IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ABIOMED, INC.

Petitioner

v.

WHITE SWELL MEDICAL LTD.

(record) Patent Owner

IPR2021-01565

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U.S. Patent No. 10,639,460

Issued: May 5, 2020

Inventors: Yaacov Nitzan, Menashe Yacoby, Tanhum Feld

Title: Systems and methods for treating pulmonary edema

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,639,460**

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P.O. Box 1450
Alexandria, VA 22313-1450

# TABLE OF CONTENTS

## TABLE OF EXHIBITS

| Exhibit No. | Description |
|---|---|
| 1001 | U.S. Patent No. 10,639,460 |
| 1002 | Declaration of Steven W. Day |
| 1003 | Curriculum vitae of Steven W. Day |
| 1004 | Declaration of Lawrence Garcia |
| 1005 | Curriculum vitae of Lawrence Garcia |
| 1006 | U.S. Published Patent App. 2006/0064059 ("Gelfand") |
| 1007 | U.S. Patent No. U.S. 9,878,080 ("Kaiser") |
| 1008 | File History of U.S. Patent No. 10,639,460 |
| 1009 | U.S. Provisional Application No. 62/006,206 |
| 1010 | U.S. Provisional Application No. 61/927,038 |
| 1011 | International Published Patent Application WO2013/061281 ("Caron") |
| 1012 | Michael P. Bannon et al., *Anatomic Considerations for Central Venous Cannulation*, 4 Risk Mgmt. & Healthcare Pol'y 27 (2011) ("Bannon") |
| 1013 | Screenshot of Bannon on PubMed.gov |
| 1014 | Declaration of Duncan Hall and Accompanying Exhibits |
| 1015 | Atsushi Shimizu et al., *Embolization of a Fractured Central Venous Catheter Placed Using the Internal Jugular Approach*, 5 Int'l J. Surgery Case Reps. 219 (2014) |

| | |
|---|---|
| 1016 | Yancy et. al., *2013 ACCF/AHA Guideline for the Management of Heart Failure,* 128 Circulation e240 (2013), https://www.ahajournals.org/doi/pdf/10.1161/cir.0b013e31829e8776 |
| 1017 | U.S. Published Patent Application 2009/0131785 ("Lee") |
| 1018 | *Intravascular*, THE AMERICAN HERITAGE MEDICAL DICTIONARY (2007), https://medical-dictionary.thefreedictionary.com/intravascular |
| 1019 | *Central Venous Pressure*, FARLEX PARTNER MEDICAL DICTIONARY (2012), https://medical-dictionary.thefreedictionary.com/central+venous+pressure |
| 1020 | *Compliance and Compliant*, THE NEW SHORTER ENGLISH OXFORD DICTIONARY (4th ed. 1993). |
| 1021 | U.S. Patent No. 5,097,840 ("Wallace") |
| 1022 | Swan et al., *Catheterization of the Heart in Man with Use of a Flow-directed Balloon-tipped Catheter*, 283 New Eng. J. Med. 447 (1970) |
| 1023 | Mauro Moscucci et al., *Grossman & Baim's Cardiac Catheterization, Angiography, and Intervention* (8th ed. 2014) |

# I. INTRODUCTION

Petitioner respectfully requests *inter partes* review ("IPR") under 35 U.S.C. § 311 *et seq*. and 37 C.F.R. § 42.100 *et seq*. of Claims 1-24 of U.S. Patent 10,639,460 ("the '460 Patent"), which is assigned to White Swell Medical Ltd. ("WhiteSwell").

Petitioner believes there is a reasonable likelihood that it will prevail with respect to at least one of the claims challenged in this Petition, and respectfully asks the Board to institute *inter partes* review and hold Claims 1-24 unpatentable and canceled. This Petition is supported by the declarations of Steven W. Day (Ex. 1002), an expert in medical devices that interact with the circulatory system, and Lawrence Garcia (Ex. 1004), an expert in interventional cardiology.

# II. MANDATORY NOTICES (37 C.F.R. § 42.8)

## A. Real Parties-in-Interest

The real party-in-interest is Abiomed, Inc. ("Petitioner" or "Abiomed").

## B. Related Matters

Concurrently with the present Petition, Petitioner is filing a second petition challenging Claims 1-24 of the '460 Patent (IPR2021-01564), which presents different grounds for the invalidity of the challenged claims. Petitioner has also filed a separate post-grant review petition regarding U.S. Patent No. 10,926,069 (PGR2021-00107) and *inter partes* review petitions regarding U.S. Patent No.

10,653,871 (IPR2021-01477 and IPR2021-01478). These two patents claim priority to certain of the applications to which the '460 Patent claims priority.

### C. Designation of Lead and Backup Counsel, and Service Information

| Lead Counsel | Backup Counsel |
|---|---|
| Sharonmoyee Goswami<br>Reg. No. 68,806<br>CRAVATH, SWAINE & MOORE LLP<br>825 Eighth Avenue<br>New York, NY 10019<br>(212) 474-1000<br>(212) 474-3700 (facsimile)<br>sgoswami@cravath.com | Keith R. Hummel<br>CRAVATH, SWAINE & MOORE LLP<br>825 Eighth Avenue<br>New York, NY 10019<br>(212) 474-1000<br>(212) 474-3700 (facsimile)<br>khummel@cravath.com |
| | **Additional Backup Counsel** |
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A motion to permit Keith R. Hummel and Andrei Harasymiak to appear *pro hac vice* as backup counsel in this action is filed concurrently with this petition. Under 37 C.F.R. § 42.10(b), a power of attorney from Abiomed is attached. Abiomed consents to electronic service at the email addresses listed above.

## III. PAYMENT OF FEES UNDER 37 C.F.R. § 42.15

The required fees are submitted herewith in accordance with 37 C.F.R. § 42.15(b).

# IV. REQUIREMENTS FOR *INTER PARTES* REVIEW

## A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the '460 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting such review.

## B. Precise Relief Requested and Asserted Grounds

Petitioner respectfully requests cancellation of Claims 1-24 of the '460 Patent as unpatentable under 35 U.S.C. §§ 102 and 103 on the following grounds:

| No. | Ground |
|---|---|
| 1 | Claims 1-10, 12-22 and 24 are anticipated by U.S. Patent No. 9,878,080 ("Kaiser"). |
| 2 | Claims 1-24 are obvious over Kaiser and U.S. Published Patent App. 2006/0064059 ("Gelfand"). |
| 3 | Claims 1-10, 12-22, and 24 are obvious over Kaiser and Michael P. Bannon et al., *Anatomic Considerations for Central Venous Cannulation*, 4 Risk Mgmt. & Healthcare Pol'y 27 (2011) ("Bannon"). |
| 4 | Claims 1-24 are obvious over Kaiser, Gelfand and Bannon. |
| 5 | Claims 11 and 23 are obvious over Kaiser and the knowledge of a person of ordinary skill in the art (POSA). |
| 6 | Claims 11 and 23 obvious over Kaiser, Bannon and the knowledge of a POSA. |
| 7 | Claims 11 and 23 obvious over Kaiser, Gelfand and the knowledge of a POSA. |
| 8 | Claims 11 and 23 obvious over Kaiser, Gelfand, Bannon and the knowledge of a POSA. |

A claim listing is provided in Appendix B. To the extent the challenged claims may require construction, proposed constructions are set forth in Section VI solely for purposes of this Petition. A detailed explanation of why each claim is unpatentable appears in Sections VII-XIV, including identification of supporting evidence to support the challenge and the relevance of the evidence to the challenge.

## V. BACKGROUND

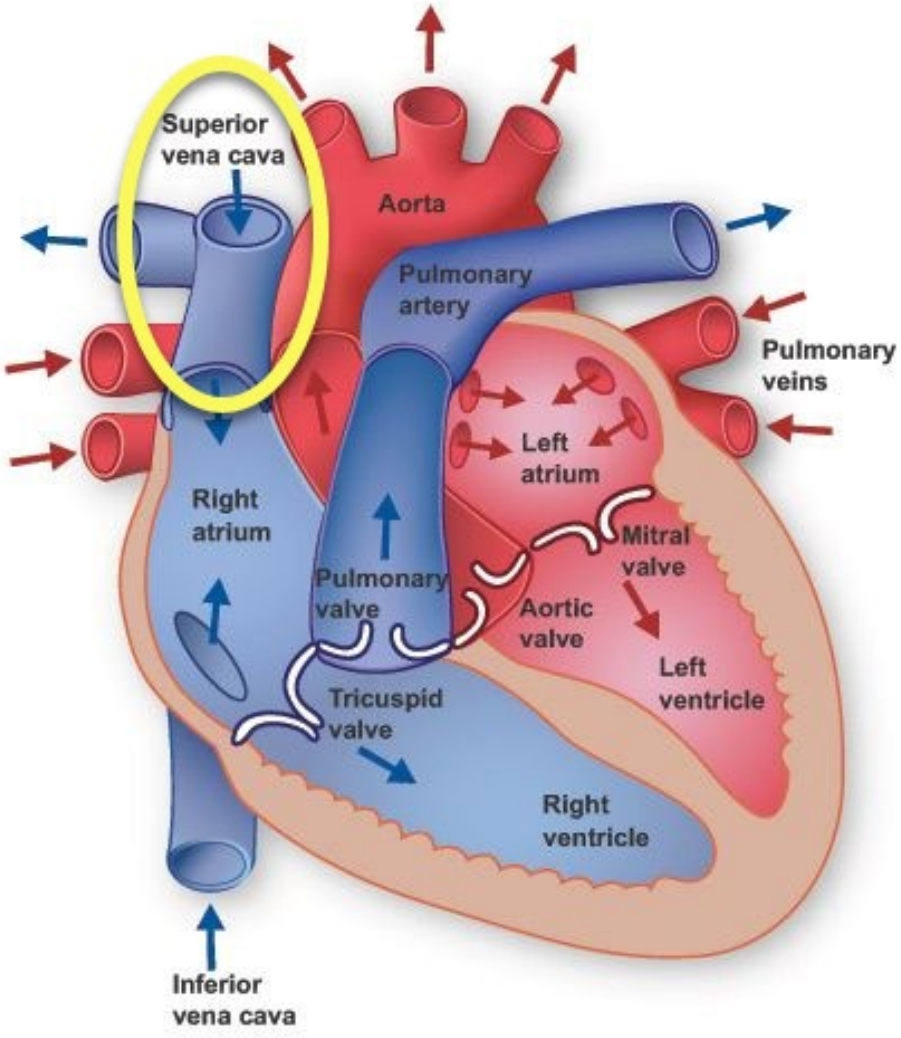
### A. Technical Background

The claims of the '460 Patent are directed to methods for treating "heart failure" using a "catheter apparatus" with one or more "restrictors," such as a balloon catheter, that can be activated to regulate venous blood return through the superior vena cava ("SVC") by at least partially occluding the SVC. The catheter apparatus contains one or more "sensors" that send feedback to a "control module," which uses that feedback to control and adjust the restrictors.

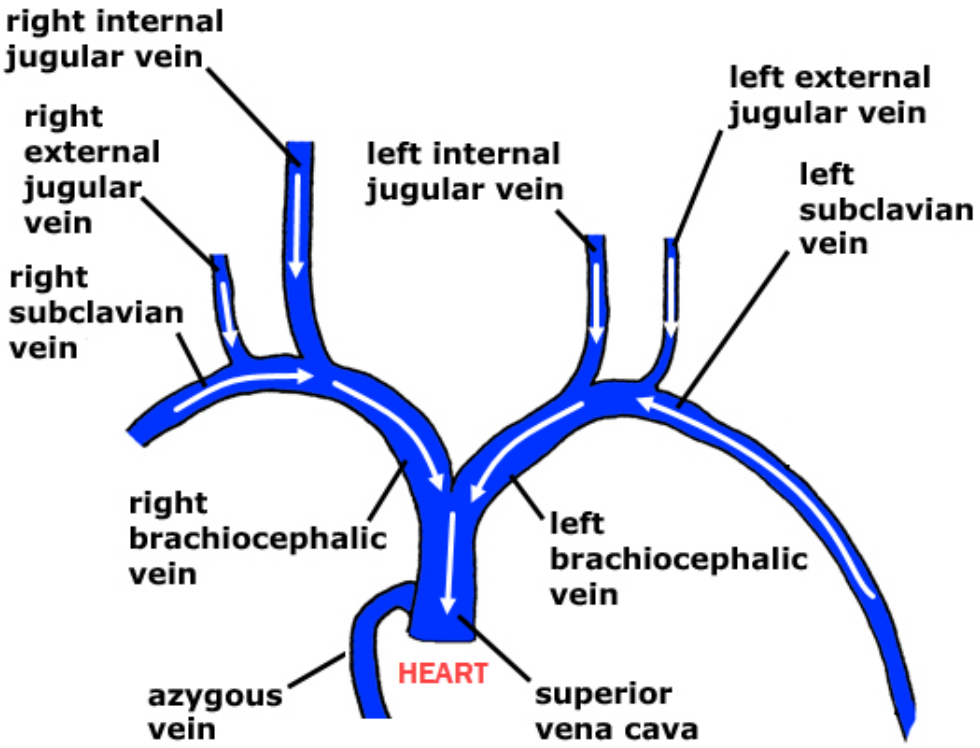
A catheter is a thin tube that can be inserted into the body for various medical reasons. A balloon catheter has one or more inflatable balloons, typically

near its tip.[1] After the catheter is inserted into the patient's body, with the balloon in a deflated state, it is advanced through a body vessel, often a blood vessel, until the balloon is in the desired position. The balloon is then inflated, with the timing, duration and degree of inflation dependent on the therapeutic objective. When inflated in a blood vessel, the balloon fully or partially "occludes" the vessel. Blood flow is restricted, creating a gradient or differential between blood pressure upstream of the balloon and downstream of the balloon. The more the balloon is inflated, the more the blood vessel is occluded, the less blood can flow through the vessel, and the more blood pressure increases upstream and decreases downstream. *See* Ex. 1002, § V.A-B; Ex. 1004, § V.A.

[1] A catheter may use other expandable structures that function like a balloon. The discussion of balloon catheters applies equally to such devices.




The SVC (circled above) is a large vein through which venous blood from the upper body returns into the right atrium of the heart. Approximately one-third of all venous blood returns through the SVC. The figure below shows the relationship of the SVC to other veins mentioned in the '460 Patent: the jugular, subclavian and innominate (or "brachiocephalic" (Ex. 1002, ¶ 46)) veins, which feed directly or indirectly into the SVC.




*See* Ex. 1002, § V.D.

Heart failure is "a complex clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection of blood." (Ex. 1016, p. 7.) In other words, heart failure occurs when the heart is unable to circulate enough blood through the body, either because it is unable to fill with enough blood or eject enough blood. A common cause of heart failure is myocardial infarction (heart attack). *See* Ex. 1004, § V.B.

### B. Overview of the '460 Patent

According to the '460 Patent:

> methods and devices are provided ***for reducing edema conditions***, such as pulmonary edema, in a patient ***by lowering the outflow***

> ***pressure in a region around the thoracic/lymphatic duct outflow***. As a result of lowering the outflow pressure at the thoracic and/or lymphatic ducts, higher lymphatic return will be achieved . . . .

(Ex. 1001, 6:50-55.)[2] Edema is excessive accumulation of fluid in body tissues. (Ex. 1002, ¶ 48.)

Figure 1 shows a schematic of the lymph-clearing system:

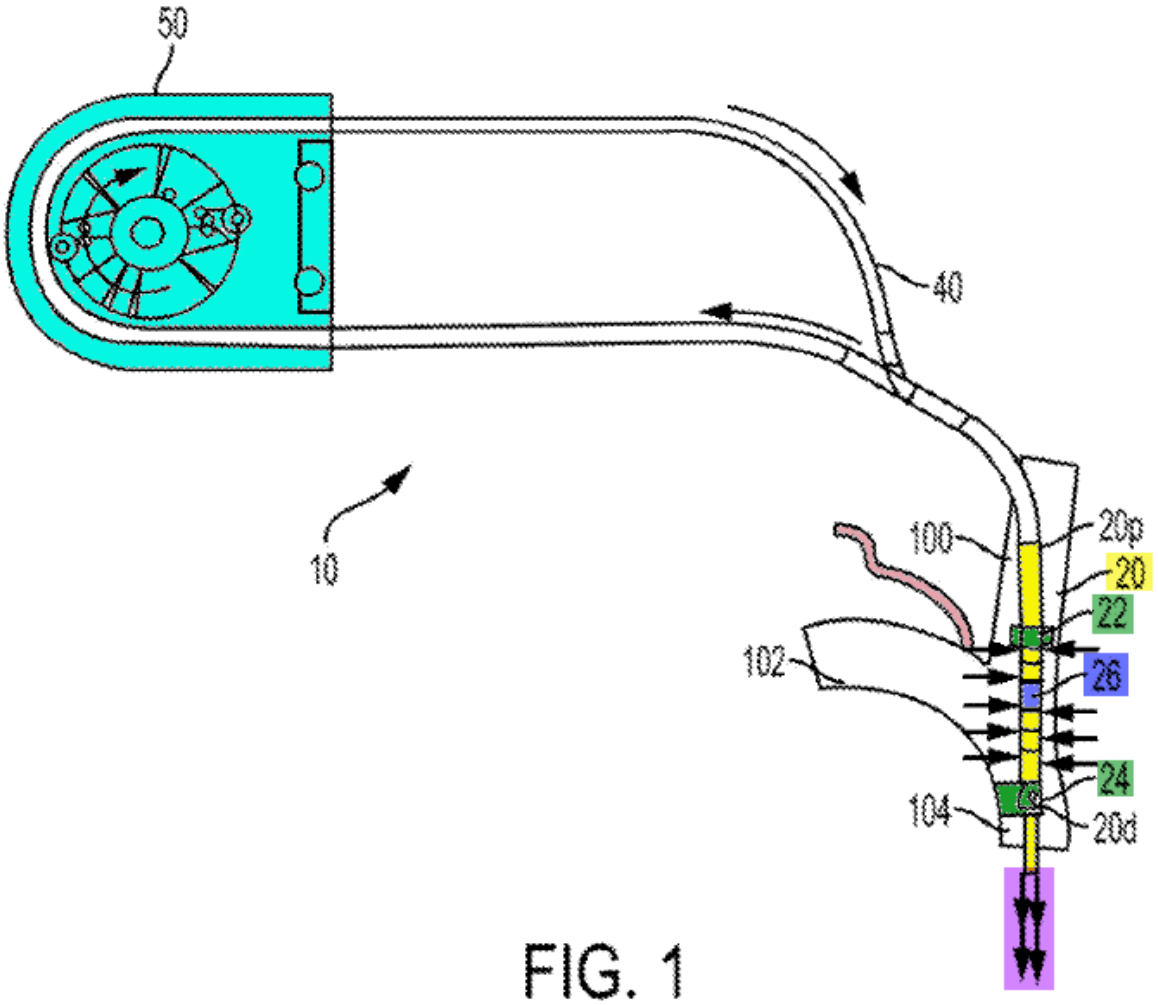



FIG. 1

[2] All emphases in quotations have been added unless otherwise noted.

The lymph duct is the squiggly structure (highlighted pink[3]); its outlet is near the jugular-subclavian junction. (Ex. 1002, ¶ 53.)

To lower pressure near a lymph duct, the '460 Patent teaches inserting a catheter (highlighted yellow) with one or more "restrictions"[4] (highlighted green) into the venous system. (Ex. 1001, 4:37-40; 6:61-67.) The '460 Patent teaches that "restrictions can take a variety of forms as long as they are effective to at least partially occlude the vessel within which they are deployed" (Ex. 1001, 10:15-18) and that a "restriction can be a selectively expandable balloon" (2:19-20). Activating a restrictor occludes the vein, which reduces blood flow and thus lowers pressure near the lymph duct outflow. (7:21-25.) A pump (highlighted turquoise) removes fluid from the occluded area through a suction port (highlighted blue) and

[3] Throughout this Petition, highlighting or other color elements that appear on a patent figure have been added to aid discussion.

[4] The claims of the '460 Patent use the terms "restrictor" or "resistor"; the specification generally uses "restriction" (*See, e.g.*, Ex. 1001, 24:3, 6:64) but also uses "restrictor" interchangeably with "restriction" (*e.g.,* 10:24).

discharges it at a point (highlighted purple) distal[5] to the occluded area, thereby maintaining the low-pressure area. (7:28-36.)

Figure 3, highlighted with the same colors, shows part of the system after insertion and expansion of the restrictors (balloons).

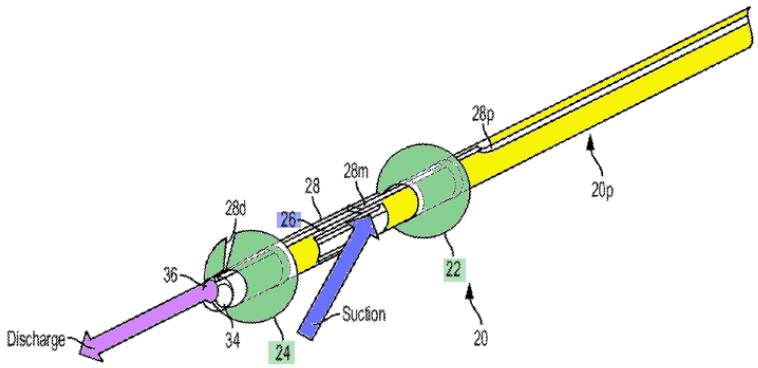



FIG. 3

"[T]he system may include sensors that may help optimize the lymphatic regulation." (13:13-14.) As illustrated schematically in Figure 10, data from these sensors is sent to a control module that can control the pump or alter the volume of the restriction(s). (*See* 15:17-32.)

[5] The specification explains that the "term 'proximal' refers to the portion of the instrument closest to the clinician and the term 'distal' refers to the portion located furthest from the clinician." (Ex. 1001, 6:41-44.) These definitions are consistent with how these terms are generally used in the field of medical devices. *See* Ex. 1002, ¶ 59, n.5.

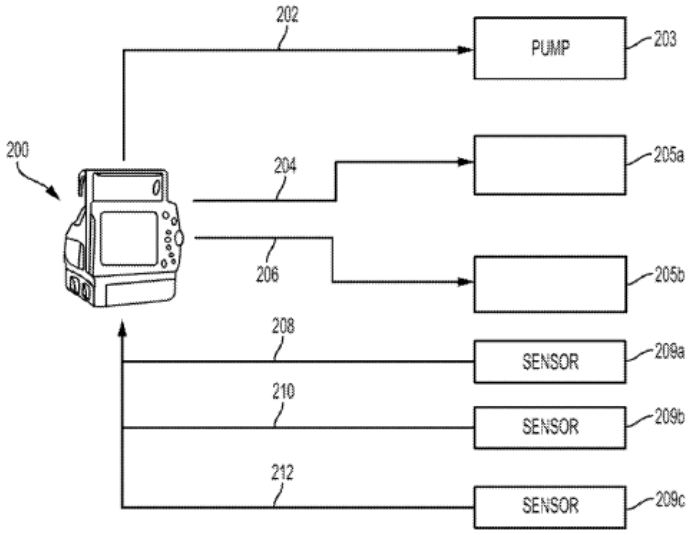



FIG. 10

The only mechanism of action taught in the specification is increasing lymph drainage. (Ex. 1002, ¶ 61; Ex. 1004, ¶ 40.) Although all claims of the '460 Patent require "treating heart failure," the specification does *not* contain that term. In fact, it refers to "heart failure" only twice (Ex. 1004, ¶ 41)—teaching *prevention* of heart failure by lymph removal (Ex. 1001, 7:62-65) or reduction of heart failure through removal and ultrafiltration of blood (14:9-11). However, the claims are not restricted to removing lymph or treating blood through ultrafiltration.

Similarly, although all claims recite "activating the ***one*** or more ***restrictors within the superior vena cava*** to at least partially occlude flow," the specification nowhere describes a single adjustable restrictor occluding the SVC. Instead, the

SVC is adjustably occluded[6] only in the embodiment shown in the annotated version of Figure 27[7] below, which depicts two "restrictions" (*i.e*, the claimed "restrictors") as well as "suction port(s)" between them:

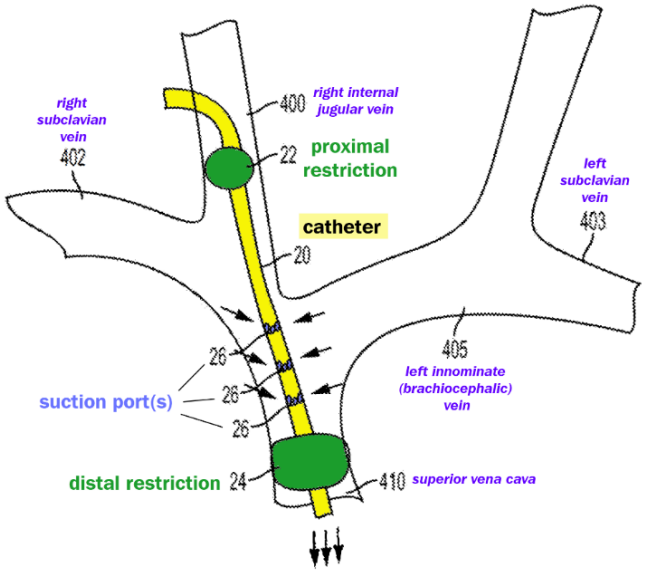


FIG. 27

[6] The specification discloses joining the jugular and SVC with a stent (*e.g.,* Ex. 1001, Fig. 28, 22:21-29), but the stent cannot be adjusted using sensor feedback. (Ex. 1002, ¶ 67.)

[7] The specification erroneously identifies reference number 403 as "left innominate vein," (Ex. 1001, 22:19) and 405 as "left subclavian vein," (22:48-49); 403 and 405 actually reference the subclavian vein and innominate/brachiocephalic vein, respectively. (Ex. 1002, ¶ 65.)

*See* Ex. 1002, ¶¶ 62-68. The specification explains that the purpose of this arrangement is to promote the drainage of lymph into the venous system while allowing blood to continue to flow through the SVC (and into the heart) through the suction ports and out the tip of the catheter. (Ex. 1001, 22:12-20.) None of the claims require the use of two restrictors or using suction, including using suction ports or a pump, to move blood through the SVC.

### C. Prosecution History of the '460 Patent

As initially filed, the claims were directed to a method of treating edema with a single restrictor placed upstream of a lymph duct outflow, or an apparatus with a single restrictor proximal of an inflow port, in each case to create a low-pressure zone downstream of the restrictor. The applicants cancelled all claims in a preliminary amendment and substituted versions of the current method claims.

In the sole office action, the Examiner rejected all pending claims for obviousness-type double patenting, and most claims for anticipation by U.S. Published Patent Appl. No. 2012/0029466 ("Callaghan") and obviousness by Callaghan in view of U.S. Patent No. 8,679,057 ("Fulton"). *See* Ex. 1008, p. 85-92. However, the Examiner believed that "[t]he prior art does not teach or suggest the method . . . wherein the restrictors are adjusted/controlled based on feedback from the pressure sensors." (p. 91.) Such limitations were then found only in dependent claims, but the Examiner indicated that such claims would be allowable

if these limitations were included in independent claims. The applicants then filed terminal disclaimers, added a limitation reciting a sensor-feedback-adjusted restrictor to the existing independent claim and added a new independent claim reciting a sensor-feedback-controlled restrictor. The Examiner then allowed all pending claims "for the reasons set forth in the previous office action." (p. 13.)

As demonstrated below, the prior art in this petition Petition repeatedly teaches the restrictor control/adjustment features found missing from Callaghan, as well as the other limitations of the challenged claims.

**D. Priority Date**

Although the '460 Patent claims priority to U.S. Provisional Application No. 62/006,206, filed on June 1, 2014, its claims are not entitled to this priority date.

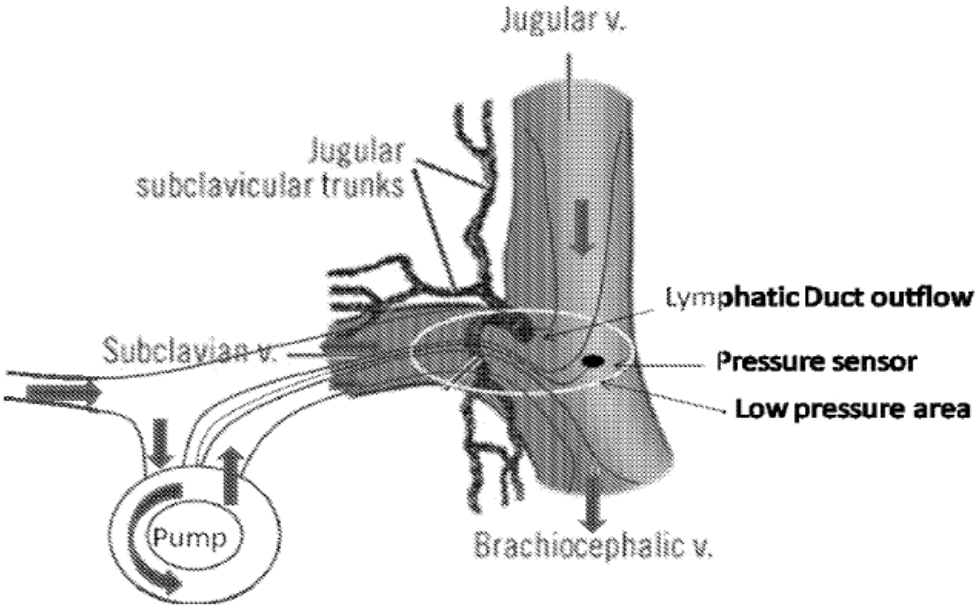
A patent claim has the benefit of the filing date of a provisional application only if that application provides written description support for the claim. *See* 35 U.S.C. § 119(e)(1); *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002). Here, because the provisional cannot support the only independent claims (Claims 1 and 13), it cannot support any of the claims. *See* Ex. 1002, § VI.B.

Claim 1 recites that "***the one or more restrictors*** are ***adjusted*** based on feedback from the one or more pressure sensors," and Claim 13 recites a "c***ontrol***

***module*** that. . . ***controls the one or more restrictors*** based on the ***feedback*** from the one or more sensors." (Ex. 1001, 23:49-51, 24:24-26.) As noted above, the Examiner allowed the challenged claims because of these limitations. However, the provisional does not disclose that sensor data is used to control or adjust a restrictor and thus cannot support the claims.

Figure 3

Acute and/or chronic solution with pressure sensor activating the pump



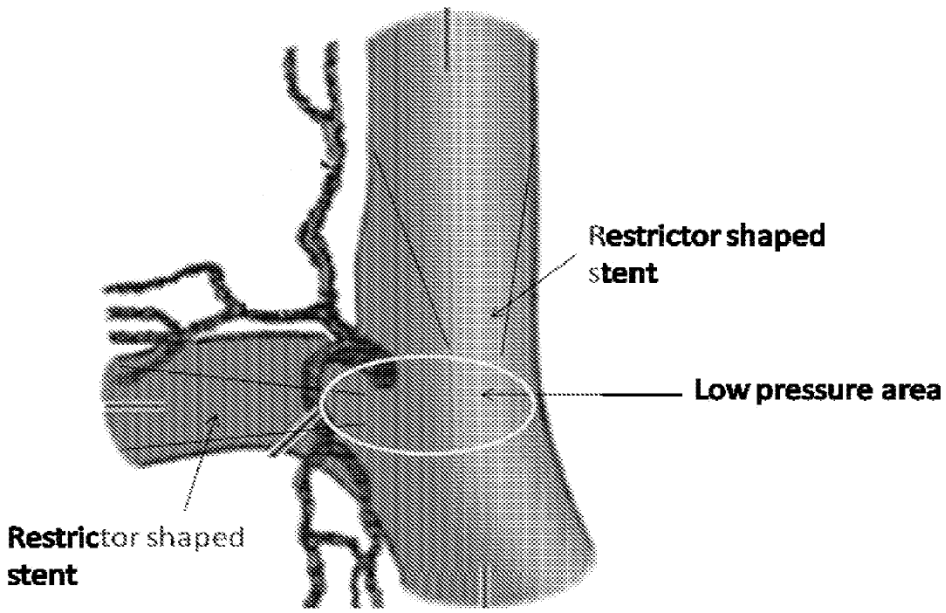

The provisional discloses only that sensor data may be used ***to activate a pump*** to remove fluid near the lymph duct: "a pressure sensor . . . can detect the pressure rise in the lung cavity and actuate the pump to enable higher flow volumes thus enhanced lymphatic clearance." (Ex. 1009, p. 58.) Similarly, Figure 3 of the provisional shows a sensor described only as regulating the work of this pump: "Figure 3 is a schematic illustration of apparatus that includes pressure

sensor that regulate[s] the pump work both in the chronic and the acute devices." (p. 60.) *See* Ex. 1002, ¶¶ 75-76.

Moreover, the provisional does not describe occluding a vein with a controllable or adjustable restrictor. Instead, as shown in Figure 4 below, it teaches placing a stent in the subclavian and jugular veins, but does not teach that this stent can be adjusted. (p. 59; *see also* Ex. 1002, ¶ 77.) When the provisional teaches a balloon, the balloon is implanted in the thoracic cavity, instead of a vein, and works by *increasing* pressure on the lymph vessels themselves instead of reducing pressure in veins near the lymph outflow. (Ex. 1009, p. 59; *see also* Ex. 1001, 21:30-37; Ex. 1002, ¶¶ 78-79.)

Figure 4

Restrictor shaped stent that increases the velocity of the blood and therefore reduces the pressure in the outflow area of the Lymphatic and/or Thoracic duct



In addition, the provisional does not support the Claim 1 and 13 limitations "activating the one or more restrictors ***within the superior vena cava*** to at least partially occlude flow ***through the superior vena cava***." None of the provisional's figures show the SVC, and the provisional only mentions the SVC when describing occluding jugular or subclavian veins and pumping blood into the SVC. (Ex. 1009, p. 57.) Accordingly, the provisional only teaches occluding blood flow in veins other than the SVC, while preserving, not reducing, SVC blood flow. *See* Ex. 1002, ¶¶ 81-84.

Because the provisional does not provide support for any claim of the '460 Patent, the earliest possible priority date for its claims is February 19, 2015, the date of filing of the earliest non-provisional application (No. 14/625,930) to which the '460 Patent claims priority.

### E. Level of Ordinary Skill in the Art

The claims of the '460 Patent are directed to methods of treating heart failure that require use of a medical device. Therefore, a person of ordinary skill in the art (POSA) at the time of the alleged inventions would be a multidisciplinary team consisting of at least (1) a person ("Engineer POSA") with either (a) a bachelor's or master's degree in mechanical engineering, biomedical engineering or a similar field, as well as two or more years of work experience with catheters or similar medical devices, or (b) a Ph.D. in mechanical or biomedical engineering, or

in a similar field; working with (2) a person with an M.D. or analogous degree and five or more years of work experience in interventional cardiology, hemodynamics or a similar discipline ("Clinician POSA"). Alternatively, the POSA would be an Engineer POSA receiving assistance from, or equivalent to that provided by, a Clinician POSA; a Clinician POSA receiving assistance from, or equivalent to that provided by, an Engineer POSA; or a single person with the qualifications of both an Engineer POSA and a Clinician POSA. (Ex. 1002, § VIII; Ex. 1004, § VIII.)

## VI. CLAIM CONSTRUCTION

### A. "maintaining intravascular pressure" (Claim [1f] and [13g])

The specification does not use this term, and it was not defined during prosecution of the '460 Patent.

The ordinary meaning of "intravascular" is "within blood vessels or a blood vessel." (Ex. 1018.) The specification uses the word only in referring to the drawbacks of prior art edema treatments in removing lymph:

> A significant problem with current treatment protocol is that it is based on the need to ***reduce intravascular blood pressure*** to move lymphatic fluid back into the vasculature. The ***reduction of intravascular blood pressure*** leads to leads to hypotension and activates the Renin Angiotenesin Aldesterone System, which leads to an increase in blood pressure.

(Ex. 1001, 1:59-64.) "Maintaining intravascular pressure" could thus be read to mean not reducing pressure like prior treatments, *i.e.*, maintaining systemic pressure, but the specification does not state the alleged inventions do this.

Moreover, the specification uses "maintain" in conjunction with blood pressure in other contexts. For example, it teaches "maintaining" an artificially low pressure zone near the lymph ducts, *i.e.*, by using a sensor to control suction by the pump. (13:5-6 ("maintaining the pressure of the isolated area"), 15:35 ("maintain a low pressure zone").)

In addition to "maintaining" a low-pressure zone, the specification also teaches using a pump to "maintain" blood pressure *outside* that zone, *i.e.*, upstream and downstream of the zone in a two-restrictor embodiment. (17:49-50 ("maintain the jugular and innominate vein pressure"), Figs. 11A, 11B, 15:33-17:33 (discussing feedback loops based on pressure inside and outside the low-pressure zone).)

After reviewing these various teachings, a POSA would conclude that "maintaining intravascular pressure" should be interpreted consistent with the ordinary meaning of "intravascular," *i.e.*, "within blood vessels or a blood vessel." This interpretation encompasses all of these teachings, as opposed to only some of them. Therefore, "maintaining intravascular pressure" should be construed to

mean **"maintaining pressure within blood vessels or a blood vessel."** *See* Ex. 1004, § VII.A.

**B. "distal restrictor" (Claims 10 and 22)**

Claims 10 and 22 recites, "wherein the one or more restrictors comprise ***a distal restrictor*** and the method further comprises measuring a pressure distal of and proximal of the ***distal restrictor***."

As noted above (Section V.B, n.5), the specification expressly defines "distal": "the term 'distal' refers to the portion located furthest from the clinician." (Ex. 1001, 6:42-44.) The specification does not define "distal restrictor," and its meaning was not discussed during prosecution.

Claims 10 and 22 recite "the *one* or more restrictors comprise a distal restrictor," but the specification has no embodiment with a single "distal" restriction. (*Compare* 7:55-57, 10:12-14, 18:24-25 (describing other single restrictions).) It uses "distal restriction" only in describing two-restrictor claim embodiments that have a "proximal restriction" closer to the clinician and a "distal restriction" further away (*e.g.*, 3:5-7, 10:18-22, 17:45-52)—including the only SVC embodiment (22:12-20). However, given the express definition of "distal" and no indication that its meaning varies by number of restrictors, "distal restrictor" should be construed to mean **"the restrictor that is located furthest from the clinician."** *See* Ex. 1002, § VII.B.

### C. "the catheter extends across a vein wall" (Claims 12 and 24)

Claims 12 and 24 depend from Claims 1 and 13, respectively, but there is no antecedent for the term "the catheter." However, Claims 1 and 13 recite "the catheter apparatus," which is apparently synonymous.

The specification does not define or use the term "extends across a vein wall." The only use of "extend" in connection with the catheter are inapposite (*see* Ex. 1001, Abstract, 2:10, 8:14, 11:5-8), as are any uses of "across." (12:33-35, 17:52-56.)

The specification, however, discusses the relationship of the catheter to a "venous wall":

> the ***catheter can alternately be inserted into open veins*** such as the subclavian, external jugular or auxiliary veins. The placement technique is well known to those skilled in the art and it can typically be conducted using a 12 Fr sheath to ***puncture the venous wall***.

(17:40-44; *see also* 19:65-20:6.) This is consistent with how catheters are generally inserted and with how the Examiner of the '460 Patent read this limitation during prosecution: "the catheter is inserted into the vasculature across a vein wall proximal of the superior vena cava." (Ex. 1008, p. 86.)

Therefore, this limitation should be construed to mean **"catheter extends through a vein wall."** *See* Ex. 1004, § VII.B.

### D. "resistors" (Claims 5-7 and 17-19)

Although certain claims recite "***the*** one or more ***resistors***," none of the claims contains an antecedent for the term "resistors," and the specification does not mention any "resistors." However, viewed in the context of the claims, "resistors" was apparently meant to read "restrictors." Moreover, specification passages potentially relevant to the "resistor" claim limitations refer to "restrictions" (*compare* Claim 5 *with* Ex. 1001, 17:54-56; Claim 6 *with* 9:29-32), which are synonymous with "restrictors." Therefore, "resistors" should be construed to mean **"restrictors."** *See* Ex. 1002, § VII.D.

## VII. GROUND 1: CLAIMS 1-10, 12-22, AND 24 ARE ANTICIPATED BY KAISER

### A. Overview of Kaiser

Kaiser is prior art to the '460 Patent under at least post-AIA 35 U.S.C. § 102(a)(2), but was not of record during the prosecution of the '460 Patent or any of its predecessor applications.

Kaiser's application was filed on January 14, 2015, and claims priority to a provisional application filed on January 12, 2014. The priority date of the '460 Patent is no earlier than February 19, 2015, because the June 1, 2014 provisional application does not support any of its claims. (Section V.D.) But even if the '460 Patent were accorded a June 1, 2014 priority date, Kaiser is prior art because its

January 14, 2014 provisional contains the invalidating disclosures of the Kaiser patent, as shown below.[8]

Kaiser is directed to "methods for prevention and/or remediation of heart disease," including in "patients suffering from . . . congestive ***heart failure***." (Ex. 1007, 1:16-20.) Kaiser notes that "[t]he primary treatment for patients with heart failure is to give diuretic medications to reduce total body [fluid] volume" and postulates that "[a] device that is able to induce 'mechanical diuresis' where excess

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[8] In *Dynamic Drinkware, LLC v. National Graphics, Inc*., the Federal Circuit held that under pre-AIA Section 102, a prior art reference patent has the priority date of its provisional application only if the provisional *supports the* ***claims*** of the reference patent. 800 F.3d 1375, 1381-82 (2015); *see also* MPEP § 2136.03 ("*at least one of the* ***claims*** in the reference patent" must be supported). AIA Section 102(d) states that a prior art patent "shall be considered to have been effectively filed, *with respect to any subject matter* ***described*** in the patent . . . as of the filing date of the earliest such [prior filed] application that describes the subject matter." The Federal Circuit has expressly declined to address this inconsistency. *Dynamic Drinkware*, 800 F.3d at 1381 n.2. If the Board finds that *Dynamic Drinkware* applies, Petitioner demonstrates in Appendix A that at least Kaiser Claim 1 is supported by the Kaiser provisional. *See* Ex. 1002, § X.A.3.

fluid is sequestered elsewhere in a patient's body may be able to optimize intracardiac pressures and cardiac output similarly to diuretics." (2:54-55, 59-63.) Kaiser teaches such a solution through

> control[ling] the intra-cardiac filling pressures by creating a pressure differential in a vessel . . . . The pressure differential may sequester extraneous blood volume to the high-capacitance of the venous system . . . manifest[ing] an effective 'mechanical diuresis' to improve myocardial hemodynamics.

(4:57-63; *see also* 2:59-67.) Kaiser also teaches that reducing intracardiac pressure prevents negative heart remodeling. (5:16-18.)

Kaiser accomplishes these goals by using an "adjustable component . . . configured to be placed percutaneously and selectively expanded in the vena cava with a mechanism to induce a pressure gradient." (6:37-40.) While Figure 1, below, shows the adjustable component in the heart, Kaiser teaches that it can also "at least partially fill . . . and/or occlude flow into or through a body lumen . . . *adjacent* the heart." (10:12-14.) The SVC is such a body lumen, and Kaiser specifically teaches that its method and device can be used in the SVC. (6:60-64; *see also* 5:64-6:1, Claim 17.)

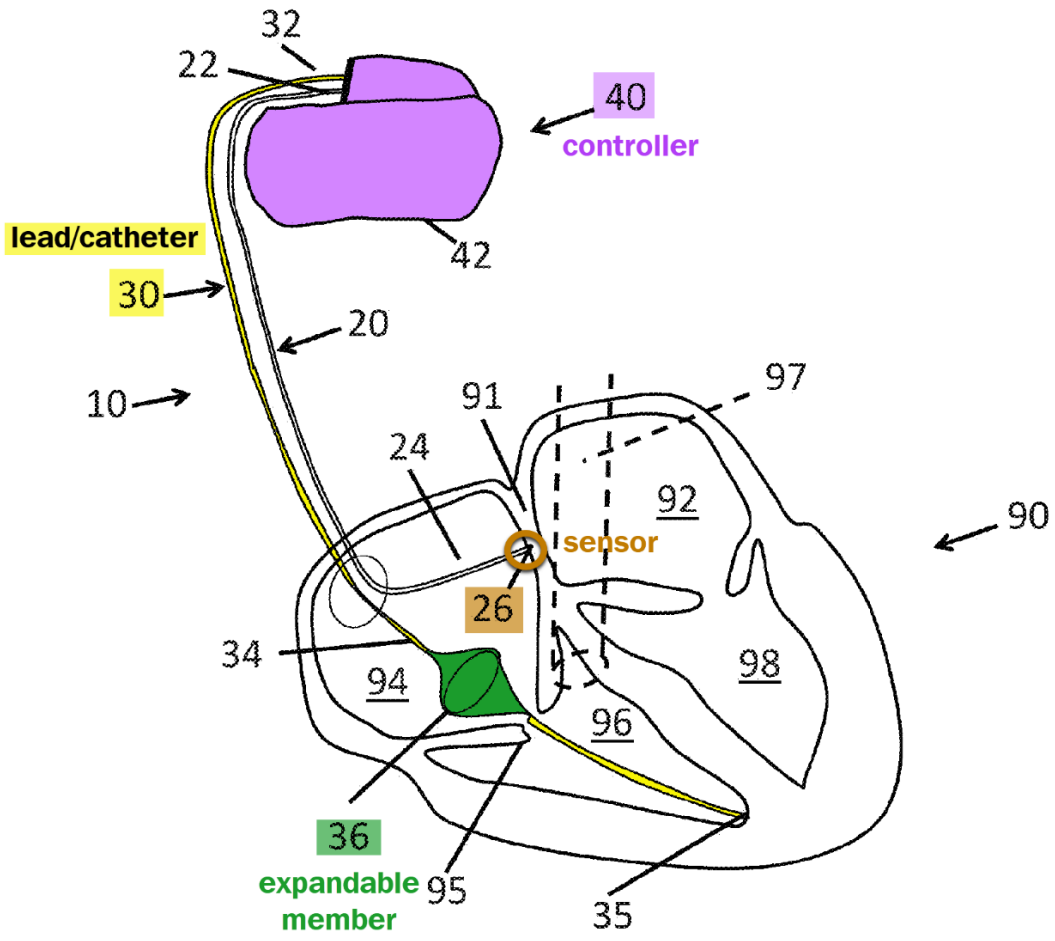



FIG. 1

In Figure 2, below, the adjustable component is shown in the IVC, but as noted above, Kaiser teaches that its method and device may be used in the SVC instead.

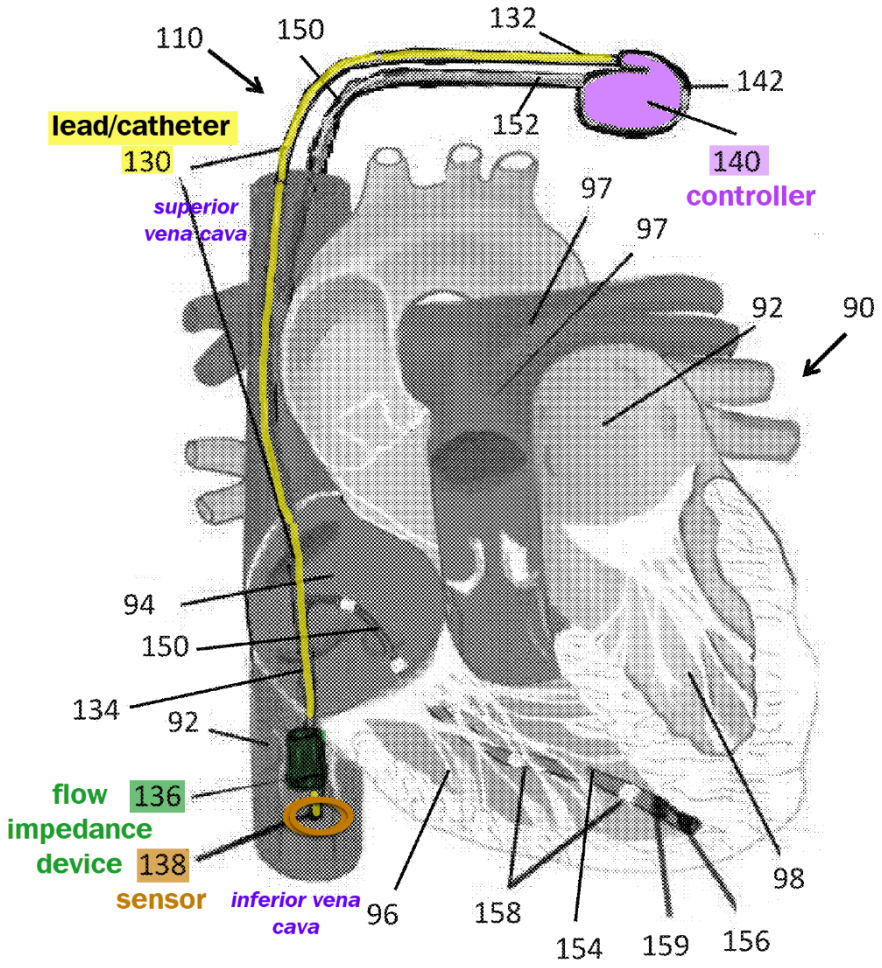



FIG. 2

As shown in Figures 1 and 2, Kaiser's apparatus includes an "elongate member" (highlighted yellow) generally called a "lead" (9:53-57, 10:26-29, 12:11-15, 28-30), but which may be a ***"catheter"*** (*e.g.*, 7:59-64, 10:26-29).[9]

[9] In the Figure 1 embodiment, the relevant lead is identified as "second lead 30," while in the Figure 2 embodiment it is identified as "first lead 130." This Petition will refer to each as simply a "lead/catheter."

To restrict blood flow and induce a pressure gradient, the lead/catheter has an "***adjustable component***," alternatively called "expandable member 36" or "flow impedance device 136," highlighted green. (9:57-58, 12:55-56; *see also* 8:2-4.) This Petition will use "Adjustable Component" to refer to any of these three terms. The Adjustable Component may be a balloon. (10:9-14; *see also* 6:41-43.)

The lead/catheter also has one or more ***sensors***, examples of which are circled in brown in the figures above, "configured to provide sensor data corresponding to pressures within or near the heart."[10] (7:67-8:2; *see also* 9:45-52, 10:4-8, 12:65-13:2.)

Kaiser discloses that the lead/catheter is connected to a "***controller***" identifed with the reference number 40 or 140 and highlighted purple above. (9:33-37, 12:11-15, Figs. 1, 2.) The controller receives input from the sensor(s) and controls the degree of occlusion created by the Adjustable Component. (6:49-51, 10:9-46, 11:3-9, 11:20-23, 12:16-30, 12:52-58, 13:14-18.) *See generally* Ex. 1002, § IX.A.1; Ex. 1004, § IX.A

[10] In Figure 1, the sensor is shown on another lead, but Kaiser teaches that the two leads can be combined. (Ex. 1007, 10:4-9.)

### B. Independent Claims

#### 1. Independent Claim 1

The text of all claims is in Appendix B. Petitioner has added numbering and lettering in brackets ("[1a]," "1[b]," etc.) to facilitate identification.

##### a. Claim [1p]

Kaiser's "invention relates to apparatus, systems, and ***methods*** for prevention and/or ***remediation of heart disease*** . . . [in] patients suffering from conduction disease, atrial fibrillation, and/or congestive ***heart failure***." (Ex. 1007, 1:15-20; *see also* 5:18-25; Ex. 1010, 1:4-6, 5:9-28, 11:1-4.) As discussed below, these methods comprise the remaining steps and components of Claims 1 and 13. *See* Ex. 1004, § IX.C.1.

##### b. Claim [1a]

Kaiser discloses using "a ***catheter***, lead, or other elongate member sized for implantation within a patient's body, e .g., such that at least one end of the lead is positioned within . . . a blood vessel, and/or other body lumen." (Ex. 1007, 7:62-66; Ex. 1010, 7:3-5.) Kaiser generally refers to this component as a "lead," but specifically provides that it "***may be a catheter*** including an inflation lumen." (Ex. 1007, 10:26-27; Ex. 1010, 8:7-9, 15:10-13.) Kaiser's lead/catheter corresponds to the claimed "catheter apparatus."

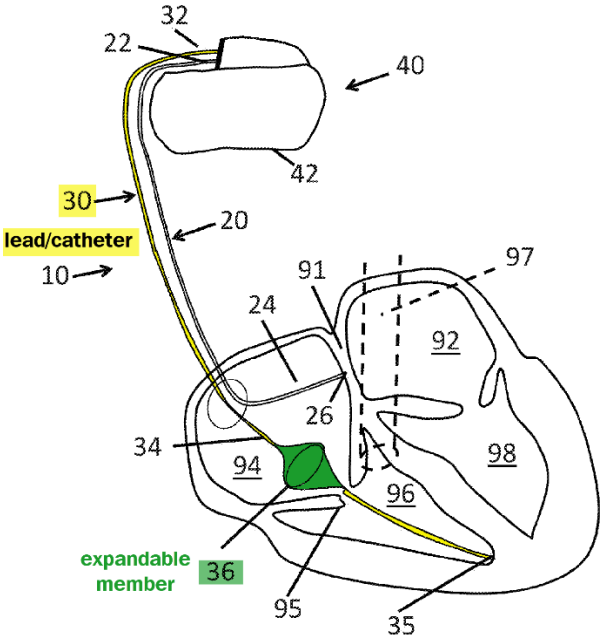



FIG. 1

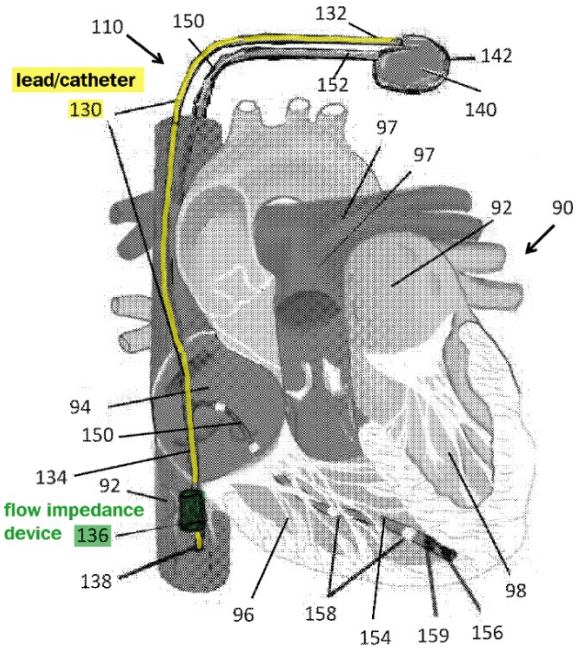



FIG. 2

Kaiser further discloses using an Adjustable Component (the claimed "restrictor"), such as a balloon, located on the lead/catheter to occlude blood flow:

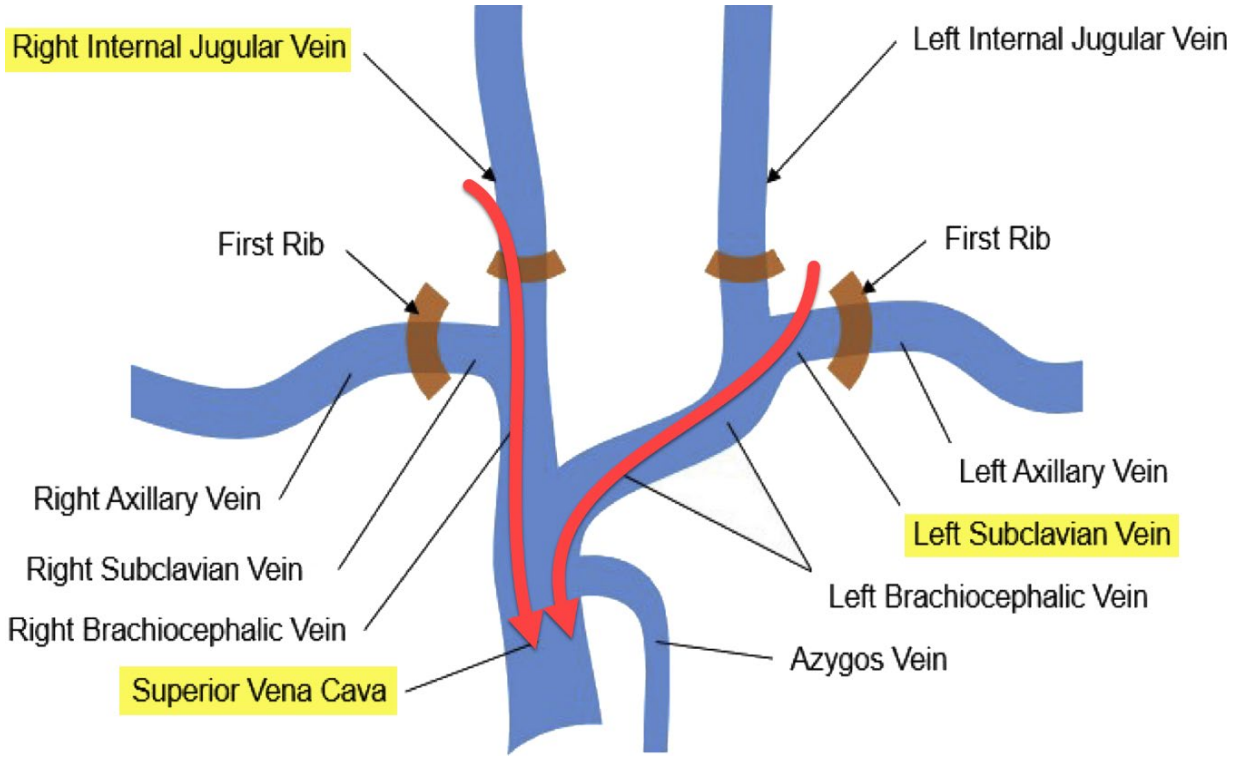
> "The second lead 30 includes an expandable member 36 on the distal end 34 . . . [which] may be a compliant balloon configured to expand between a collapsed configuration and one or more expanded configurations, e.g., that at least . . . occlude flow into or through a body lumen within or adjacent the heart."

(Ex. 1007, 9:57-10:14; *see also* 7:60-8:4, 10:16-46, 12:52-64; Ex. 1010, 7:1-5, 7:21-24, 7:29-8:2, 8:12-18, 15:3-4.) *See* Ex. 1002, § IX.B.1.b.

**c. Claim [1b]**

Kaiser teaches that the Adjustable Component carried by its lead/catheter "may be configured to be placed percutaneously and selectively expanded in the

vena cava," (Ex. 1007, 6:38-39), including the SVC. (6:64; Ex. 1010, 13:20-22.) "Percutaneous" placement refers to inserting the lead/catheter carrying the Adjustable Component through a vein close to the skin surface, and then advancing it deeper into the body via the venous system, thus avoiding invasive surgery to place the Adjustable Component directly in the SVC. A POSA would know that percutaneous insertion encompasses using a jugular or subclavian vein because these veins are large, easily accessed, commonly used in catheterization, and provide a straight and direct route to the SVC. (*See* Section IX.A.) *See* Ex. 1004, § IX.C.2.



**d. Claim [1c]**

Kaiser teaches that its Adjustable Component "may be configured to be placed percutaneously and selectively expanded in the ***vena cava***" (Ex. 1007, 6:37-39) and that the Adjustable Component on the lead/catheter (the claimed "catheter apparatus") can be placed (*i.e.*, "advance[ed]") into the SVC (Section VII.A; Ex. 1007, 5:64-6:1; Ex. 1010, 6:1-3). *See* Ex. 1002, § IX.B.1.d.

**e. Claim [1d]**

Kaiser's lead/catheter includes sensors to measure blood pressure (Ex. 1007, 7:60-8:2 (lead/catheter has pressure sensors), 10:62-64 (controller receives pressure sensor data), 12:65-13:2 (sensor measures pressure upstream of Adjustable Component), Claim 10; Ex. 1010, 8:25-26, 15:3-4), examples of which are circled in brown below.

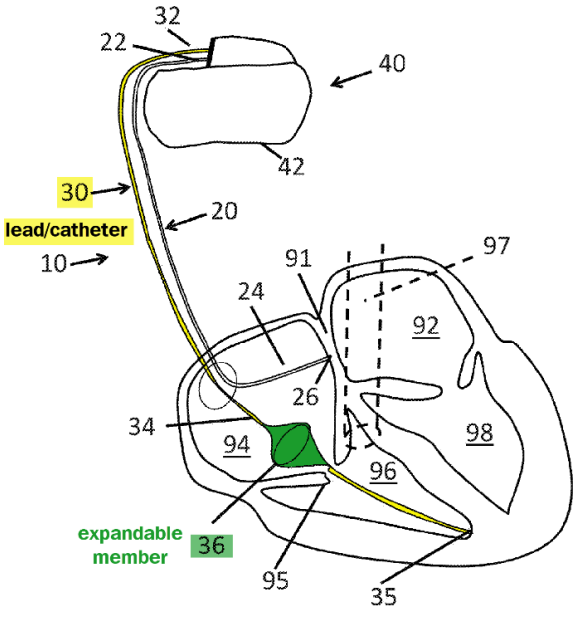



FIG. 1

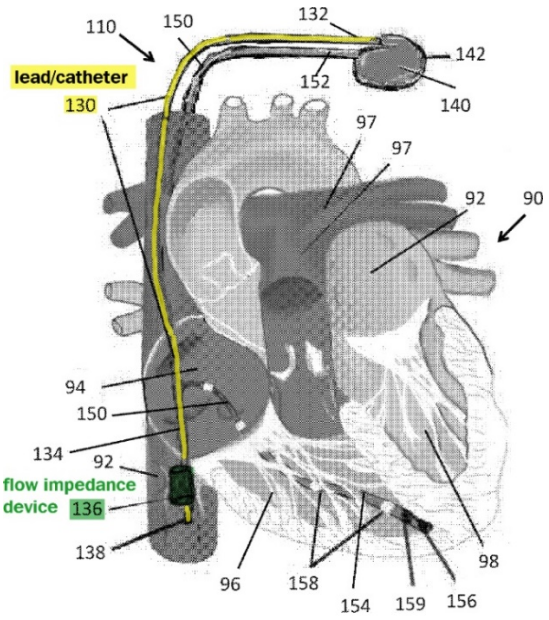



FIG. 2

(*See also* Ex. 1007, 10:4-7 (explaining that the Figure 1 sensor may be on the same lead/catheter as the Adjustable Component); Ex. 1010, 7:26-28.) Kaiser also teaches that additional sensors can be placed in locations such as the SVC, right atrium or pulmonary artery. (Ex. 1007, 6:31-35; Ex. 1010, 10:12-14.) *See* Ex. 1002, § IX.B.1.e.

**f. Claim [1e]**

Kaiser discloses that its Adjustable Component (the claimed "restrictor") "*may be configured to be* placed percutaneously and *selectively expanded in the vena cava* . . . . " (Ex. 1007, 6:37-39; Ex. 1010, 6:1-3, 13:2-9, 13:20-26.) Kaiser further teaches that "the expandable member 36 may be . . . configured to . . . at least partially . . . *occlude flow* into or *through a body lumen* within or *adjacent the heart* 90 . . . ." (Ex. 1007, 10:9-15; Ex. 1010, 7:29-8:2.) Kaiser repeatedly confirms such teachings apply to the SVC; for example: "the adjustable component may create a pressure gradient by at least one of the following . . . *adjusting blood flow impedance through the* ***superior vena cava*** . . . ." (Ex. 1007, 6:60-64; Ex. 1010, 13:20-22; *see also* Ex. 1007, 5:64-6:1, Claims 10, 17; Ex. 1010, 6:1-3.) Occluding the SVC regulates venous blood return and at least partially occludes flow through the SVC. *See* Ex. 1002, § IX.B.1.f.

**g. Claim [1f]**

"Maintaining intravascular pressure" means "maintaining pressure in a blood vessel or vessels." (Section VI.A.) Kaiser maintains intravascular pressure in at least two ways.

First, Kaiser explains that using its invention "move[s] extraneous and congesting fluid to the high capacitance vessels below a pressure gradient device placed within or downstream of the inferior vena cava." (Ex. 1007, 2:64-67.) Through this process "a large volume of blood can be relocated, with a significant decrease in intra-cardiac pressures [but] *only a minimal (if any) increase in pressure below our device*." (3:1-4.) As noted above, Kaiser teaches that its device and method may also be used to occlude the SVC, which produces the same result: pressure downstream of the balloon in the SVC and the heart decreases significantly, while pressure upstream of the balloon remains steady because of the capacitance of blood vessels in the entire upper part of the body.

Second, Kaiser discloses that its device uses blood pressure data from sensors to control and adjust the size of the Adjustable Component to maintain blood pressure at a target level, thereby also "maintaining intravascular pressure." (*E.g.*, Ex. 1007, 11:31-33 ("the controller 40 substantially continuously or periodically or otherwise intermittently acquire[s] pressure data and adjust[s] the

size of the expandable member 36 . . . ."); Ex. 1010, 9:6-13; Sections VII.B.1.h, VII.B.2.d.) *See* Ex. 1004, § IX.C.3.

**h. Claim [1g]**

Kaiser discloses that its Adjustable Component (the claimed "restrictor") is adjusted by the controller based on feedback from sensors: "the controller 40 may *adjust the size and/or configuration of the expandable member 36 over time*, e.g., based upon . . . *pressure measurements*." (Ex. 1007, 11:20-23; Ex. 1010, 9:6-13; *see also* Ex. 1007, 11:31-33, Claims 10, 17; Ex. 1010, 15:10-13.) *See* Ex. 1002, § IX.B.1.h.

**i. Claim [1h]**

The method, components and steps described above are used to treat heart failure. *See* Claim [1p] (Section VII.B.1.a). *See* Ex. 1004, § IX.C.1; Ex. 1002, § IX.B.1.i.

**2. Independent Claim 13**

**a. Claim [13p], [13b], [13c], [13f], [13g] and [13h]**

These limitations are also found in Claim 1 and are discussed above:

| Claim 13 | Claim 1 | Prior Discussion |
|---|---|---|
| [13p] | [1p] | Section VII.B.1.a |
| [13b] | [1b] | Section VII.B.1.c |
| [13c] | [1c] | Section VII.B.1.d |

| | | |
|---|---|---|
| [13f] | [1e] | Section VII.B.1.f |
| [13g] | [1f] | Section VII.B.1.g |
| [13h] | [1h] | Section VII.B.1.i |

**b. Claim [13a]**

As further discussed above (Sections VII.B.1.b and VII.B.1.e), Kaiser discloses advancing a catheter (the claimed "catheter apparatus") that has an Adjustable Component (the claimed "restrictor") and pressure sensors. These pressure sensors correspond to the claimed "sensors." The sensor locations shown in Figures 1 and 2 are circled in brown below.

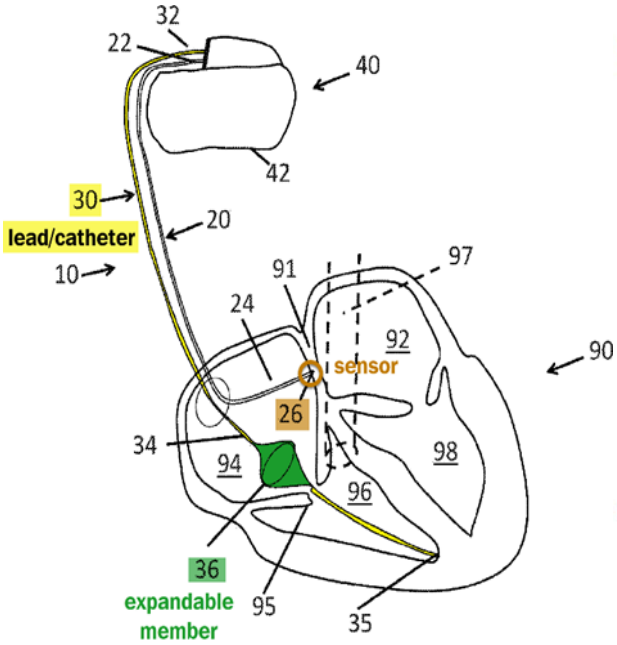



FIG. 1

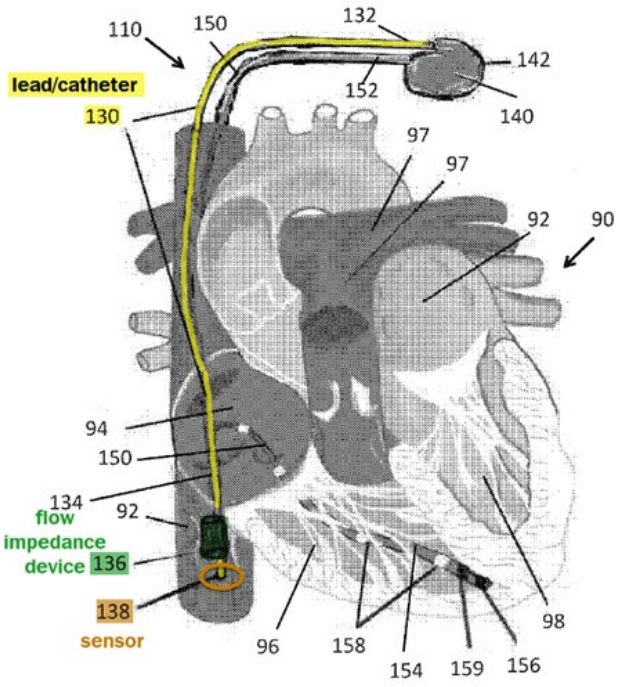



FIG. 2

Kaiser teaches that additional sensors can be placed in locations such as the SVC, right atrium or pulmonary artery. (Section VII.B.1.e.) *See* Ex. 1002, § IX.B.2.b.

**c. Claim [13d]**

Kaiser discloses that its method uses a "controller" (the claimed "control module") that is operably coupled to the lead/catheter (the claimed "catheter apparatus"). (Ex. 1007, 9:34-37; *see also* 8:7-10, 12:28-30, 12:52-54; Ex. 1010, 7:5-10, 13:7-9.) The controller is highlighted purple below:

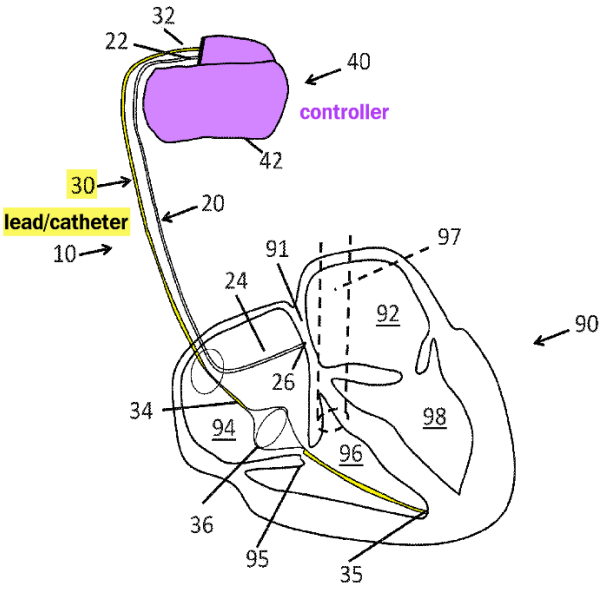



FIG. 1

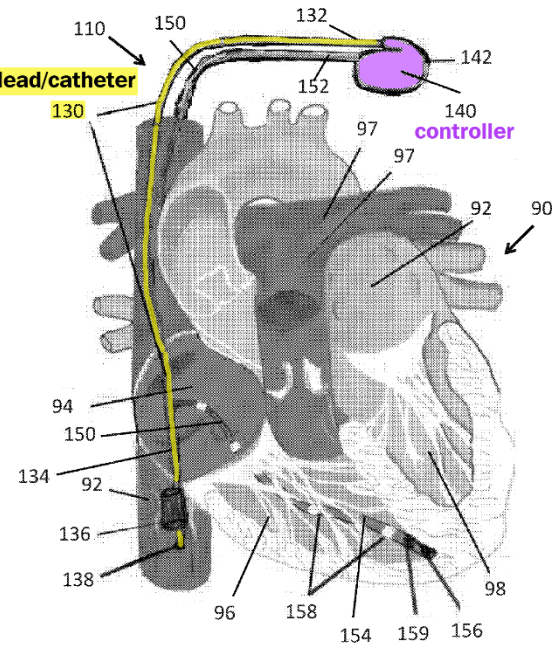



FIG. 2

Kaiser's controller is operably coupled to the catheter because it operates the Adjustable Component ("expandable member") on the catheter:

> controller 40 may include a pump or other source of inflation media . . . which may be delivered into and/or removed from the balloon 36 via the inflation lumen, e.g., to direct the balloon 36

between the collapsed configuration and the one or more expanded configurations.

(Ex. 1007, 10:29-34; *see also* 6:49-51, 10:43-46, 12:55-58, Claims 10, 17; Ex. 1010, 8:7-11, 7:8-10, 8:17-18, 15:10-14.) *See* Ex. 1002, § IX.B.2.c.

**d. Claim [13e]**

Kaiser discloses that its controller (the claimed "control module") receives signals or data (the claimed "feedback") from its catheter's sensors and uses them to control the Adjustable Component (the claimed "restrictor"). (Ex. 1007, 7:66-8:9; *see also* 6:49-51, 7:8-10, Claims 10, 17.) For example, Kaiser teaches that "based at least partially on the signals acquired by the sensor(s) 26, the controller 40 may expand the expandable member 36 to one or more desired sizes. (Ex. 1007, 11:3-5; Ex. 1010, 8:25-29.) Similarly, "first lead 130 may also include a sensor 138 on the distal end 134 . . . [that] may be coupled to the controller 140 to measure the pressure of blood beyond the flow impedance device 136." (Ex. 1007, 12:65-13:2.) Data from this sensor 138, *i.e.,* pressure differentials across the "flow impedance device" (*i.e.*, Adjustable Component), can be used in algorithms that control the pressure differential created by the flow impedance device. (*See* 15:45-16:18, 8:61-62.) *See* Ex. 1002, § IX.B.2.d.

### C. Dependent Claims 2-10, 12, 14-22, 24

#### 1. Claims 2 and 14

Kaiser discloses that "the expandable member 36 may be a compliant balloon . . . [with] one or more *expanded configurations*, e.g., *that* ***at least partially*** fill . . . [a] *body lumen*) *and/or occlude flow into or through a body lumen . . . adjacent the heart*." (Ex. 1007, 10:9-14; *see also* 9:62-64 ("the expandable member 36 may be sized *to expand and* ***at least partially*** *fill* a . . . body lumen"), Claim 11; Ex. 1010, 7:29-8:2.) By specifying that the body lumen (*i.e.*, a vein) is "at least partially" filled and that blood flow is "at least partially" occluded, Kaiser discloses that the Adjustable Component (the claimed "restrictor") can be used to fully fill and occlude the vein, which would fully restrict blood flow. Kaiser confirms this by disclosing that "the balloon 36 may be inflated to a variety of different expanded sizes, e.g., to . . . enhance ***sealing engagement*** between the balloon 36 and surrounding tissue." (Ex. 1007, 10:15-20; Ex. 1010, 8:2-5.) A balloon that has a "sealing engagement" with venous tissue fully restricts flow.

Kaiser expressly teaches that its device may be used in the SVC (*see* Section VII.B.1.d) and does not teach that the extent of occlusion is different there. Because the SVC drains one-third of the venous system into the heart, some period of full occlusion would fulfill Kaiser's objective of "sequester[ing] extraneous blood volume to the high-capacitance of the venous system" to achieve

"mechanical diuresis," as well as "optimizing intracardiac filling pressures and cardiac output." (Ex. 1007, 4:59-60, 6:23, 9:30-31, Abstract; *see also* 2:59-63; Ex. 1010, 1:4-6, 5:9-28, 11:1-4.) *See* Ex. 1004, § IX.D; Ex. 1002, § IX.C.1

**2. Claims 3 and 15**

Kaiser discloses that the Adjustable Component (the claimed "restrictor") "may be an expandable member, e.g., an inflatable ***balloon***." (Ex. 1007, 6:41-43; *see also* 5:64-66, 10:9-10; Ex. 1010, 6:1-3, 7:29-8:2.) *See* Ex. 1002, § IX.C.2.

**3. Claims 4 and 16**

Kaiser discloses that "the expandable member 36 may be a ***compliant*** *balloon* configured to expand between a collapsed configuration and one or more expanded configurations." (Ex. 1007, 10:9-11; *see also* 6:41-43 ("the adjustable component may be an expandable member, e.g., an *inflatable balloon*"); Ex. 1010, 7:29-8:3.) *See* Ex. 1002, § IX.C.3.

**4. Claims 5 and 17**

Kaiser discloses that activating (*i.e.*, expanding) its Adjustable Component (the claimed "restrictor"/"resistor"[11]) creates a pressure gradient across that component: "the adjustable component may ***create a pressure gradient*** by . . . adjusting blood flow impedance through the superior vena cava." (Ex. 1007, 6:60-

[11] "Resistor" is synonymous with "restrictor." Section VI.D.

64; *see also* 11:5-11, 12:55-58, Claim 10; Ex. 1010, 8:30-9:5.) Whenever the Adjustable Component is inflated inside a blood vessel, a new pressure gradient is created: blood pressure upstream of the Adjustable Component increases because less blood flows through the occlusion while pressure downstream of the Adjustable Component decreases. *See* Ex. 1002, § IX.C.4.

### 5. Claims 6 and 18[12]

Kaiser discloses that sensors on its lead/catheter may be distal to the Adjustable Component (the claimed "restrictor"/"resistor"): "the first lead 130 may also include a ***sensor 138*** on the distal end 134 ***distally beyond the flow impedance device 136***." (Ex. 1007, 12:65-67; *see also* Claim 7; Ex. 1010, 10:12-14.) These sensors, which include sensor 138 and sensor 26, are pressure sensors. Distal placement of the sensor 138 is illustrated in Figure 2, where it measures upstream pressure in the IVC:

[12] Claims 6-7 parallel Claims 18-19, except Claims 6-7 recite pressure sensors.

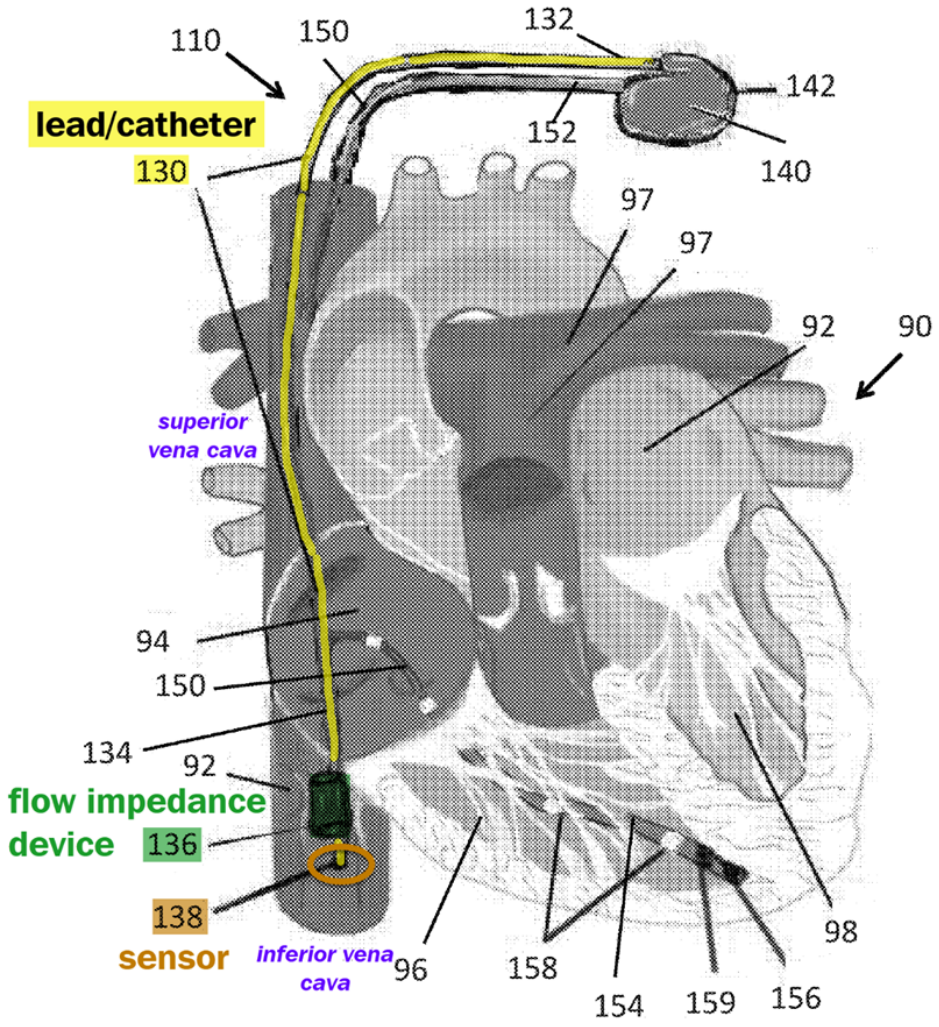
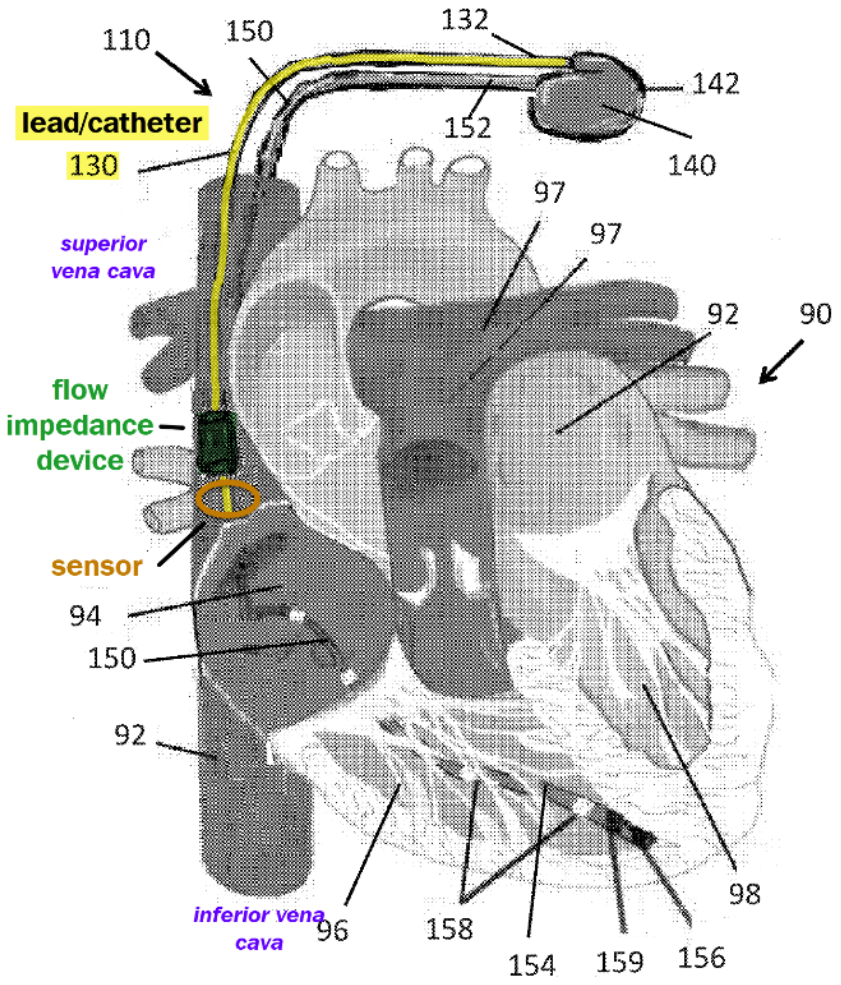



FIG. 2

If the Adjustable Component were moved up to the SVC, this sensor would measure downstream pressure in the SVC, as shown in the modified version of Figure 2 below.




MODIFIED FIG. 2

Additionally, Kaiser discloses placing a pressure sensor in the right atrium and the pulmonary artery (Ex. 1007, 6:31-33; Ex. 1010, 5:29-6:1, 10:12-14, 14:23-25), which are distal to an Adjustable Component placed in the SVC. *See* Ex. 1002, § IX.C.5.

### 6. Claims 7 and 19

Kaiser discloses that its system may have an Adjustable Component (the claimed "restrictor"/"resistor") placed in the SVC (Section VII.B.1.d) and pressure

sensors spaced apart from it, *i.e.*, upstream, in the right atrium and pulmonary artery. (Ex. 1007, 6:31-36, 12:65-67; Ex. 1010, 5:29-6:1, 10:12-14, 14:23-25.) Kaiser's Figure 2 shows the upstream sensor spaced apart from the Adjustable Component.

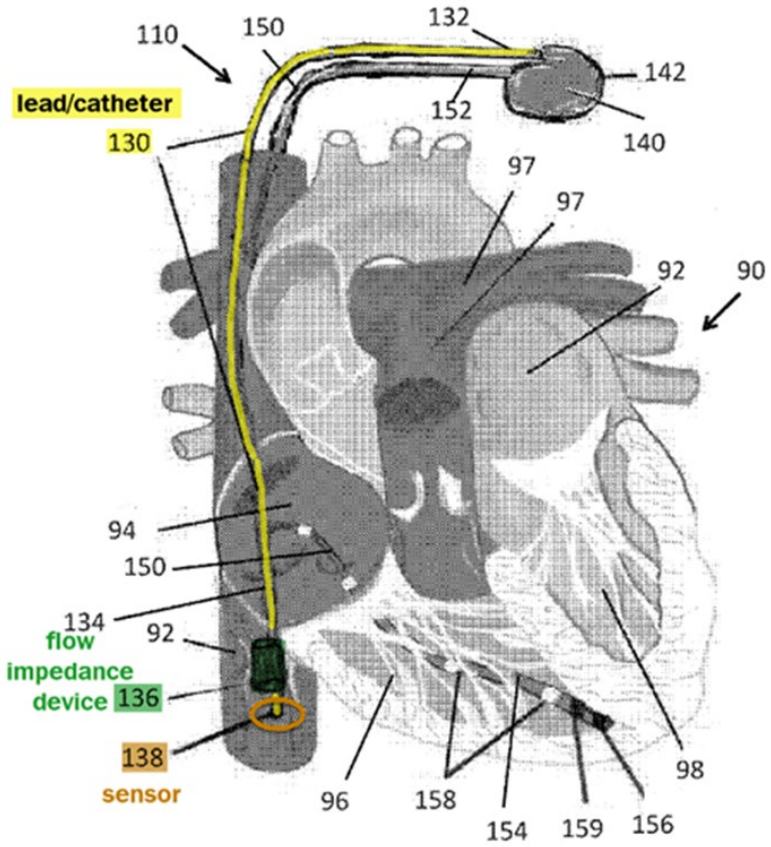



FIG. 2

The upstream sensor 138 is a pressure sensor (Sections VII.B.1.e and VII.C.5). *See* Ex. 1002, § IX.C.6.

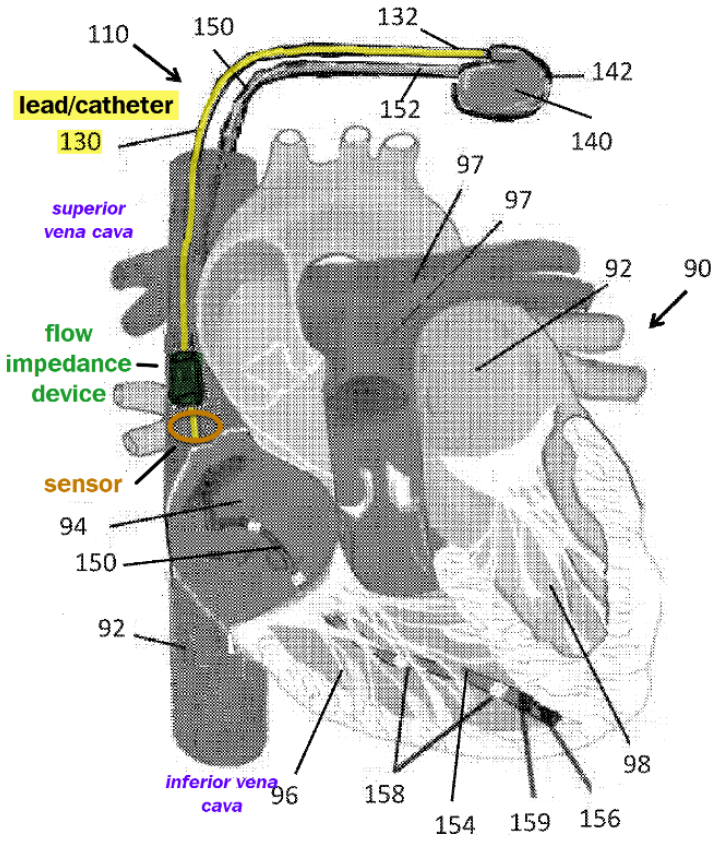
### 7. Claims 8 and 20

Kaiser teaches that that its methods "create a pressure differential [using] one or more shunts, balloons . . . to ***increase a pressure drop*** through the . . .

superior vena cava." (Ex. 1007, 5:65-6:2; Ex. 1010, 6:1-4; *see also* Ex. 1007, 6:60-64; Ex. 1010, 13:20-22.) This is accomplished by expanding (*i.e.*, "activating") an Adjustable Component to create a pressure gradient, which concomitantly creates a downstream pressure drop. *See* Ex. 1002, § IX.C.7.

**8. Claims 9 and 21**

Kaiser discloses placing downstream sensors in the SVC or right atrium to facilitate adjusting the pressure gradient. Specifically, Kaiser teaches that "pressure gradient and heart rate may be adjusted to optimize the filling pressures inside of the heart" (Ex. 1007, 5:31-32), that "[m]onitoring intracardiac filling pressure may include one or more pressure sensors located in the . . . vena cava" (5:37-40), and that pressure can also be sensed in the right atrium (6:33). Either an SVC or right-atrium sensor can monitor heart filling pressure because there is no valve between the SVC and right atrium. As noted above (Section VII.C.5), Kaiser's Figure 2 sensor (138) would monitor downstream pressure if the Adjustable Component were moved to the SVC, as shown below.




MODIFIED FIG. 2

Kaiser also discloses that its Adjustable Component can create a pressure drop in the SVC (Ex. 1007, 5:64-6:2; Ex. 1010, 6:1-4), *i.e.*, downstream of the Adjustable Component. (Section VII.C.7.) This pressure drop would be detected by either the right-atrium or SVC sensor and could be used to adjust the pressure gradient to optimize filling pressure. *See* Ex. 1002, § IX.C.8.

### 9. Claims 10 and 22

"Distal restrictor" means "**the restrictor that is located furthest from the clinician.**" (Section VI.B.) Kaiser discloses that the Adjustable Component is a

distal restrictor because there are no other such components distal to it on the lead/catheter. (*E.g.*, Ex. 1007, Fig. 2.)

In the IVC embodiment, Kaiser discloses measuring pressure proximal to the Adjustable Component, *e.g.*, in the right atrium or pulmonary artery (6:31-35; Ex. 1010, 10:12-14, 5:29-6:1, 14:23-25), which can be used in monitoring intracardiac filling pressures (Section VII.C.8). Kaiser also discloses measuring pressure distal to the Adjustable Component, *i.e.,* upstream in the IVC (Ex. 1007, 12:65-13:2, Claim 7), which a POSA would know would be useful to ensure pressure does not get too high.

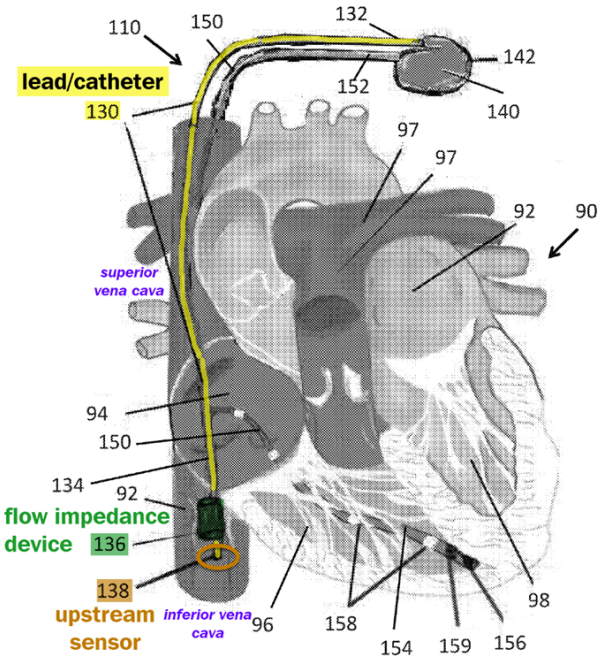
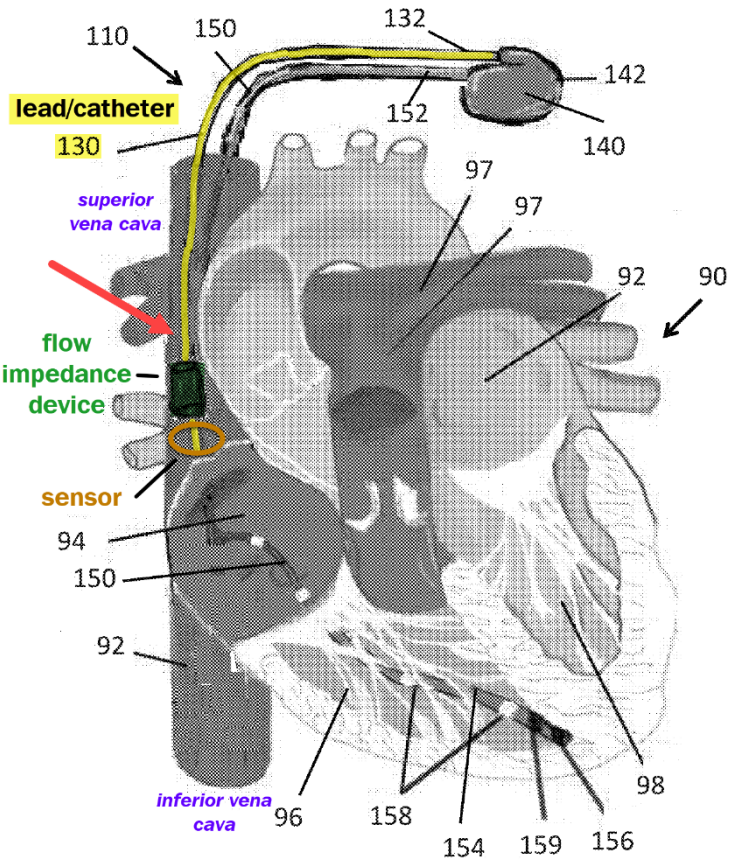



FIG. 2

If the Adjustable Component is in the SVC, as also taught by Kaiser (Section VII.B.1.d), the right-atrium or pulmonary-artery sensor would be distal to

the Adjustable Component. The upstream sensor would be proximal, *i.e.*, in the location shown by the red arrow below:




MODIFIED FIG. 2

*See* Ex. 1002, § IX.C.9.

### 10. Claims 12 and 24

"Catheter extends across a vein wall" means "catheter extends through a vein wall." (Section VI.C.) Kaiser teaches that the Adjustable Component carried by its lead/catheter "may be configured to be placed percutaneously and selectively expanded in the vena cava" (Ex. 1007, 6:38-39), including the SVC. (6:64; Ex.

1010, 13:20-22.) A lead/catheter inserted through any vein except the SVC itself—which would require unnecessarily invasive surgery—would necessarily extend through a vein wall "proximal" of the SVC by definition (Section V.B, n.5) because the insertion site would be closer to the clinician than the SVC. *See* Ex. 1004, § IX.E; Ex. 1002, § IX.C.10.

## VIII. GROUND 2: CLAIMS 1-24 ARE OBVIOUS OVER KAISER AND GELFAND

As demonstrated above, Kaiser discloses a method of treating heart failure by partially or fully occluding the SVC using a lead/catheter with an Adjustable Component whose operation is controlled by a "controller" on the basis of sensor readings. As discussed below, because Gelfand discloses a device used to occlude the SVC that has the same components and features as Kaiser's, it would have been obvious to use Gelfand's device in practicing Kaiser's method of treating heart failure, which would meet each of the claims of the '460 Patent

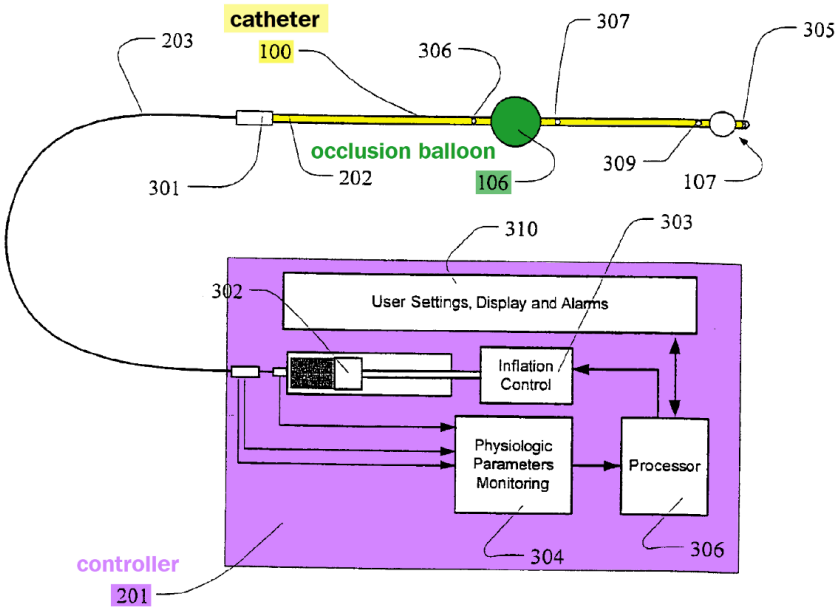
### A. Overview of Gelfand

Gelfand was filed on September 21, 2005, and published on March 23, 2006. Gelfand is prior art to the '460 Patent under at least post-AIA 35 U.S.C. § 102(a)(1), but was not of record during the prosecution of the '460 Patent or any of its predecessor applications.

Gelfand is directed to "reduc[ing] the severity and complications of MI [myocardial infarct, *i.e.*, heart attack] by reducing infarct size and/or expansion by reducing stress (tension) in the wall of the ventricles of the heart by controllably reducing the amount of blood that fill the ventricles." (Ex. 1006, ¶ [0014].) Gelfand notes that "[a]pproximately 85% of these new cases of heart failure are a direct consequence of a large MI." (¶ [0013].)

To reduce complications of MI, including heart failure, Gelfand teaches "reducing tension in the walls of the heart by temporarily partially occluding parts of the circulatory system such as the great veins that re-fill the heart with blood after each ejection cycle." (¶ [0016]; *see also* ¶ [0058].) Gelfand teaches that one of the "great veins" occluded by its method can be the SVC. (¶ [0029].)

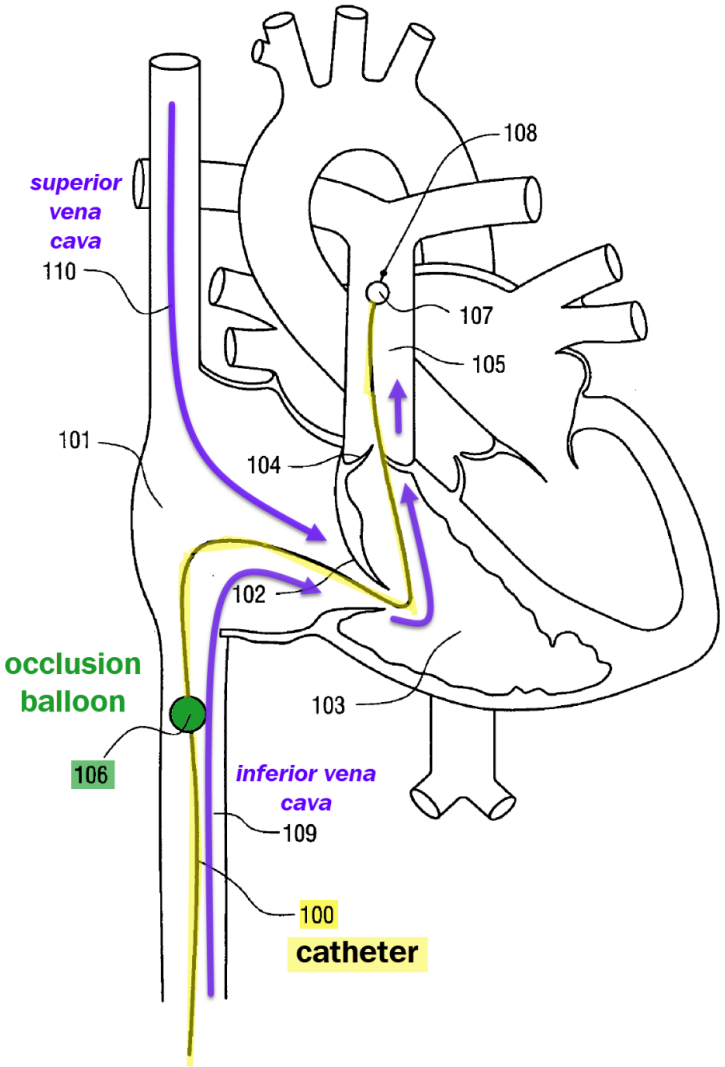
Figure 3



Gelfand explains that "[t]he degree of partial occlusion controls the blood flow." (¶ [0019].) To occlude blood flow, Gelfand discloses a device that "basically consists of the vascular catheter 100, inflatable occlusion balloon 106 proximal to the distal tip 108 of the catheter and the controller 201." (¶ [0031]; *see also* ¶ [0033].) These components are shown in Figure 3, above.

Placement of Gelfand's device in the IVC is illustrated in Figure 1:

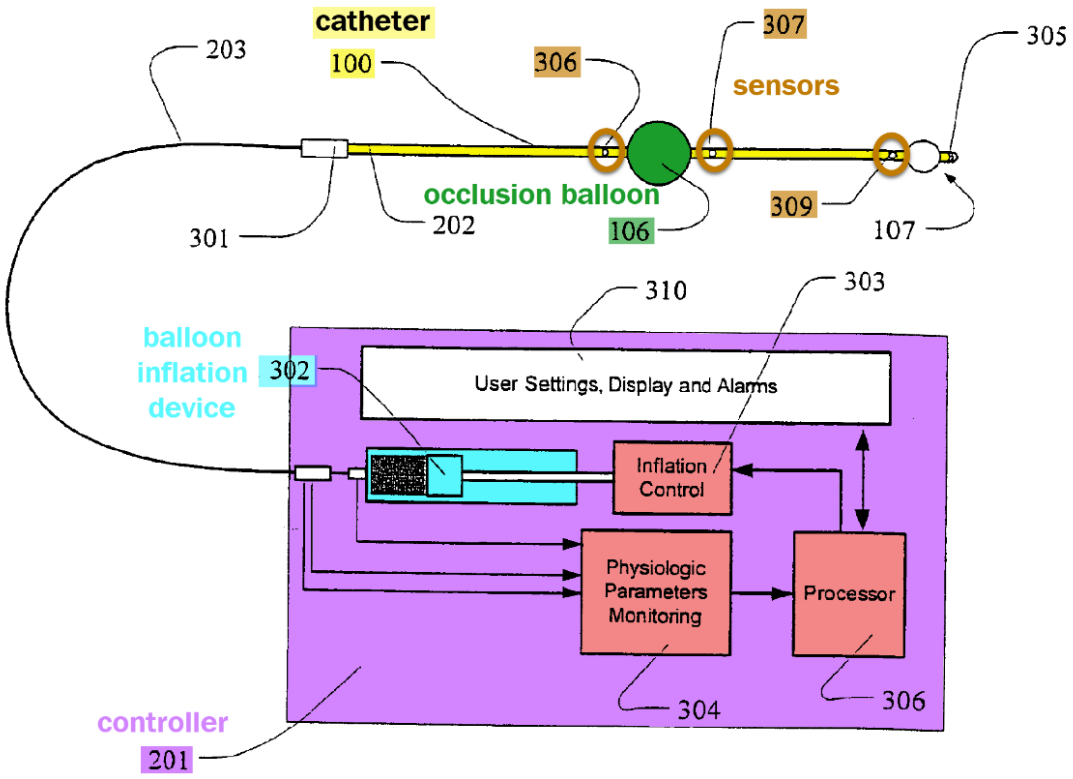
**Figure 1**



However, Gelfand expressly teaches that the device can be placed in the SVC to achieve the same blood-flow-limiting objective without "substantially chang[ing] the invented method, system or device." (¶ [0029]; *see also* ¶ [0017].)

Gelfand further teaches that "[a]dvanced micro tip catheter blood pressure transducers . . . can be integrated with the catheter 100 to obtain reliable and accurate measurements of pressure . . . ." (¶ [0051].) Exemplary pressure sensor locations (*see id.*) are shown circled in brown in Figure 3 below:

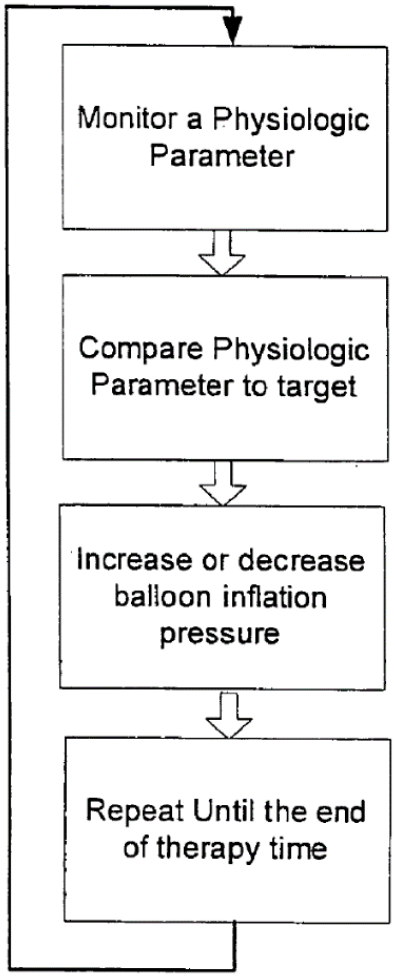
Figure 3




A "controller" (highlighted purple) controls balloon inflation/deflation using a "balloon inflation device" (*e.g.*, a pump), highlighted turquoise, and other

subcomponents, highlighted red, including a processor. (¶¶ [0049]-[0050].) Sensor feedback is used to automatically control and adjust balloon inflation to keep physiologic parameters such as blood pressure within safe limits, as shown in the exemplary algorithm of Figure 4. (¶¶ [0053]-[0054]; *see also* Section VIII.D.1.h.) *See* Ex. 1002, § X.A.

Figure 4



### B. Application of the *Graham* Factors

The analysis in this ground and subsequent obviousness grounds below applies the *Graham* obviousness factors as follows. Factors 1 (scope and content of the prior art) and 3 (differences between the claimed invention and the prior art) are addressed by the discussion of the prior art references, including which references disclose which limitations of Claims 1-24, and by the motivation to combine these disclosures as in the claimed invention with reasonable expectation of success. Factor 2 (level of skill in the art) is addressed in Section V.E and by analyzing the cited references from the perspective of a POSA.

Petitioner is not aware of any relevant secondary considerations (Factor 4), and the patentee has the burden of production. *See ZUP, LLC v. Nash Mfg., Inc*., 896 F.3d 1365, 1373 (Fed. Cir. 2018). Petitioner reserves the right to respond to any alleged secondary considerations advanced by the patentee

### C. Motivation to Combine and Expectation of Success

Kaiser and Gelfand teach methods of treating heart disease by using a device to occlude the SVC, and each teaches that doing so can counteract negative heart remodeling. Kaiser's method treats heart failure using a device whose components and features are analogous to those of Gelfand's device. Each device has a catheter with an adjustable blood-flow-occluding component such as a balloon. Each device is introduced percutaneously and advanced into the SVC. Each device

occludes the SVC to control the amount of blood returning to the heart and creates a pressure differential across the balloon. In each device, a computerized controller adjusts the size of the balloon, and with it the degree of blood occlusion, based on feedback from sensors on the catheter. The differences are in some of their intended effects—in Kaiser, optimized intracardiac pressures and "mechanical diuresis"; in Gelfand, reducing heart wall stress—but these effects are all obtained through the common mechanism of sensor-controlled SVC occlusion.

Accordingly, a POSA would know that Gelfand's vein-occluding device could be used not only to treat MI complications as taught by Gelfand, but also heart failure according to Kaiser's method. A POSA would be motivated to use Gelfand's device instead of Kaiser's because it uses conventional, off-the-shelf components familiar to clinicians—Swan-Ganz catheters, balloon pumps and sensors (Ex. 1006, ¶¶ [0026]-[0028], [0030], [0036]-[0045], [0049])—and describes some features such as sensor operation or balloon operation in greater detail, making the device potentially easier to implement and use. *See generally* Ex. 1002, ¶ 236; Ex. 1004, ¶¶ 92-93, 120, 122. A POSA would have every expectation of success because Gelfand's device has the features of Kaiser's device and the functionality required by Kaiser's method, including percutaneous SVC placement and computerized sensor-controlled occlusion of the SVC according to

Kaiser's algorithms. Additional discussion of motivation to combine and expectation of success is found below. *See* Ex. 1002, § X.B; Ex. 1004, § X.B.4.

### D. Independent Claims

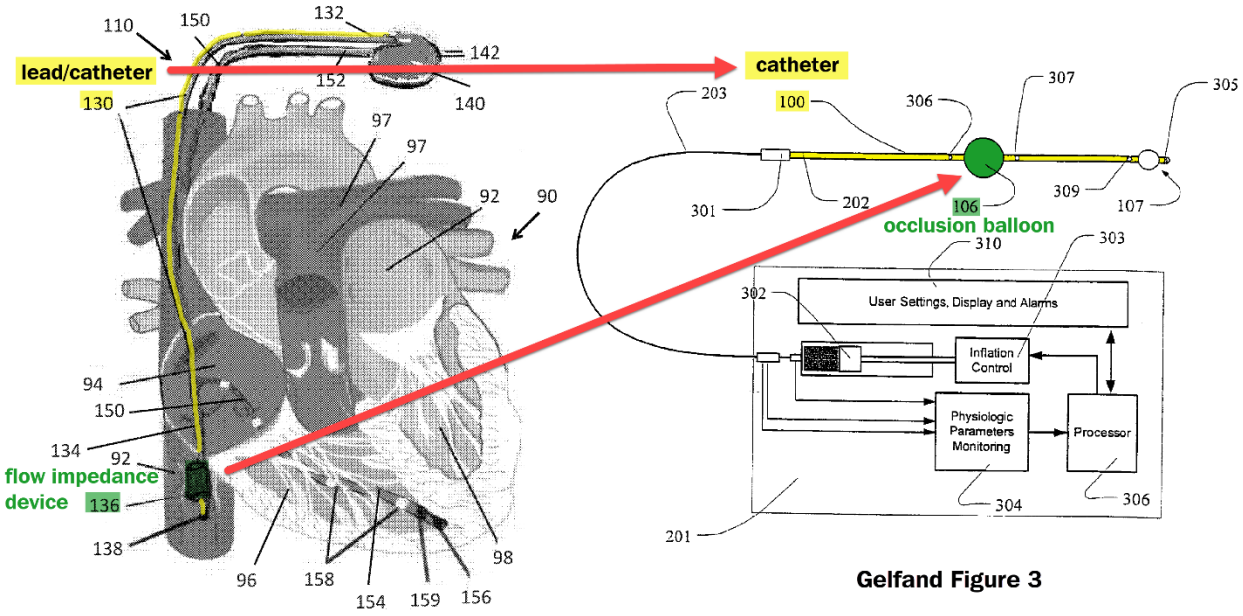
#### 1. Independent Claim 1

##### a. Claim [1p]

Kaiser discloses a method for treating heart failure using a sensor-controlled balloon-catheter-type device to controllably occlude the SVC. (Section VII.B.1.a.) Similarly, Gelfand discloses a method for treating the consequences of an MI (heart attack), including heart failure, by using a device like Kaiser's in essentially the same way as Kaiser to occlude the SVC. (Ex. 1006, ¶¶ [0002]-[0007], [0013]-[0014].) It would have been obvious and straightforward to use Gelfand's device for Kaiser's method, and doing so meets the remaining limitations of Claims 1 and 13, as discussed below. *See* Ex. 1004, § X.B.1; Ex. 1002, § X.C.1.a.

##### b. Claim [1a]

Both Kaiser and Gelfand's methods involve advancing a catheter apparatus with at least one restrictor into a patient, and, as discussed above, these components have the same function in each method.

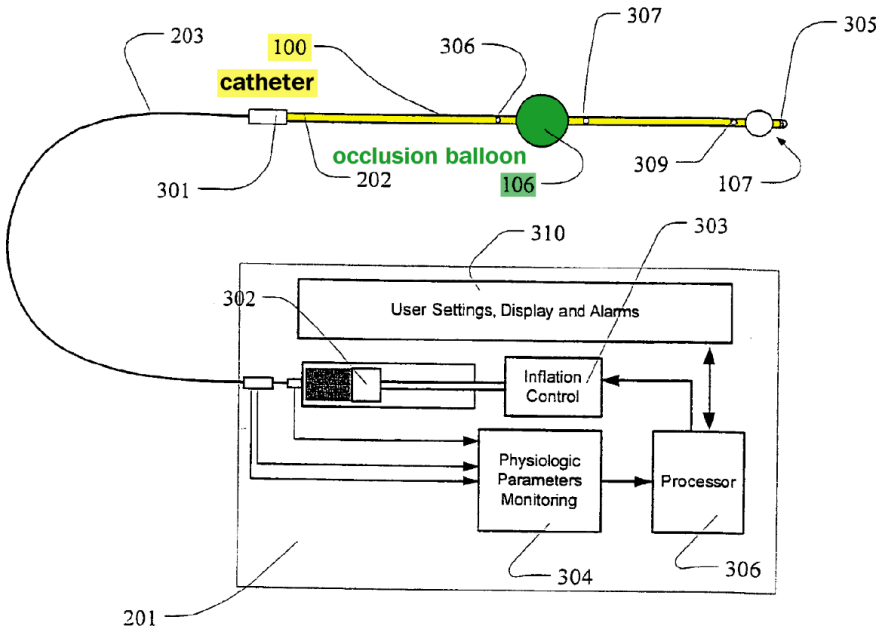



Kaiser FIG. 2

Gelfand Figure 3

Like Kaiser (Section VII.B.1.b), Gelfand provides a ***catheter*** with an ***occlusion balloon*** that can be placed in the SVC. (Ex. 1006, Abstract; *see also* ¶¶ [0018], [0026], [0028]-[0029], [0031], [0048].)

Figure 3



Gelfand's occlusion balloon performs the same function as Kaiser's Adjustable Component and the claimed "restrictor" —to occlude the vessel in which it is deployed (¶ [0018])—and therefore corresponds to the "restrictor." Indeed, the '460 Patent discloses that the "restrictor" may be a balloon. (Ex. 1001, 2:19-21.) *See* Ex. 1002, § X.C.1.b.

**c. Claim [1b]**

Kaiser teaches that the Adjustable Component carried by its lead/catheter may be placed "percutaneously" in the SVC. (Section VII.B.1.d.) Percutaneous placement refers to inserting the lead/catheter carrying the Adjustable Component through a vein close to the skin surface, and then advancing it deeper into the body via the venous system, thus avoiding unnecessarily invasive surgery to place the Adjustable Component directly in the SVC.

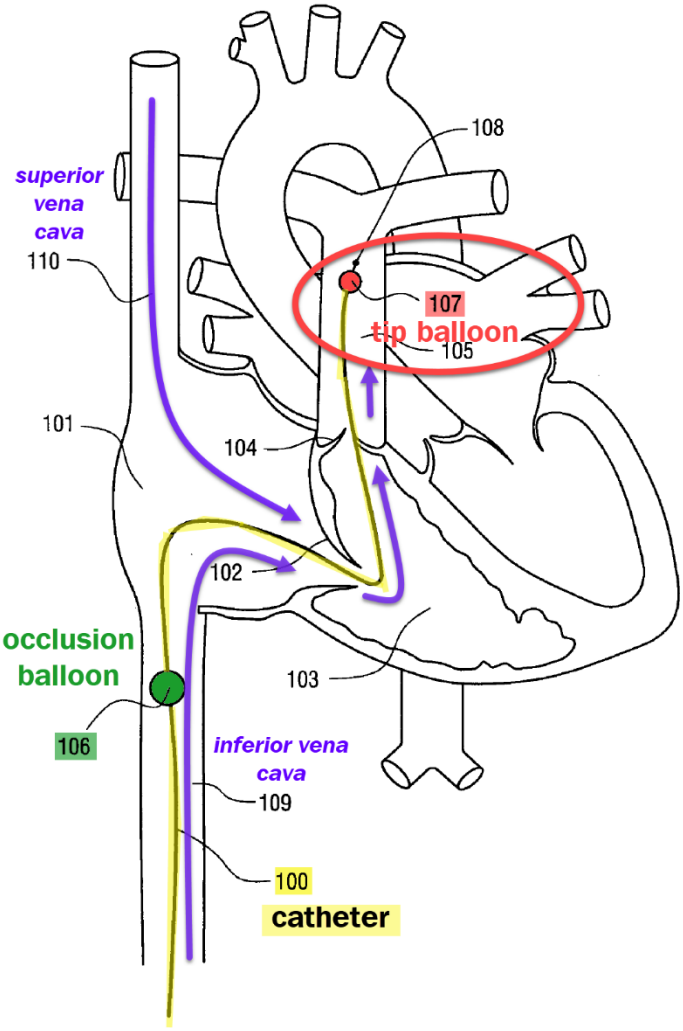
Gelfand also teaches percutaneous insertion of its catheter and occlusion balloon, and does so with reference to particular veins. In its exemplary embodiment, Gelfand teaches advancing the catheter through the femoral vein to place its balloon in the IVC (Ex. 1006, ¶¶ [0028], [0032]), but Gelfand also expressly teaches positioning the balloon in the SVC (Ex. 1006, ¶ [0029]).

Gelfand explains that its "catheter 100 [] is similar to a common Swan-Ganz right heart catheterization catheter" (¶ [0026]), and that "[d]uring catheterization using a standard Swan-Ganz, a physician inserts the catheter 100 into the right side

of the heart through a large vein. ***Typically, a vein in the right side of the neck*** is used" (¶ [0027]). The right internal and external jugular veins are the only large veins on the right side of the neck, and the right internal jugular vein is commonly used in Swan-Ganz catheterization because it is larger, is easily accessible, and provides the shortest distance to the heart. (Ex. 1004, ¶¶ 109; Ex. 1012.) From the internal jugular vein, a catheter can advance through the SVC to enter the right atrium of the heart and may extend further into the heart and pulmonary artery. (Ex. 1006, ¶ [0027].)

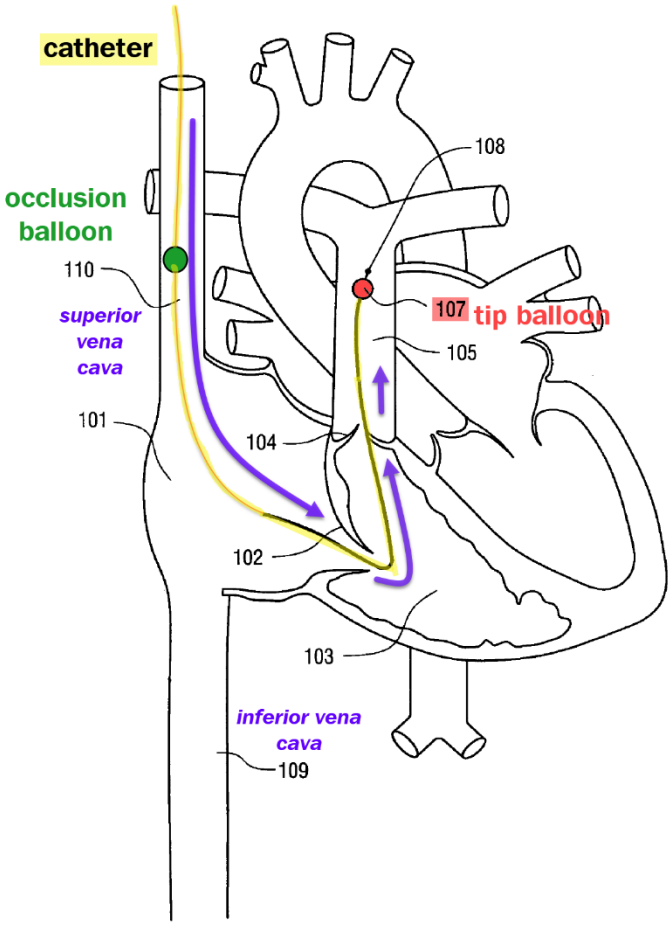
Accordingly, to place Gelfand's occlusion balloon in the SVC, a POSA would use the common Swan-Ganz technique discussed by Gelfand of inserting and advancing the catheter through a large neck vein, *i.e.*, a jugular vein. This technique utilizes the placement features included on a Swan-Ganz catheter and Gelfand's catheter. (Ex. 1006, ¶¶ [0026]-[0028], [0032].) Gelfand discloses that its catheter, just like the Swan-Ganz catheter, has a small "conventional distal 1.5-cc PA balloon 107" at its distal tip. (¶¶ [0028], [0032].) This tip balloon harnesses blood flow to place the catheter: "Catheter floats into the heart chambers following the flow of blood that carries with it the tip balloon 107." (¶ [0032].) The tip balloon is highlighted red below, while blood flow direction is shown by arrows. *See* Ex. 1004, ¶¶ 104-106.

**Figure 1**




If the catheter were inserted through the femoral vein and the tip balloon were carried through the heart as intended, to place the occlusion balloon in the SVC, the catheter would have to advance partway into the SVC and then make a U-turn. Consequently, the catheter should instead be inserted upstream of the SVC, as shown in (modified) Figure 1 below.

**Figure 1**




A POSA also knows that jugular insertion typically provides a shorter, safer and more direct path to the SVC. *See* Ex. 1004, ¶¶ 107-110; Section IX.A.

A POSA using Gelfand's device to practice Kaiser's method would be motivated to follow Gelfand's teachings for placing that device in the SVC—inserting and advancing the catheter through a jugular vein, as in Gelfand's description of Swan-Ganz catheterization. (Ex. 1006, ¶ [0027].) The POSA would have a reasonable expectation of success for the reasons discussed in Sections

VII.C.1, VIII.C, X, including because the jugular vein "is often the access site of choice" (Ex. 1012, p. 4) for this type of conventional catheterization. The resulting combination of using Gelfand's placement technique to advance Gelfand's device to the SVC to practice Kaiser's occlusion method discloses Claim [1b], rendering it obvious. *See* Ex. 1004, § X.B.2; Ex. 1002, § X.C.1.c; s*ee also* Ex. 1004, § IX.C.2.

**d. Claim [1c]**

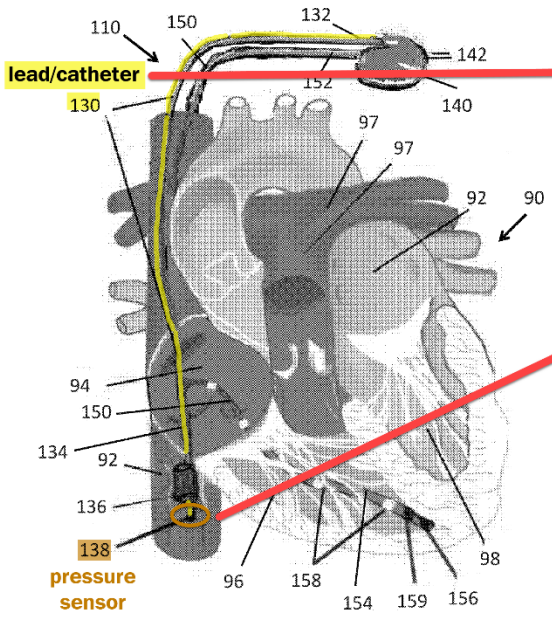
Kaiser teaches that its lead/catheter and Adjustable Component are inserted percutaneously and advanced into the SVC. (Sections VII.B.1.c, VII.B.1.d.)

Gelfand discloses that the catheter is inserted percutaneously, through a puncture in a vein proximal to the IVC, and then "*advanced* downstream (towards the heart) into the venous tree *into the IVC* . . . ." (Ex. 1006, ¶ [0032]; *see also* ¶ [0028], Fig. 2 (showing catheter advanced so that balloon is positioned in the IVC).)

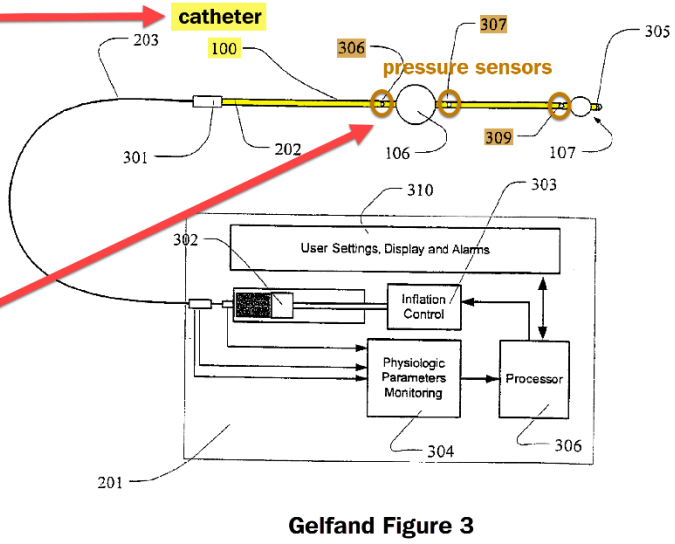
Gelfand also teaches that "it is understood that the occlusion balloon 106, shown in the IVC 109, can be positioned in other places . . . such as . . . ***Superior Vena Cava (SVC)*** . . . [without] substantially chang[ing] the invented method, system or device." (¶ [0029]; *see also* Ex. 1002, ¶ 252-53.) Gelfand thus discloses that its catheter can be advanced into the superior vena cava of a patient as in Kaiser's method. *See* Ex. 1002, § X.C.1.d.

**e. Claim [1d]**

Both Kaiser and Gelfand disclose pressure sensors on their respective catheters.




Kaiser FIG. 2

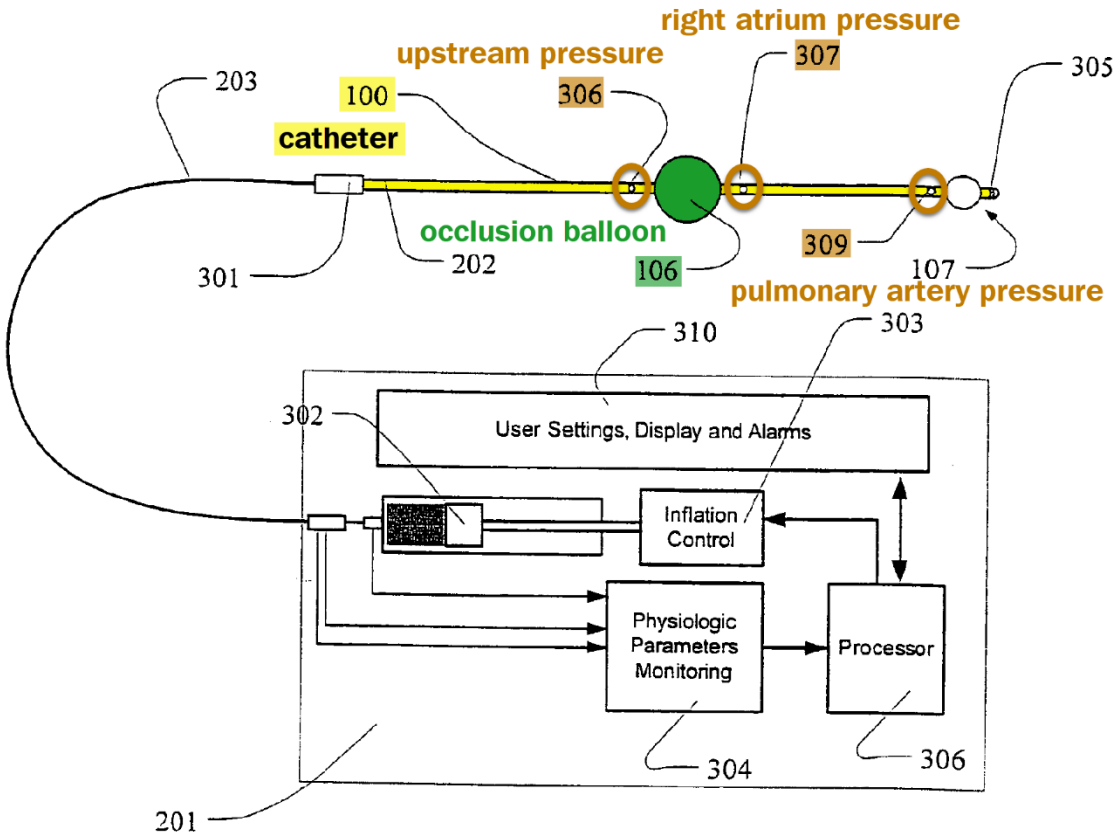



Gelfand Figure 3

Kaiser discloses that its lead/catheter may contain one or more pressure sensors, whose locations include upstream of the restrictor, and in the SVC, right atrium or pulmonary artery. (Section VII.B.1.e.)

Gelfand teaches that one or more of the sensors in its catheter can be pressure sensors: "Other[] sensors located along the shaft of the catheter 100 can include . . . miniature solid-state pressure sensors." (Ex. 1006, ¶ [0046]; *see also* ¶ [0051] ("[a]dvanced micro tip catheter blood pressure transducers . . . can be integrated with the catheter"; sensors located upstream of balloon, in right atrium and in pulmonary artery), ¶¶ [0036]-[0040], [0043]-[0046] (listing commercially

available catheters with pressure sensors), Claims 6, 8.) These sensors are in the same locations, and are connected to Gelfand's controller for the same purposes, that are taught by Kaiser (Sections VII.B.1.e, VII.B.1.h, VII.B.2.d.):




A POSA using Gelfand's device to practice Kaiser's method would thus be motivated to use Gelfand's pressure sensors, and would have a reasonable expectation of success in doing so. *See* Ex. 1002, § X.C.1.e.

**f. Claim [1e]**

Kaiser discloses operating its lead/catheter to regulate venous blood return to the heart through the SVC by activating (*i.e.*, inflating) the Adjustable Component

to at least partially occlude flow through the SVC. (Section VII.B.1.f.) Gelfand discloses that the occlusion balloon (the claimed "restrictor") on its catheter performs the same functions.

Gelfand teaches that its invention "relates to the reduction of the volume of the heart by partial occlusion of the vena cava" (Ex. 1006, ¶ [0003]; *see also* ¶¶ [0016], [0058]); that "the amount of venous blood returning to the heart (filling the heart) is reduced by creating a partial temporary obstruction (occlusion)" (¶ [0018]); and that "[o]bstruction can be achieved with an intravascular inflatable balloon placed inside the IVC" (*id.*). Gelfand confirms that "[t]he degree of partial occlusion controls the blood flow." (¶ [0019].)

Gelfand emphasizes that its teachings, including "reducing the filling of the heart," can be practiced in the SVC. (¶ [0029].) The specifics of how Gelfand's catheter balloon is inflated and operated are not altered by placement in the SVC. (*Id.*; Ex. 1002, ¶ 265.) Thus, inflating ("activating") Gelfand's balloon in performing Kaiser's method results in the claimed regulation of venous blood return and occlusion of blood flow through the SVC. *See* Ex. 1002, § X.C.1.f.

**g. Claim [1f]**

Maintaining intravascular pressure" means "maintaining pressure within blood vessels or a blood vessel." (Section VI.A.) Kaiser discloses that its method of treating heart failure by occluding the SVC maintains intravascular pressure in

several ways. (Section VII.B.1.g.) Because a POSA motivated to use Gelfand's device to practice Kaiser's method would occlude the SVC in exactly the manner taught by Kaiser, Gelfand's device would also successfully maintain intravascular pressure in the ways taught by Kaiser. *See* Ex. 1004, § X.B.3; Ex. 1002, § X.C.1.g.

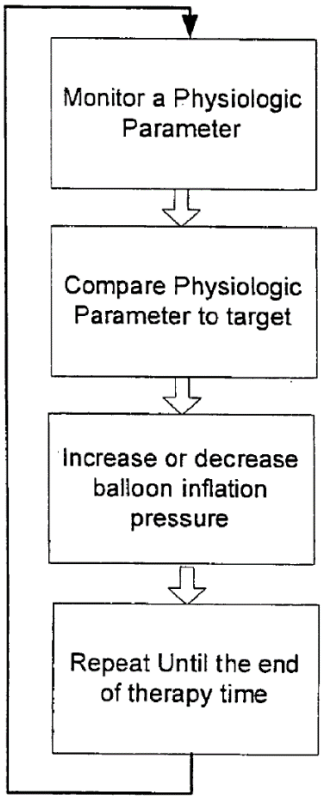
**h. Claim [1g]**

Kaiser discloses that its Adjustable Component is adjusted by the controller based on feedback from sensors. (Section VII.B.1.h.) Gelfand's balloon (the claimed "restrictor") is similarly adjusted.

Gelfand teaches that the catheter's sensors can monitor a variety of physiologic parameters, including blood pressure (*e.g.,* Ex. 1006, ¶ [0051]; *see also* ¶¶ [0036]-[0046]; Sections VIII.A, VIII.D.1.e). Gelfand also teaches that its sensors send these physiologic parameters (the claimed "feedback") to the controller (¶ [0051]), which uses them to adjust Gelfand's balloon (the claimed "restrictor"):

> FIG. 4 exemplifies one possible fully automatic algorithm embedded in the software of the controller processor 306. Physiologic parameters indicative of the performance of the patient's heart are monitored continuously . . . . Each one of these parameters can be used as a *feedback to control the inflation of the occlusion balloon* 106 . . . . Software algorithm compares the selected parameter to the target values . . . . Algorithm commands the inflation or deflation of the balloon based on these physiologic *feedbacks* with the objective of achieving the desired safe values . . . .

Figure 4




(¶¶ [0052]-[0053]; *see also* ¶¶ [0019] (reducing size of balloon based on low blood pressure data), [0051], [0054] ("Control signals can be applied continuously or periodically to adjust the size of the balloon."), Claim 9.) As a result, Gelfand's computerized controller could successfully execute adjustment algorithms of Kaiser's method. *See* Ex. 1002, § X.C.1.h.

**i. Claim [1h]**

Kaiser's invention is directed to the treatment of heart disease, including in patients suffering from congestive heart failure. (Section VII.B.1.a.) Because its components and functions are all found in Gelfand's device, as described above, Gelfand's device could also be used in Kaiser's method of treating heart failure.

The resulting combination comprises the prior steps and components recited in Claim 1. Ex. 1004, § X.B.1; Ex. 1002, § X.C.1.i.

### 2. Independent Claim 13

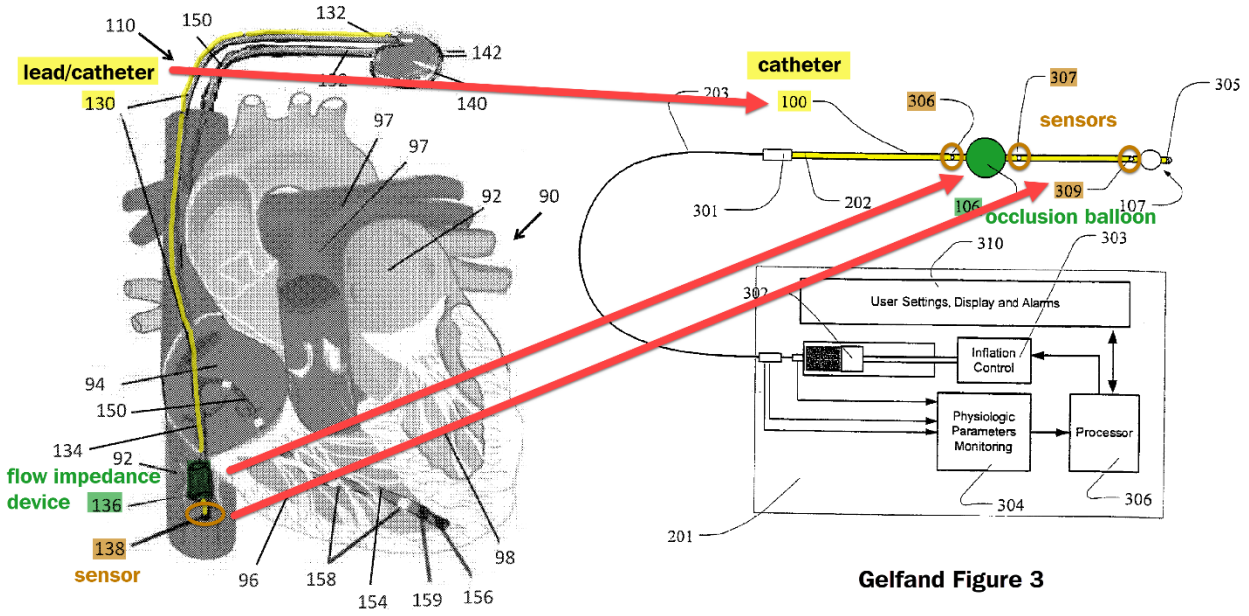
#### a. Claim [13p], [13b], [13c], [13f], [13g] and [13h]

These limitations are also found in Claim 1 and are discussed above:

| Claim 13 | Claim 1 | Prior Discussion |
|---|---|---|
| [13p] | [1p] | Section VIII.D.1.a |
| [13b] | [1b] | Section VIII.D.1.c |
| [13c] | [1c] | Section VIII.D.1.d |
| [13f] | [1e] | Section VIII.D.1.f |
| [13g] | [1f] | Section VIII.D.1.g |
| [13h] | [1h] | Section VIII.D.1.i |

#### b. Claim [13a]

As further discussed above (Sections VIII.D.1.b and VIII.D.1.e), Kaiser and Gelfand each disclose advancing a catheter apparatus with at least one sensor and at least one restrictor into a patient.




Kaiser FIG. 2

Gelfand Figure 3

*See* Ex. 1002, § X.C.2.b.

### c. Claim [13d]

Kaiser discloses providing a system using a controller that is operably coupled to the lead/catheter. (Section VII.B.2.c.)

Similarly, Gelfand discloses providing a system in which its catheter is attached (*i.e.*, "coupled") by a "flexible conduit 203" to a component corresponding to the claimed "control module." Gelfand generally refers to this component as "controller 201" (*e.g.*, Ex. 1006, ¶ [0031]) but sometimes as "control and monitoring console 201" (¶¶ [0035], [0048]).

In Figures 2 and 3 below, the flexible conduit is teal, while the controller is purple and the catheter is yellow.

**Figure 2**

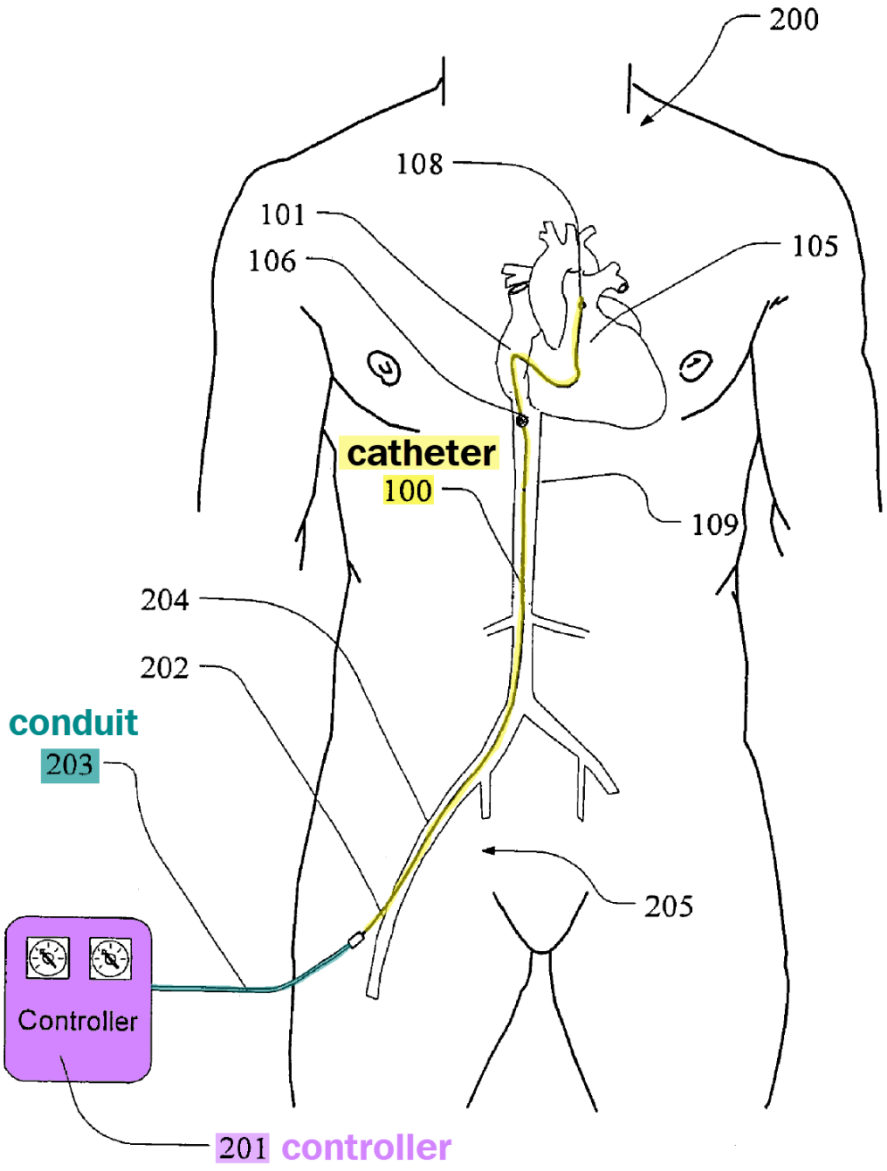
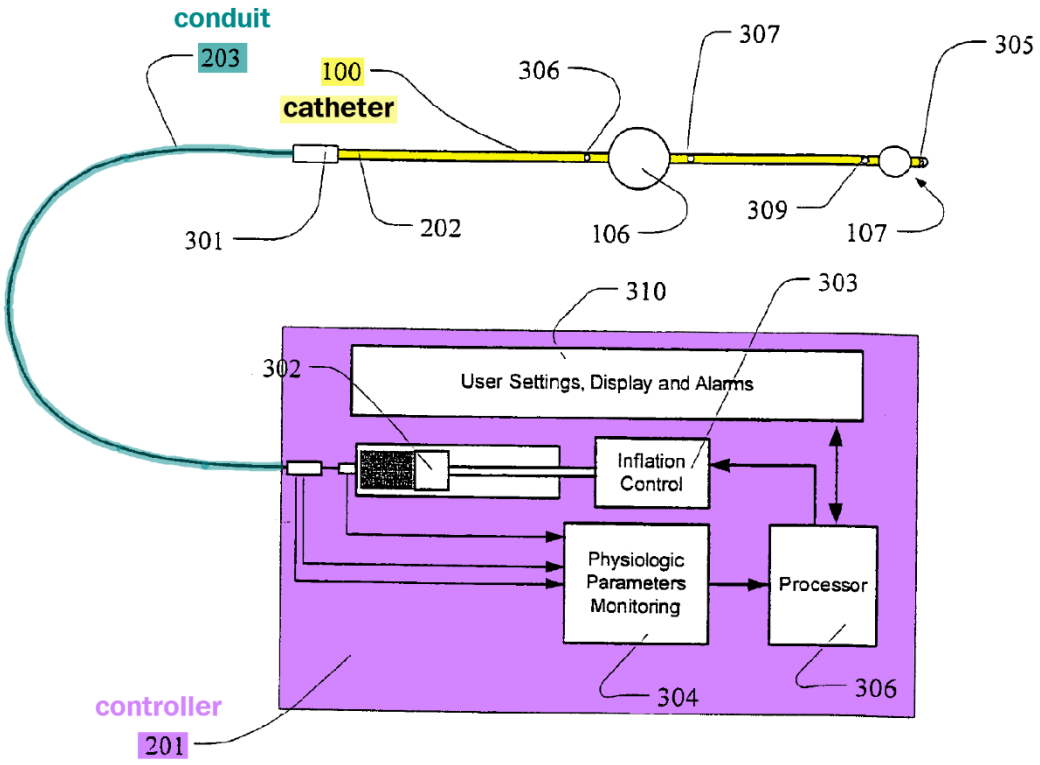

200
108
101
106
105
catheter
100
109
204
202
conduit
203
205
Controller
201 controller

Figure 3



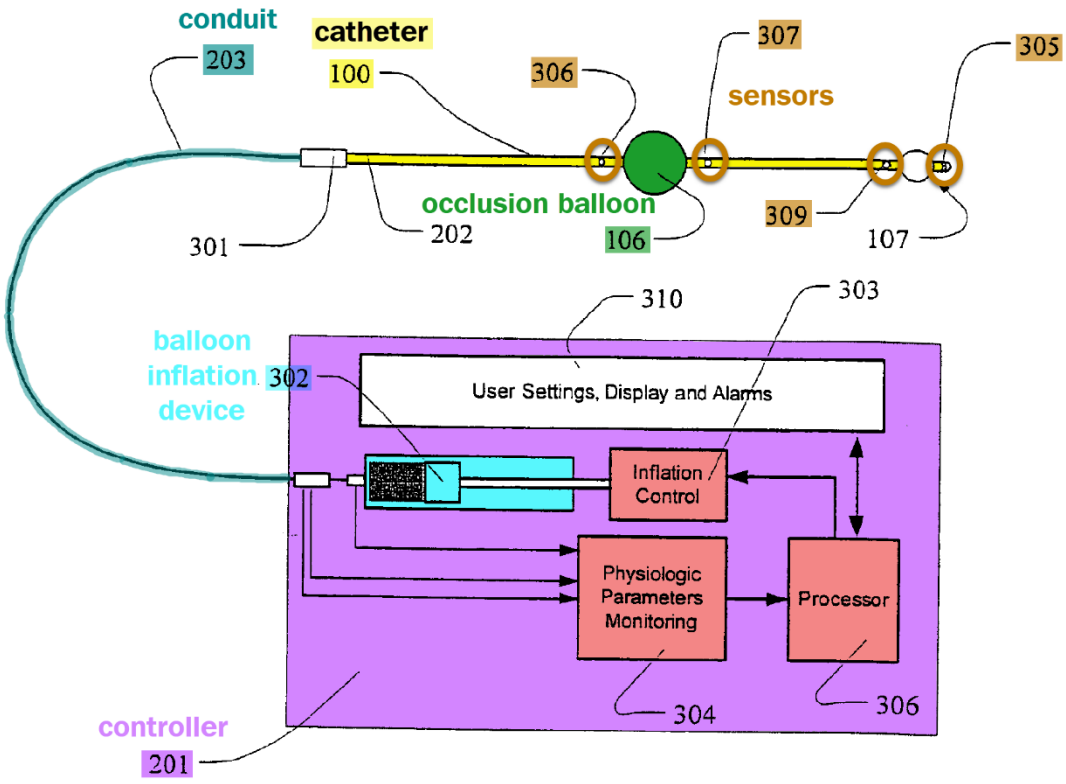

Gelfand teaches that the flexible conduit contains inflation lumens and signal-conducting means used in controller and catheter operation. (¶ [0035]; *see also* ¶ [0048].) For example, the controller controls operation of the catheter balloon via the inflation lumen. (¶¶ [0049]-[0050].) Thus, Gelfand discloses that its controller and catheter are "operably coupled" in the same manner as Kaiser's controller and lead/catheter *See* Ex. 1002, § X.C.2.c.

**d. Claim [13e]**

Kaiser discloses that its controller receives signals or data (*i.e.*, feedback) from its lead/catheter's sensors and uses them to control the Adjustable Component. (Section VII.B.2.d.)

Likewise, Gelfand discloses that its controller (the claimed "control module") receives signals containing "feedback" from the catheter's sensors and uses that feedback to control the catheter's balloon (the claimed "restrictor"). Figure 3 schematically illustrates this process:

Figure 3



Gelfand describes the operation of the controller shown above:

> Controller 201 also includes a monitoring sub-system 304 . . . . Signals from sensors are transmitted via thin electric wires or fiber optics (not shown) enclosed inside the catheter 100, the conduit 203 and terminate inside the monitoring electronics (sub-system) 304 . . . . Physiologic signals from the monitoring sub-system 304 are transmitted to the processor 306 that in turn controls the deflation and (optionally) the inflation of the balloon 106 [by] controlling the inflation control system 302.

(¶ [0051].) Gelfand's controller controls catheter balloon inflation using a balloon inflation device (highlighted turquoise), such as a pump, and controller subcomponents that include a processor (highlighted red). (¶¶ [0049]-[0050].)

Gelfand specifically teaches the use of "feedback" from the sensors to control inflation of the balloon: "Physiologic parameters indicative of the performance of the patient's heart are monitor[ed] continuously . . . . Each of these parameters can be used as a *feedback to control the inflation of the occlusion balloon* 106 . . . ." (¶ [0052]; *see also* ¶ [0051] ("[s]ensors integrated with the catheter are used to make actual [physiologic] measurements"), ¶ [0053] ("[a]lgorithm commands the inflation or deflation of the balloon based on these physiologic *feedbacks*").) Thus, Gelfand's controller could execute Kaiser's analogous occlusion algorithms, which also rely on sensor feedback. *See* Ex. 1002, § X.C.2.d.

#### 3. Obviousness of Claims 1 and 13

As discussed above (Section VIII.C), a POSA would be motivated to practice Kaiser's method with Gelfand's device and have a reasonable expectation of success. The resulting combination discloses each and every limitation of Claims 1 and 13, thus rendering them obvious. (Ex. 1002, § X.C.3.)

### E. Dependent Claims 2-12, 14-24

#### 1. Claims 2 and 14

Kaiser discloses that its method can involve full occlusion of the SVC. (Section VII.C.1.) A POSA motivated to use Gelfand's device to practice Kaiser's method of treating heart failure would similarly follow Kaiser's teachings regarding full occlusion. The POSA would have a reasonable expectation of success because it would require little to no modification of Gelfand's device—at most a slightly larger balloon that, upon inflation, would match the diameter of the SVC—or how it is used by the clinician. The resulting combination of Gelfand's device and Kaiser's method discloses every element of Claims 2 and 14, rendering them obvious. *See* Ex. 1004, § X.C; Ex. 1002, § X.D.1.

#### 2. Claims 3 and 15

Like Kaiser, Gelfand discloses that its device has an "occlusion balloon." (Sections VII.C.2, VIII.D.1.b.) A POSA motivated to use Gelfand's device to practice Kaiser's method would therefore retain and use Gelfand's balloon, which

corresponds to the claimed "restrictor." A POSA would have a reasonable expectation of success because Gelfand teaches that its balloon can occlude the SVC, which is the basis of Kaiser's method, and balloon catheters are conventional for occluding veins. The resulting combination discloses every element of Claims 3 and 15, rendering them obvious. *See* Ex. 1002, § X.D.2.

**3. Claims 4 and 16**

Kaiser discloses a "compliant" balloon. (Section VII.C.3.) Because Gelfand discloses that its occlusion balloon is both "inflatable" and "distendable" (Ex. 1006, ¶ [0028])—which means it is capable of yielding to the physical pressure of the inflation medium and undergoing elastic deformation—Gelfand also discloses a "compliant" balloon (Ex. 1020, p. 3).

In view of these parallel teachings and the conventional use of compliant balloons in catheters, a POSA would be motivated to use Gelfand's compliant balloon in practicing Kaiser's method, and have a reasonable expectation of success. The resulting combination discloses every element of Claims 4 and 16, rendering them obvious. *See* Ex. 1002, § X.D.3.

**4. Claims 5 and 17**

Kaiser discloses that activation of its Adjustable Component creates a pressure gradient across that component, including in the SVC. (Section VII.C.4.)

Because Gelfand's device operates exactly like Kaiser's to adjust flow impedance through the SVC—by expanding a balloon—it can create the pressure gradient taught by Kaiser. (Sections VIII.A, VIII.D.1.f.) Accordingly, a POSA motivated to use Gelfand's device in Kaiser's method would successfully create Kaiser's pressure gradient across Gelfand's balloon (the claimed "restrictor"/"resistor") by adjusting its size. The resulting combination discloses every element of Claims 5 and 17, rendering them obvious. *See* Ex. 1002, § X.D.4.

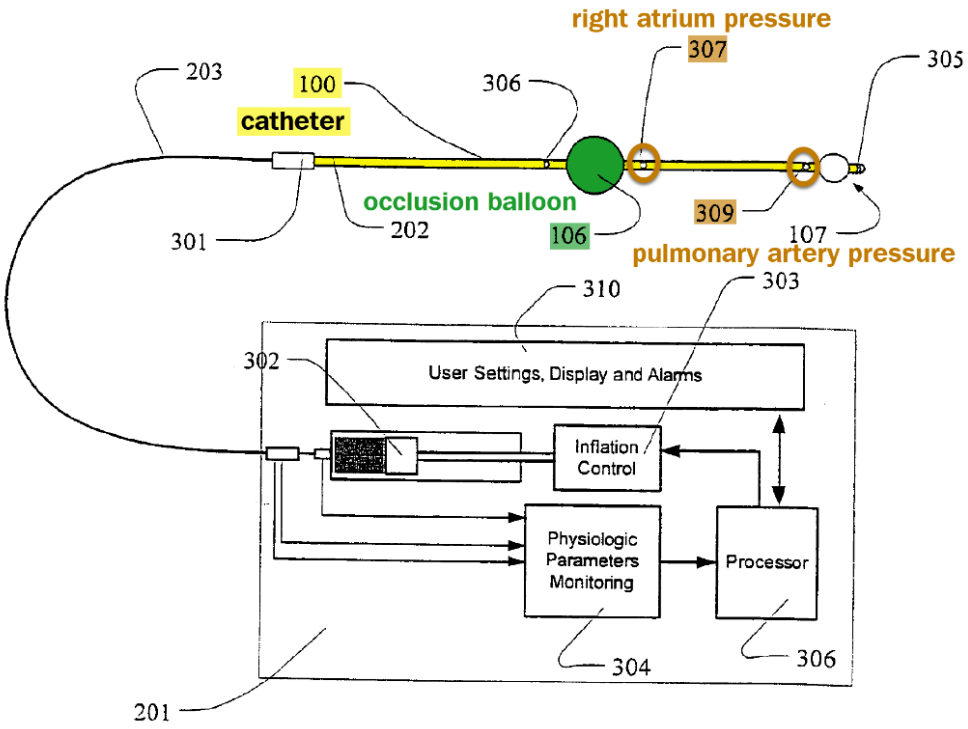
**5. Claims 6 and 18[13]**

Kaiser discloses that sensors on its lead/catheter may be distal to the Adjustable Component, for example, to measure downstream SVC pressure, right-atrial pressure or pulmonary artery pressure. (Section VII.C.5.)

Gelfand discloses sensors distal to the balloon (the claimed "restrictor"/ "resistor"), which measure pressure in distal locations taught by Kaiser—*i.e.*, in the right atrium and pulmonary artery (Ex. 1006, ¶ [0051])—and it would be easy to add a sensor to measure downstream SVC pressure as well simply by connecting it

[13] *See* Section VII.C.5 n.12.

to the controller using a wire extending through the catheter, as taught by both Kaiser and Gelfand (Ex. 1007, 9:49-52; Ex. 1010, 7:17-18; Ex. 1006, ¶ [0051]).

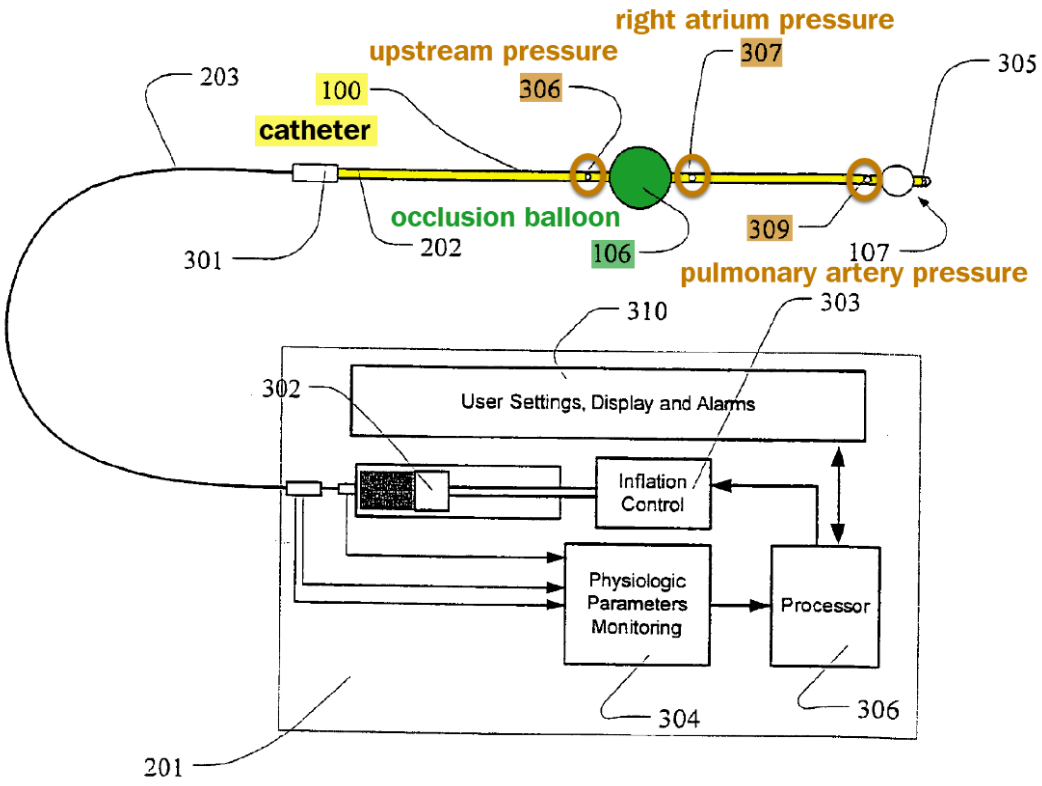



Consequently, a POSA using Gelfand's device for Kaiser's method would be motivated to use distal pressure sensors and have a reasonable expectation of success. The resulting combination discloses every element of Claims 6 and 18, rendering them obvious. *See* Ex. 1002, § X.D.5.

### 6. Claims 7 and 19

Kaiser discloses that its system may have an Adjustable Component placed in the SVC and pressure sensors spaced apart from it, *i.e.*, upstream, in the right atrium and pulmonary artery. (Section VII.C.6.) Gelfand's catheter 100 has pressure sensors in these locations—identified by reference numbers 306, 307 and

309 and circled in brown—that are similarly spaced apart from occlusion balloon 106 (the claimed "restrictor"/"resistor"), and a POSA could easily add any additional sensors taught by Kaiser (Section VIII.E.5).



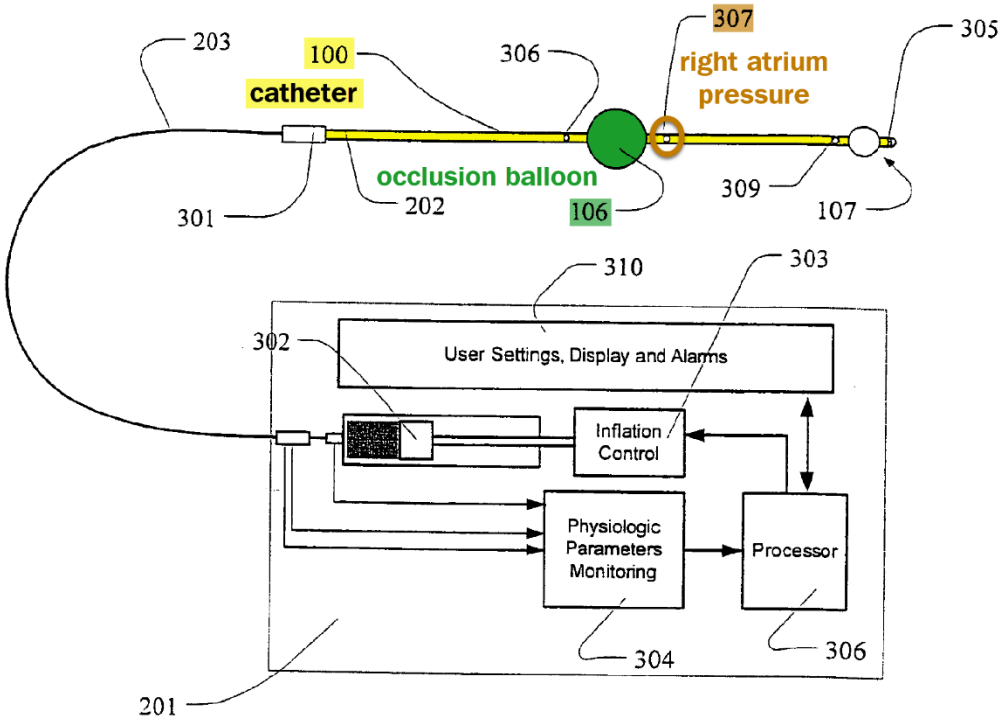

(*See* Ex. 1006, ¶ [0051].) Consequently, a POSA using Gelfand's device for Kaiser's method would be motivated to use the spatial configuration of Gelfand's pressure sensors and would have reasonable expectation of success. The resulting combination discloses every element of Claims 7 and 19, rendering them obvious. *See* Ex. 1002, § X.D.6.

### 7. Claims 8 and 20

Kaiser teaches that its method creates a pressure drop in the SVC, which is accomplished by activating the Adjustable Component to create a pressure gradient. (Section VII.C.7.) A POSA using Gelfand's device to occlude the SVC in practicing Kaiser's method would succeed in creating exactly the same pressure drop simply by inflating ("activating") the balloon (the claimed "restrictor"). (Section VIII.E.4.) Indeed, Gelfand teaches that "the amount of venous blood returning to the heart . . . is reduced by creating a partial temporary obstruction (occlusion)," (Ex. 1006, ¶ [0018]), which can be in the SVC (¶ [0029]) and would therefore create a pressure drop. (*See also* ¶ [0019] (noting possible downstream hypotension).) The resulting combination discloses every element of Claims 8 and 20, rendering them obvious. *See* Ex. 1002, § X.D.7.

### 8. Claims 9 and 21

Kaiser discloses placing downstream sensors in the SVC or right atrium to facilitate adjusting the pressure gradient, and those sensors would detect a pressure drop in the SVC. (Section VII.C.8.)




Gelfand's device measures pressure in the right atrium and could easily be modified to add a downstream SVC sensor. Accordingly, a POSA using Gelfand's device would be motivated to use its sensors to detect pressure, including pressure drops, as taught by Kaiser's method. Because Kaiser's method involves SVC occlusion, the POSA would be further motivated by Gelfand's teaching that such occlusion can cause excessively low downstream pressure, which sensor detection can counteract by causing balloon deflation. (Ex. 1006, ¶¶ [0019], [0056]; *see also* ¶ [0052] (Gelfand monitors Central Venous Pressure—*i.e.*, pressure in the SVC and IVC; Ex. 1004, ¶ 116)—to control the balloon).) The POSA would have a reasonable expectation of detecting such pressure drops because Gelfand's device

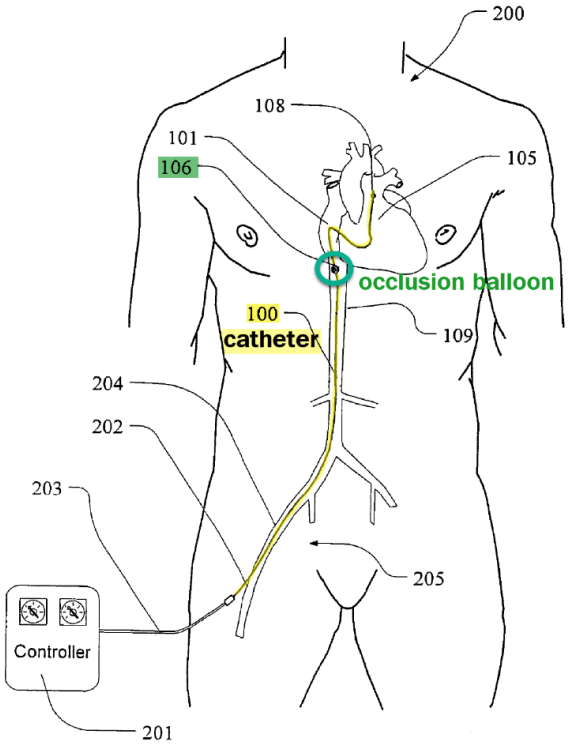
is used for this purpose. The resulting combination discloses every element of Claims 9 and 21, rendering them obvious. *See* Ex. 1002, § X.D.8.

### 9. Claims 10 and 22

"Distal restrictor" means **"the restrictor that is located furthest from the clinician."** (Section VI.B.)

Like Kaiser's Adjustable Component (Section VII.C.9), Gelfand's balloon 106 (highlighted green) is a "distal restrictor" because it is the only "restrictor" and thus furthest away from the clinician, as shown in Figure 2 below.

**Figure 2**



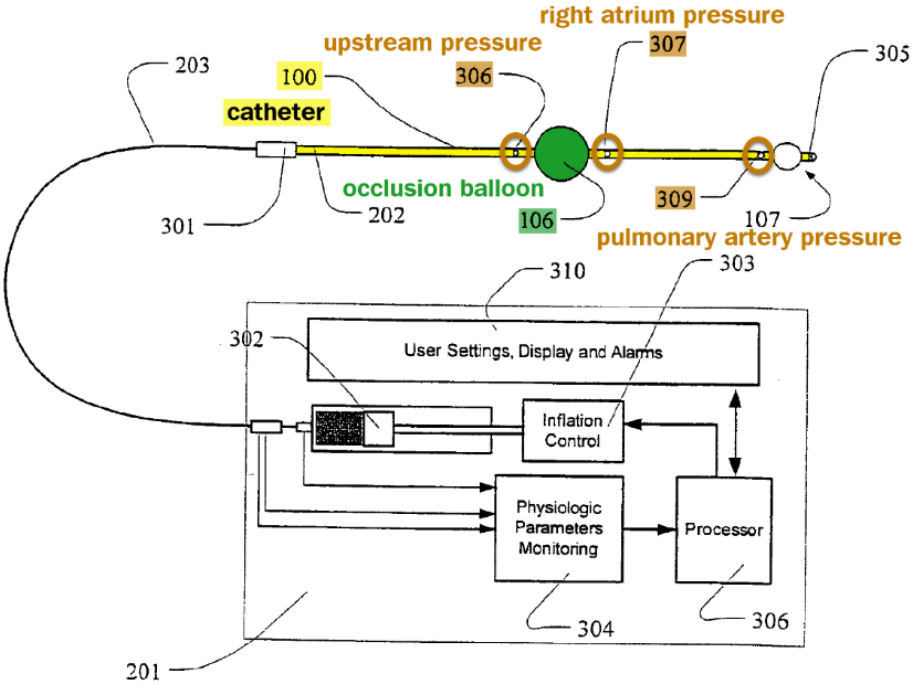

Gelfand's tip balloon 107 is not a claimed "restrictor"—it is used for catheter placement, not for occlusion, and is not sensor-controlled. *See* Ex. 1002, ¶ 331.

Kaiser discloses that its method involves measuring pressure proximal and distal to the Adjustable Component, *i.e.*, upstream pressure, right-atrial pressure and pulmonary-artery pressure. (Section VII.C.9.) Gelfand discloses sensors (circled brown below) that measure pressure in these locations:

> [a]dvanced micro tip catheter blood pressure transducers . . . can be integrated with the catheter 100 to obtain reliable and accurate measurements of pressure in the RA [right atrium] of the heart 307, in the IVC position 306 or PA [pulmonary-artery] position 309 along the catheter."

(Ex. 1006, ¶ [0051]; as noted, the IVC position can be the SVC position (¶ [0029]); *see also* ¶¶ [0019], [0056] (teaching desirability of detecting and counteracting excessive downstream pressure decreases).)

Figure 3



Consequently, including for the reasons discussed above (Sections VIII.E.5-VIII.E.8), a POSA using Gelfand's device for Kaiser's method would have been motivated to measure pressure in locations proximal and distal to the balloon and would have had a reasonable expectation of success because Gelfand's device discloses the requisite sensors. The resulting combination discloses every element of Claims 10 and 22, rendering them obvious. *See* Ex. 1002, § X.D.9.

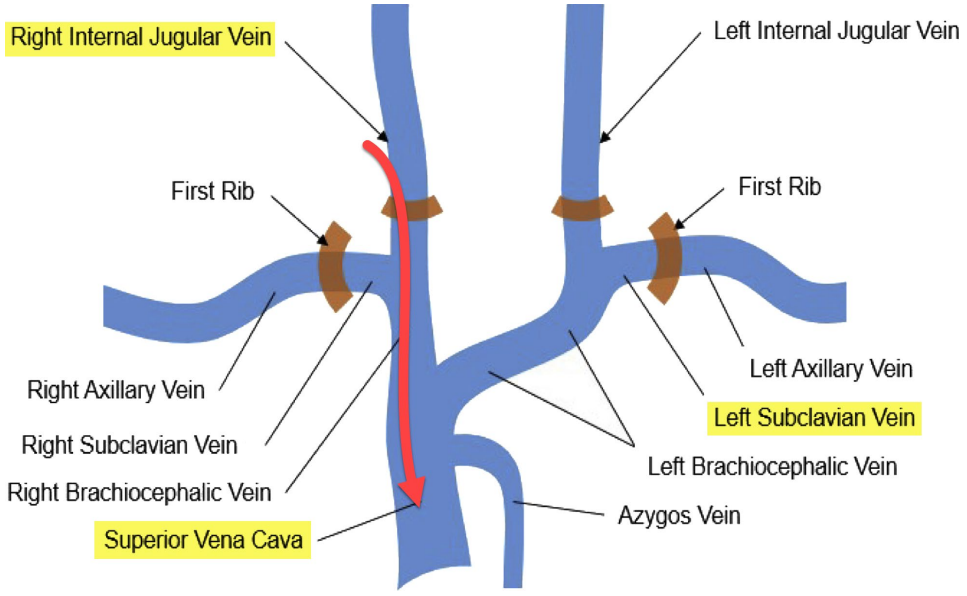
**10. Claims 11 and 23**

A POSA motivated to use Gelfand's device for Kaiser's method would measure blood pressure, as taught by Kaiser, with that device. (*E.g.*, Section VII.B.1.h, VII.B.2.d) Gelfand discloses that its catheter "has multiple internal lumens for," among other things, "monitoring of blood pressure." (Ex. 1006, ¶ [0032].) A POSA knows that in monitoring blood pressure, such a catheter lumen terminates in an opening on the wall of the catheter in contact with the blood whose pressure is measured. *See* Section XI.A.

Accordingly, a POSA would be motivated to use Gelfand's conventional lumen and its associated opening for Kaiser's method and would have a reasonable expectation of success because these components would measure blood pressure just as in Gelfand's method of occluding the SVC. The resulting combination discloses every element of Claims 11 and 23, rendering it obvious. *See* Ex. 1002, § X.D.10.

### 11. Claims 12 and 24

"Catheter extends across a vein wall" means "catheter extends through a vein wall." (Section VI.C.) Each of Kaiser and Gelfand teach percutaneous insertion, and Gelfand discloses that its catheter should be inserted through a jugular vein to reach the SVC. A POSA practicing Kaiser's method would thus be motivated to percutaneously insert Gelfand's device, including through a jugular vein as taught by Gelfand and as illustrated below, and would have a reasonable expectation of success for the reasons discussed above in Sections VII.B.1.c and VIII.D.1.c. (*See also* Section IX.) Insertion into any vein other than the SVC would result in Gelfand's catheter extending through a vein wall that is closer to the clinician (*i.e.,* "proximal") than the SVC. The resulting combination discloses every element of Claims 12 and 24, rendering them obvious. *See* Ex. 1004, § X.D; Ex. 1002, § X.D.11.



# IX. GROUND 3: CLAIMS 1-10, 12-22, AND 24 ARE OBVIOUS OVER KAISER AND BANNON

If the Board finds that Gelfand does not disclose insertion of its catheter through a jugular vein, such insertion would nonetheless have been obvious in view of Bannon.

## A. Overview of Bannon

Bannon is a 2011 paper teaching safe procedures for percutaneous central venous cannulation—the insertion of a catheter through a peripheral vein to reach the SVC or IVC and the heart. (Ex. 1012, p. 1.) Bannon is prior art under at least Section 102(a)(1) because it was publicly available before June 1, 2014, as evidenced by its online publication and by archived webpages. *See* Ex. 1004, § XI.A.1; Ex. 1012, p. 1; Ex. 1013; Ex. 1014; Ex. 1015.

Bannon describes many advantages of insertion through the right internal jugular vein, which is "often the access site of choice." (Ex. 1012, p. 4.) These include a location close to the skin surface; a short and straight course to the SVC (shown in Bannon's Figure 2 and the graphic below); easy ultrasonic visualization; and the lowest incidence of catheter malposition.

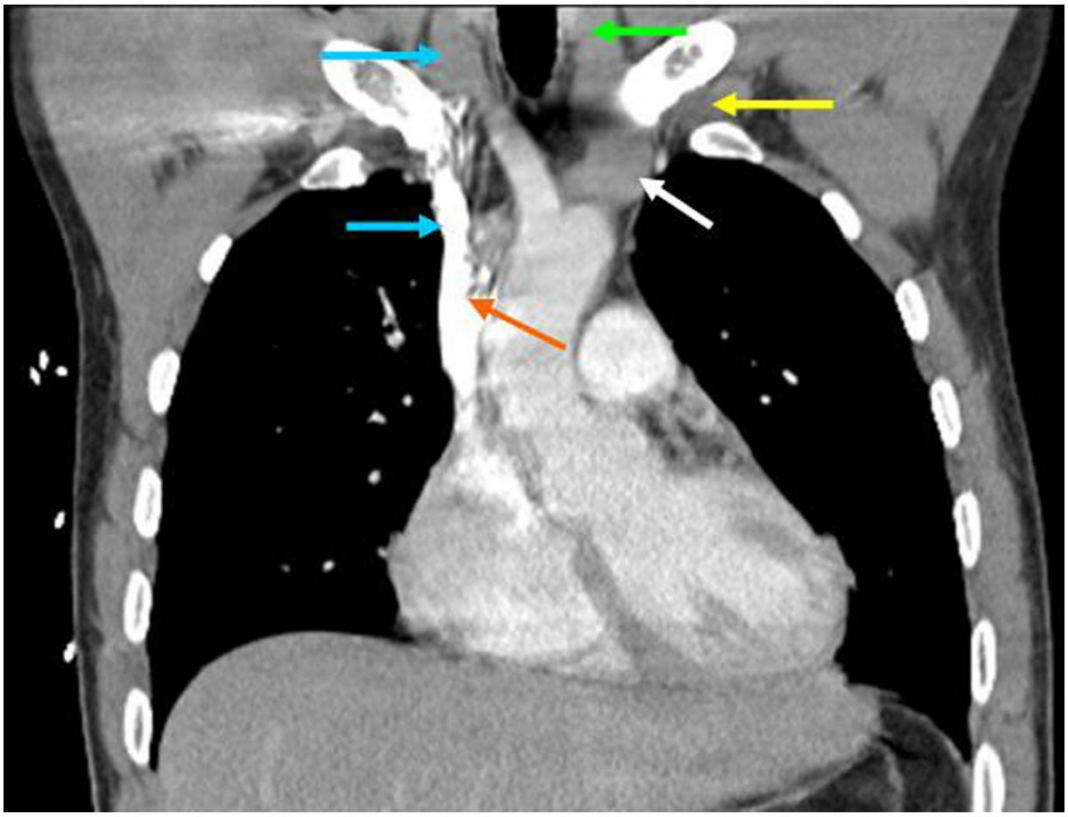
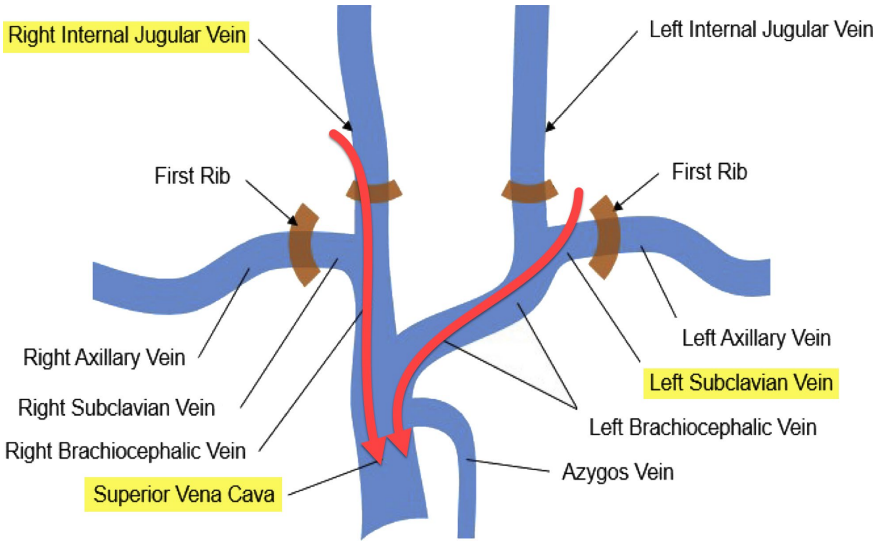


**Figure 2** Computed tomography scan showing venous course from right internal jugular vein (blue arrows) and venous course from left subclavian vein (yellow arrow) through the innominate vein (white arrow) to superior vena cava (orange arrow); course from left internal jugular vein (green arrow) with turns at junctions with innominate vein and superior vena cava.



Bannon also teaches that the subclavian vein is "long favored by surgeons," that it has "fewer infectious complications than the internal jugular vein," and that the left subclavian vein has a "gently curving" trajectory to the SVC. (p. 7, p. 3.)

By contrast, Bannon teaches that the "the femoral vein is considered the third choice for catheterization and, because of higher rates of infection and thrombosis, is used only when subclavian and internal jugular approaches are not feasible." (p. 11.) *See* Ex. 1004, § XI.A.2.

### B. Claims and Limitations Involving the Location of Catheter Apparatus Insertion

As discussed above, Kaiser discloses that its lead/catheter and Adjustable Component may be placed percutaneously in the SVC. (Sections VII.B.1.c, VII.B.1.d.) If Kaiser's teaching is found not to disclose the limitations of Claims [1b], [13b], 12 and 24, Bannon discloses these limitations.

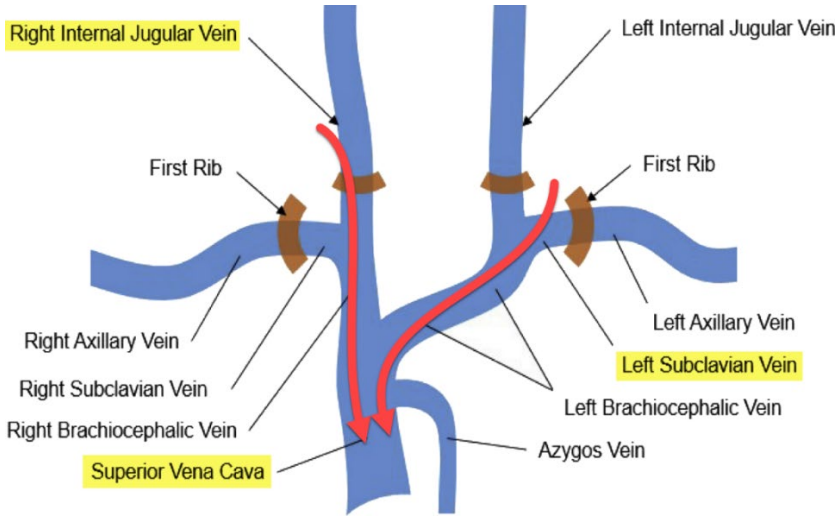
#### 1. Independent Claims [1b] and [13b]

Because placement of Kaiser's lead/catheter involves percutaneous insertion and central venous cannulation, a POSA would have been motivated by Bannon's disclosure (Section IX.A) to insert the catheter into the right internal jugular or left subclavian vein and advance it from there to the SVC. The POSA would have had a reasonable expectation of success in doing so because of the advantages of such insertion, including over femoral-vein insertion.

The resulting combination of inserting and advancing Kaiser's lead/catheter as taught by Bannon discloses Claims [1b] and [13b]. *See* Ex. 1004, § XI.B.1.

### 2. Claims 12 and 24

"Catheter extends across a vein wall" means "the catheter extends through a vein wall." (Section VI.C.) If, for the reasons above (Section IX.B), Kaiser's lead/catheter were inserted according to Bannon's teachings, it would extend through the right internal jugular vein or the left subclavian vein wall, which are each proximal to the SVC. *See* Ex. 1004, § XI.B.2.




## C. Remaining Limitations

As discussed above (Section VII), Kaiser discloses the remaining limitations of Claims 1-10, 12-22 and 24. Using the jugular or subclavian catheter insertion locations taught by Bannon in practicing Kaiser's method would ensure that Kaiser's Adjustable Component is correctly placed in the SVC (Section VII.B.1.c) and that Kaiser's sensors are correctly positioned. Using Bannon's locations

would not otherwise affect Kaiser's method or device, or how they disclose the claims as discussed above. As a result, a POSA would be motivated to use Bannon's insertion locations in practicing all aspects of Kaiser's method of treating heart failure with a reasonable expectation of success. The resulting combination of Kaiser and Bannon discloses every element of Claims 1, 3-13 and 15-24, rendering them obvious. *See* Ex. 1004, § XI.C; Ex. 1002, § XI.

## X. GROUND 4: CLAIMS 1-24 ARE OBVIOUS OVER KAISER, GELFAND AND BANNON

As discussed above in Section VIII, it would have been obvious to use Gelfand's device in practicing Kaiser's method of treating heart failure. Doing so entails inserting Gelfand's catheter in the same way as for Gelfand's method. Consequently, if Gelfand's disclosure of percutaneous right-neck-vein insertion for Swan-Ganz catheters (of which Gelfand is an example) is found not to disclose the limitations of Claims [1b], 12, [13b] and 24, Bannon's teachings would have motivated a POSA practicing Kaiser's method to insert and advance Gelfand's catheter through the right internal jugular vein with a reasonable expectation of success (which would also result in the catheter extending through a vein wall proximal of the SVC). Bannon's routes of insertion would ensure that Gelfand's balloon is placed in the SVC and Gelfand's sensors measure pressure in locations taught by Kaiser (Section VIII.D.1.e.); they would not otherwise affect performing

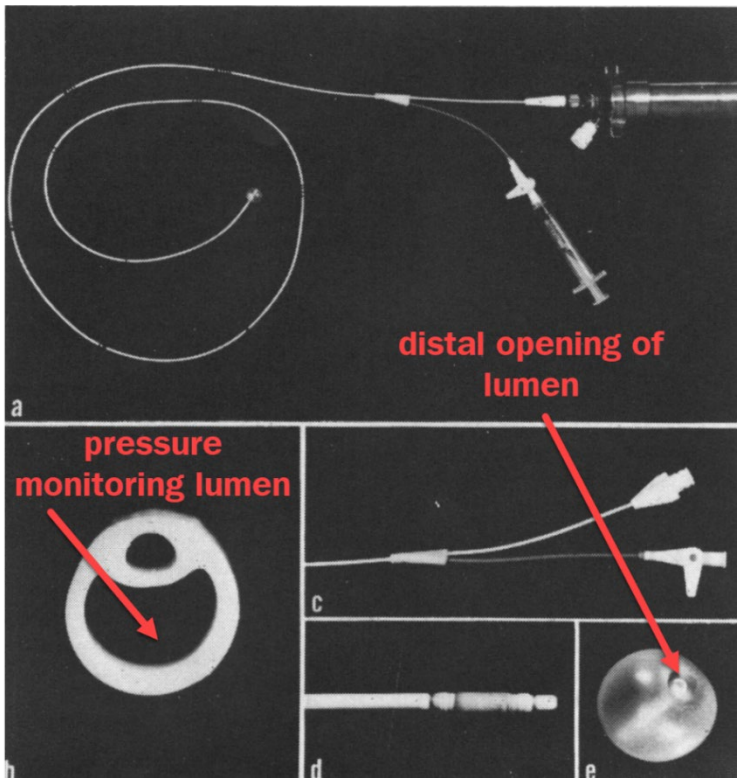
Kaiser's method. The resulting combination of Kaiser, Gelfand and Bannon discloses every element of Claims 1-24, rendering them obvious. *See* Ex. 1004, § XII; Ex. 1002, § XII.

## XI. GROUND 5: CLAIMS 11 AND 23 ARE OBVIOUS OVER KAISER AND THE KNOWLEDGE OF A PERSON OF ORDINARY SKILL IN THE ART

Because Kaiser's method of treating heart failure requires measuring blood pressure, using an opening on Kaiser's lead/catheter to facilitate pressure monitoring would have been obvious in view of the knowledge of a POSA.

### A. Knowledge of Catheter Pressure-Sensing Openings

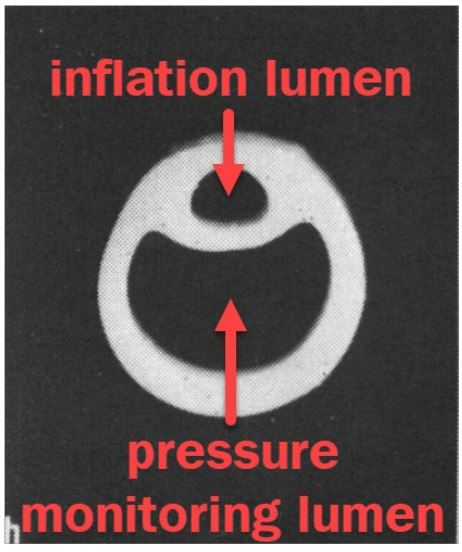
As of 2014-15, catheters with openings to facilitate pressure monitoring were conventional in the art and thus well known to a POSA. The catheter opening leads to a lumen with a pressure sensor either in the lumen or at the other end. Blood pressure at the opening is transmitted by the liquid in the lumen to the sensor. As shown in the figure to the right, such a lumen/opening was used in



the first Swan-Ganz catheters (Ex. 1022, p. 2-3); it was described as prior art by the 1980s (*e.g*, Ex. 1021, 1:41-2:5); and it is still widely used in right-heart catheterization (Ex. 1023, p. 11-12). Advantages over catheter-mounted sensors include lower cost; greater reliability, greater interchangeability and ease of use; and no electrical wires causing interference or disrupting heart function (*e.g.*, Ex. 1011, 6:28-7:7; Ex. 1002, ¶¶ 355-57). *See* Ex. 1002, § XIII.A.

**B. Obviousness of Claims 11 and 23**

For the advantages over catheter-mounted sensors listed above, a POSA would be motivated to modify Kaiser's device to implement a fluid-lumen pressure sensing system. Kaiser discloses that its lead/catheter already has an "inflation lumen" used to inflate and deflate the Adjustable Component. (Ex. 1007, 8:19-25, 10:26-34; Ex. 1010, 8:7-11.) A POSA would know that a catheter could be further subdivided to add one or more fluid pressure lumens, as shown in Figure 1b of the paper describing the first Swan-Ganz catheter, that connect distal catheter openings with proximal sensors. The POSA would have a reasonable expectation of success because measuring blood pressure in this way is a conventional approach used for decades, and any modifications to Kaiser's device would be minor and



within the skill of a POSA. The resulting combination discloses every element of Claims 11 and 23 and renders them obvious. *See* Ex. 1002, § XIII.B; Ex. 1004, § XIII.

## XII. GROUND 6: CLAIMS 11 AND 23 ARE OBVIOUS OVER KAISER, BANNON, AND THE KNOWLEDGE OF A PERSON OF ORDINARY SKILL IN THE ART

As discussed above, Kaiser discloses the limitations of Claims 1 and 13 (Section VII.B), and a POSA would have been motivated by Bannon to successfully insert and advance Kaiser's lead/catheter through the right internal jugular vein or the left subclavian vein (Section IX.B.1), thus meeting the limitations of Claims [1b], [13b]. As further discussed above (Section XI.B), a POSA would also have been motivated by her knowledge to successfully implement a fluid-lumen pressure sensing system in Kaiser's device by adding an opening on Kaiser's catheter wall to an internal lumen. Using Bannon's insertion locations would facilitate the pressure monitoring required by Kaiser's method and would not affect operability of a fluid-lumen sensor on Kaiser's lead/catheter. (*Id*.) The resulting combination of Kaiser, Bannon, and the knowledge of a POSA discloses every element of Claims 11 and 23, rendering them obvious. *See* Ex. 1002, § XI.V; Ex. 1004, § XIII.

## XIII. GROUND 7: CLAIMS 11 AND 23 ARE OBVIOUS OVER KAISER, GELFAND AND THE KNOWLEDGE OF A PERSON OF ORDINARY SKILL IN THE ART

As discussed in Section VIII, a POSA would have been motivated to use Gelfand's device to practice Kaiser's method of treating heart failure, thus disclosing the elements of Claims 1 and 13. Kaiser's method uses the pressure sensing capabilities of Gelfand's catheter as in Gelfand's method, *i.e.*, to control occlusion. As further discussed above (Section VIII.E.10), a POSA would have been motivated by her knowledge to successfully implement a fluid-lumen pressure sensing system in Gelfand's device by adding an opening on Gelfand's catheter wall. A POSA would be motivated to successfully retain and use the fluid-lumen system in practicing Kaiser's method because it could measure pressure in locations taught by Kaiser and would not otherwise affect Gelfand's device in practicing Kaiser's method. The resulting combination of Kaiser, Gelfand and the knowledge of a POSA discloses every element of Claims 11 and 23, rendering them obvious. *See* Ex. 1002, § XV; Ex. 1004, § XIII.

## XIV. GROUND 8: CLAIMS 11 AND 23 ARE OBVIOUS OVER KAISER, GELFAND, BANNON, AND THE KNOWLEDGE OF A PERSON OF ORDINARY SKILL IN THE ART

As discussed in Section X, a POSA would have been motivated to successfully use Bannon's catheter insertion locations in using Gelfand's device to practice Kaiser's method of treating heart failure, thus disclosing the elements of

Claims 1 and 13. As further discussed above (Section XIII), a POSA would have been motivated by her knowledge to successfully implement a fluid-lumen pressure sensing system in Gelfand's device, including when the catheter is used to practice Kaiser's method, by adding an opening on the catheter wall to the internal lumen. Inserting the device in the locations taught by Bannon would facilitate the pressure monitoring required by Kaiser's method and would not affect operability of a fluid-lumen sensor on Gelfand's catheter. (Sections XI.B, XIII.) The resulting combination of Kaiser, Gelfand, Bannon, and the knowledge of a POSA discloses every element of Claims 11 and 23, rendering them obvious. *See* Ex. 1002, § XVI; Ex. 1004, § XIII.

## XV. CONCLUSION

For the reasons set forth above, Petitioner has established a reasonable likelihood that the challenged claims are unpatentable. Petitioner respectfully requests that trial be instituted on all grounds in this petition and that Claims 1-24 of the '460 Patent be cancelled.

Date: September 29, 2021

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# APPENDIX A

## Support for Kaiser Claim 1 in Kaiser Provisional Application

| Claim 1 Element | Supporting Disclosure in Kaiser Provisional Application |
|---|---|
| [1p][14] | Ex. 1010, 5:9-11, 7:5-7; Ex. 1002, ¶¶ 125-26. |
| [1a] | Ex. 1010, 8:25-28; Ex. 1002, ¶ 127. |
| [1b] | Ex. 1010, 7:19-21, Fig. 3. As shown in Figure 3, the "second lead 30" is an elongate member. Because one end of the lead is the "proximal end," the "second end" is a distal end, which is confirmed by its placement in the heart. The right atrium and ventricle into which the lead is introduced are on the venous side of the heart. *See* Ex. 1002, ¶¶ 128-29. |
| [1c] | The adjustable component is "expandable member 32" (also known as "balloon 32") which is configured to be placed in the right atrium, which is a body lumen of the venous side of the heart. *See* Ex. 1010, 7:21-8:5. The volume of the expandable member/balloon may be adjusted, which determines the amount of blood flowing past the balloon (7:29-8:5, 9:2-7) and thereby creates a pressure gradient within the right (venous) side of the heart. *See* Ex. 1002, ¶¶ 130-33. |
| [1d] | Kaiser Provisional discloses a pacing component (pacing electrodes on a lead) to pace the heart. *See* Ex. 1010, 8:19-24; Ex. 1002, ¶ 134. |
| [1e] | Ex. 1010, 7:5-7; Ex. 1002, ¶ 135. |

[14] The claim text is in Appendix B.

| Claim 1 Element | Supporting Disclosure in Kaiser Provisional Application |
|---|---|
| [1f] | Ex. 1010, 7:5-7; Ex. 1002, ¶ 136. |
| [1g] | The pacing component is electrodes on the first or second lead (Ex. 1010, 8:19-24), and those leads are coupled to the housing of the controller (7:11-13, 7:19-21, Fig. 3). The controller is also coupled to "expandable member 32" (the claimed "adjustable component") (*id*., 7:7-8). *See* Ex. 1002, ¶¶ 137-39. |
| [1h] | Kaiser Provisional discloses adjustment by the controller of "expandable member 32" and "balloon 32" (the claimed "adjustable component") based on sensor data (Ex. 1010, 7:7-10, 8:25-9:13), thereby creating a pressure gradient in the right (venous) side of the heart (*see* Claim [1c]). This reduces intracardiac filling pressures, *e.g.*, left-heart pressure. (*See* 9:6-13, 5:9-26, 6:29-7:1, 10:27-11:2.) *See* Ex. 1002, ¶¶ 140-43. |

# APPENDIX B

## Claim Listings

U.S. Patent No. 10,639,460

| Claim Number | Claim Language |
|---|---|
| [1p] | A method for treating heart failure in a patient, the method comprising: |
| [1a] | advancing a catheter apparatus comprising one or more restrictors |
| [1b] | through a subclavian or jugular vein and |
| [1c] | into a superior vena cava of a patient, |
| [1d] | wherein the catheter apparatus further comprises one or more pressure sensors; and |
| [1e] | operating the catheter apparatus to regulate venous blood return through the superior vena cava, wherein operating at least comprises activating the one or more restrictors within the superior vena cava to at least partially occlude flow through the superior vena cava |
| [1f] | while maintaining intravascular pressure, |
| [1g] | wherein the one or more restrictors are adjusted based on feedback from the one or more pressure sensors, |
| [1h] | thereby treating heart failure in the patient. |
| 2 | The method of claim 1, wherein the one or more restrictors fully restrict flow through the superior vena cava. |
| 3 | The method of claim 1, wherein the one or more restrictors are one or more balloons. |
| 4 | The method of claim 3, wherein the one or more balloons are one or more compliant or semi-compliant balloons |

| Claim Number | Claim Language |
|---|---|
| 5 | The method of claim 1, wherein activating the one or more restrictors creates a pressure gradient across at least one of the one or more resistors. |
| 6 | The method of claim 1, wherein at least one of the one or more pressure sensors is distal to at least one of the one or more resistors. |
| 7 | The method of claim 1, wherein at least one of the one or more pressure sensors is spaced apart from at least one of the one or more resistors. |
| 8 | The method of claim 1, wherein activating the one or more restrictors creates a pressure drop in a vein. |
| 9 | The method of claim 8, wherein the method further comprises detecting a pressure drop in the vein via the one or more sensors. |
| 10 | The method of claim 1, wherein the one or more restrictors comprise a distal restrictor and the method further comprises measuring a pressure distal of and proximal of the distal restrictor. |
| 11 | The method of claim 1, wherein the catheter comprises an opening that is configured to facilitate pressure monitoring. |
| 12 | The method of claim 1, wherein the catheter extends across a vein wall proximal of the superior vena cava. |
| [13p] | A method for treating heart failure in a patient, the method comprising: |
| [13a] | advancing a catheter apparatus comprising one or more sensors and one or more restrictors |
| [13b] | through a subclavian or jugular vein and |
| [13c] | into a superior vena cava of a patient, |
| [13d] | wherein the catheter apparatus is operably coupled to a control module |

| Claim Number | Claim Language |
|---|---|
| [13e] | that receives feedback from the one or more sensors of the catheter apparatus and controls the one or more restrictors based on the feedback from the one or more sensors; and |
| [13f] | operating the catheter apparatus to regulate venous blood return through the superior vena cava, wherein operating at least comprises activating the one or more restrictors within the superior vena cava to at least partially occlude flow through the superior vena cava |
| [13g] | while maintaining intravascular pressure, |
| [13h] | thereby treating heart failure in the patient. |
| 14 | The method of claim 13, wherein the one or more restrictors fully restrict flow through the superior vena cava. |
| 15 | The method of claim 13, wherein the one or more restrictors are one or more balloons. |
| 16 | The method of claim 15, wherein the one or more balloons are one or more compliant or semi-compliant balloons. |
| 17 | The method of claim 13, wherein activating the one or more restrictors creates a pressure gradient across at least one of the one or more resistors. |
| 18 | The method of claim 13, wherein at least one of the one or more sensors is distal to at least one of the one or more resistors. |
| 19 | The method of claim 13, wherein at least one of the one or more sensors is spaced apart from at least one of the one or more resistors. |
| 20 | The method of claim 13, wherein activating the one or more restrictors creates a pressure drop in a vein. |
| 21 | The method of claim 20, wherein the method further comprises detecting a pressure drop in the vein via the one or more sensors. |

| Claim Number | Claim Language |
|---|---|
| 22 | The method of claim 13, wherein the one or more restrictors comprise a distal restrictor and the method further comprises measuring a pressure distal of and proximal of the distal restrictor. |
| 23 | The method of claim 13, wherein the catheter comprises an opening that is configured to facilitate pressure monitoring. |
| 24 | The method of claim 13, wherein the catheter extends across a vein wall proximal of the superior vena cava. |

U.S. Patent No. 9,878,080 (Kaiser)

| Claim Element | Claim Language |
|---|---|
| [1p] | A system to be implanted in the body of a patient with conduction disease and/or heart failure configured to monitor and/or treat the patient, the system comprising: |
| [1a] | at least one sensor configured to provide sensor data corresponding to pressures within or near the patient's heart; |
| [1b] | an elongate member comprising a proximal end and a distal end sized for introduction into a venous side of a patient's heart; |
| [1c] | an adjustable component carried on the distal end and configured to be positioned within a body lumen of the venous side of the patient's heart, the adjustable component being adjustable to create a pressure gradient to blood flow within the venous side of the patient's heart |
| [1d] | at least one pacing component configured to at least one of sense and pace the patient's heart; and |
| [1e] | a controller contained within a housing sized for implantation within the patient's body adjacent the heart, |
| [1f] | the proximal end of the elongate member coupled to the housing, |
| [1g] | the controller coupled to the at least one pacing component and the adjustable component, |
| [1h] | the controller programmed to adjust the adjustable component based at least in part on sensor data from the at least one sensor to generate a pressure gradient within the venous side of the patient's heart to reduce intracardiac filling pressures within the patient's heart. |

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that the foregoing Petition for *Inter Partes* Review, Power of Attorney, and all exhibits and other documents filed therewith, were sent via Federal Express on September 29, 2021, at the correspondence address of record for the '460 Patent:

Brown Rudnick LLP
One Financial Center
Boston, MA 02111

Date: September 29, 2021

*/Sharonmoyee Goswami/*
Sharonmoyee Goswami
Reg. No. 68,806

## CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the foregoing petition for *inter partes* review contains 13,978 words according to the word processing program used to prepare it.

Date: September 29, 2021

*/Sharonmoyee Goswami/*
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Reg. No. 68,806