 relative to the pressure gauge 22, 22a, 22b. For example, Minami states that the pressure converters 25a and 25b can be used "in an arbitrary position," which indicates that the location of the pressure converters can be freely adjusted. Ex. 1013 at ¶ [0012]. Thus, the Minami pressure tube 20 is capable of being connected to a pressure sensing port on any number of pressure sensing

machines, regardless of the location of the pressure sensing port. Ex. 1002, ¶ 164.

b. Element 23[e] – "said diaphragm having a dome shape, and being sufficiently flexible to easily distort in a manner reflective of pressure changes, to vary the volumes of said one and other compartments, said dome shaped diaphragm being capable of bowing outwardly to form said dome shape in either of two opposed directions"

Minami discloses that its diaphragm is sufficiently flexible to easily distort in a manner reflective of pressure changes, to vary the volumes of its air chamber *b* and blood chamber *a*. Ex. 1013 at ¶ [0011]. Minami does not disclose that its diaphragm 12 has a dome shape. However, it would have been obvious to substitute the diaphragm 12 of Minami with the dome-shaped diaphragm of He, for the reasons discussed above with respect to claim 12. The diaphragm of He, when applied to Minami, would still be capable of forming a dome shape in either of two opposed directions, as it does in Figs. 4 and 5 of He. Ex. 1002, ¶ 165-166.

7. Claim 26

The element of claim 26 is identical to that of claim 16, and is obvious for the reasons discussed above with respect to claim 16. Ex. 1002, ¶¶ 171-172.

G. Claim 14 is obvious based on Minami and He, as evidenced by the Dome References and Utterberg.

Utterberg (Ex. 1033) was published on January 17, 2002, and is prior art under § 102(b).

Minami and He do not explicitly teach that their diaphragms can "vary the volume of said compartments at a pressure variation of 500 mm Hg by at least 2.5

cc." However, it would have been obvious to select a diaphragm and pod size that allow for such volume variation. Ex. 1002, ¶ 132.

According to Boyle's law, the product of pressure and volume is constant for a given mass of confined gas, assuming a constant temperature. Thus, the product of (i) the total volume in a pressure pod air chamber plus the total volume in a connected pressure tube, and (ii) the pressure in the pressure pod air chamber and pressure tube, is constant. Ex. 1002, ¶ 133.

Assume that P_i is the pressure of air space that includes the pressure pod air chamber and pressure tube; V_i is the volume of air space that includes the pressure pod air chamber and pressure tube; V_{ci} is the volume of the air chamber; and V_{PT} is the volume of the pressure tube. It was known that, when a blood pump in an extracorporeal blood circuit is off, pressure of blood in the circuit is nearly equal to atmospheric pressure (i.e., 760 mmHg). It was also known that, when a blood pump is on, blood pressure downstream of the pump was typically increased by up to 500 mmHg (i.e., to 1260 mmHg). *See* Utterberg, Ex. 1033, ¶ [0007]. To maximize movement of a diaphragm in a pressure pod, and thereby maximize air volume displacement (as suggested by Kersten), the diaphragm should nearly abut the wall of the blood chamber when blood in the blood circuit is at atmospheric pressure (maximizing the air chamber volume, as shown in Fig. 4 of He), and the diaphragm should abut the wall of the air chamber when blood in the blood circuit

is at the maximum pressure (minimizing the air chamber volume, as shown in Fig. 5 of He). Ex. 1002, ¶¶ 134-135.

Accordingly, consider the above two states. In the first state, the pressure P_i is at atmospheric pressure (760 mmHg), and the volume of the air chamber is maximized at V_{cmax}. The pressure and volume in this state will be referred to as P_1 and V_1. In the second state, the pressure P_i is at atmospheric pressure + 500 mmHg = 1260 mmHg (as might be expected downstream of a blood pump), and the volume of the air chamber is 0 (because the diaphragm has moved its maximum amount towards the air chamber side of the pressure pod). The pressure and volume in this state will be referred to as P_2 and V_2. In other words: P_1 = 760 mmHg; P_2=1260 mmHg; $V_1=V_{cmax}+V_{PT;}$ $V_2=0+V_{PT}=V_{PT.}$ It is then possible to calculate the relationship between the volume of the pressure tube and the maximum volume of the air chamber. According to Boyle's law, $P_1V_1=P_2V_2$. Thus, $(760)(V_{cmax}+V_{PT}) = (1260)(V_{PT})$. So $V_{PT} = 1.52V_{cmax.}$ Ex. 1002, ¶¶ 136-37.

Below is a chart showing possible values of V_{PT} (the volume of the pressure tube) to measure the 500 mmHg increase in pressure for various possible values of V_{cmax} (the maximum volume variation of the air chamber). Ex. 1002, ¶ 138.

Vcmax (cc)	VPT (cc)
2	3.04
2.5	3.8
3	4.56
3.5	5.32

As can be seen in the above chart, a value of V_{cmax} of 2.5 cc (the value recited in claim 14) allows for measurement of a 500 mmHg pressure increase using of a pressure tube having a volume of 3.8 cc. Ex. 1002, ¶ 139.

However, it was known by the 2004-2005 time frame that pressure tubes used in extracorporeal blood sets typically had volumes ranging from 0.5 cc to 6 cc. *See* Ex. 1033 at ¶ [0007]. In order to measure a 500 mmHg pressure increase using of a pressure tube having a volume of 6 cc (as was typical by the 2004-2005 time frame), the maximum volume variation of the air chamber in the pressure pod would need to be at least 3.95 cc. Ex. 1002, ¶ 140.

Notably, an air volume of a machine portion (i.e., an air volume in a pressure gauge and a path in a dialysis machine from a connector to a pressure gauge) is assumed zero in the above calculation. An air volume of a machine portion is typically 0.5 to 10 cc. *See* Ex. 1033 at [0007]. This further increases maximum volume variation that should be achievable by the diaphragm. Ex. 1002, ¶ 141.

For these reasons, to measure a pressure variation of 500 mmHg (as was known to be typical for portions of blood tubing downstream from a blood pump) using a pressure tube having a volume of 6 cc (as was also known to be typically used), it would have been obvious to select a diaphragm and pod size that allow for an air chamber volume variation of at least ***3.95 cc***. Or, using the terminology of claim 14, it would have been obvious to select a diaphragm and pod size such that

said diaphragm of dome shape can vary the volume of said compartments at a pressure variation of 500 mm Hg by at least 3.95 cc. So it certainly would have been obvious to select a diaphragm and pod size such that "said diaphragm of dome shape can vary the volume of said compartments at a pressure variation of 500 mm Hg by at least ***2.5 cc***," an amount ***smaller*** than 3.95 cc. Ex. 1002, ¶ 142.

H. Claims 15 and 25 are obvious based on Minami, He, and Kirita, as evidenced by the Dome References.

Minami teaches that its pressure tube 20 is attached at one end to the first connection port 14 of its container 11. Minami does not explicitly disclose that the pressure tube 20 is "permanently connected" to the first connection port 14. However, there are exactly two possibilities for attaching the pressure tube 20 of Minami to the first connection port 14. Either the pressure tube 20 is permanently attached to the first connection port, or the pressure tube 20 is removably attached to the first connection port 14 (as recited in claim 16). It would have been obvious to implement either of these configurations. For example, one reason to permanently attach the pressure tube 20 to the first connection port 14 would be to avoid inadvertent disconnection of the pressure tube 20 from the connection port 14 during a medical treatment. Ex. 1002, ¶¶ 143-144, 168-169.

Minami does not explicitly disclose that the pressure tube 20 has "at its other end a remote tubing connector for connection to said machine remote pressure port during medical treatments." However, as discussed above with respect to claim 3,

the use of connectors to attach pressure tubes to a pressure gauge was standard practice in the art in the 2004-2005 time frame. For example, Kirita, discussed above with respect to claim 3, teaches a pressure transmitting device with a pressure tube that includes a connector for connection with a pressure gauge. As shown in Fig. 5 of Kirita, a connector is located at an end of the pressure tube 19, to allow the pressure tube 19 to be connected to the pressure gauge 20. A person of ordinary skill in the art would have been motivated to include a connector on the pressure tube 20 of Minami to allow for easy connection between the pressure tube 20 and the pressure gauge 22. Ex. 1002, ¶¶ 145, 170.

I. Claims 20, 21, and 28 are obvious based on Minami, He, and Kersten, as evidenced by the Dome References, and Sato.

Sato (Ex. 1020, Eng. Trans. at Ex. 1021) was published on January 31, 1989, and is prior art under § 102(b).

1. Claims 20 and 21

The diaphragm 2 of He appears to have a width that is exactly twice a depth of a dome of the diaphragm. But even ignoring what is shown in the figures of He, the claimed dimensions would have been obvious. For example, Kersten teaches such a diaphragm. Fig. 5 of Kersten shows Kersten's diaphragm with labeled dimensions. Kersten teaches that its diaphragm has a width *m* of at least 56 mm. A depth *g+h* of the dome of the Kersten diaphragm is 17 mm. Ex. 1014 at 3:61-4:11. Thus, the width of the diaphragm is at least 3.3 times the depth of the

diaphragm. Kersten teaches that its diaphragm offers "a more compact construction and thus provides packaging advantages" over relatively deep diaphragms, like the one in Gangemi. Ex. 1014 at 1:23-34. Ex. 1002, ¶ 151.

The '414 patent alleges that a benefit of the feature of claims 20 and 21 is that it reduces the risk of blood stagnation and clotting, while providing an adequate amount of air displacement on the air side of diaphragm. Ex. 1001 at 14:34-44. However, this benefit was known in the art. Calzia demonstrates that it was known that dome-shaped diaphragm becomes rippled when it is in an intermediate state (as shown, for example, in Fig. 8 of Calzia). Sato teaches that it was known that these ripples increase the possibility of stagnation and clotting. *See* Sato at ¶ [0006]. A diaphragm with a high width-to-depth ratio will ripple less than a diaphragm with a low width-to-depth ratio, and thus cause less stagnation and clotting. Thus, after substituting the a dome-shaped diaphragm, like that of He, for the flat diaphragm of Minami, a person of ordinary skill would have been motivated to modify the diaphragm (and if necessary, the Minami container 11, so that the diaphragm and container have matching dimensions) such that its width is at least twice its depth, as taught by Kersten, in order to reduce rippling, and thereby reduce stagnation and clotting, as taught by Sato. Ex. 1002, ¶¶ 152-153.

2. Claim 28

The chamber defined by the container 11 of Minami has a length that is nearly

exactly twice its width, as can be seen in Fig. 2 of Minami, and even ignoring the figures of Minami, it would have been obvious to select the container 11 of Minami such that its length is at least twice its width, for the reasons discussed above with respect to claim 19. Ex. 1002, ¶ 173.

Further, after substituting He's hollow, bulging diaphragm for the flat diaphragm of Minami, it would have been further obvious to modify the He diaphragm such that its width is at least twice its depth, for the reasons discussed above with respect to claims 20 and 21. Ex. 1002, ¶ 174.

J. Claim 24 is obvious based on Minami and He, as evidenced by the Dome References and Utterberg.

Minami and He do not explicitly teach that their diaphragms can "vary the volume of said compartments at a pressure variation of 500 mm Hg by at least 2.5 cc." However, it would have been obvious to select a diaphragm and pod size that allow for such volume variation, for the reasons discussed above with respect to claim 14. Ex. 1002, ¶ 167.

CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that Trial be instituted and that claims 1-9, 12-16, 19-26, and 28 be cancelled.

Respectfully submitted,

Dated: March 11, 2016 By: /Stephen B. Maebius/
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Certificate of Service

The undersigned hereby certifies that a copy of the foregoing Petition for *Inter Partes* Review together with all exhibits, the power of attorney, and all other papers filed therewith was served on NXSTAGE MEDICAL, INC. by placing copies into FEDERAL EXPRESS directed to the attorneys of record for the patent at the following addresses:

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