IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABIOMED, INC.

Petitioner

v.

WHITE SWELL MEDICAL LTD.

(record) Patent Owner

IPR2021-01477

U.S. Patent No. 10,653,871

Issued: May 19, 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. 10,653,871

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U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

TABLE OF CONTENTS

TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 10,653,871
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. 10,653,871
1009	U.S. Provisional Application No. 62/006,206
1010	U.S. Provisional Application No. 61/927,038
1011	File History of U.S. Patent No. 10,639,460
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)
1024	International Published Patent Application WO2013/061281 ("Caron")

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 1-16 of U.S. Patent 10,653,871 ("the '871 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 1-16 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 1-16 of the '871 Patent (IPR2021-01478), 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), which claims priority to certain of the applications to which the '871 Patent claims priority.

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

Lead Counsel	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 '871 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 1-16 of the '871 Patent as unpatentable under 35 U.S.C. §§ 102 and 103 on the following grounds:

No.	Ground
1	Claims 1, 3-16 are anticipated by U.S. Published Patent App. 2006/0064059 ("Gelfand").
2	Claims 1-16 are obvious over Gelfand and U.S. Patent No. 9,878,080 ("Kaiser").
3	Claims 3 and 16 are obvious over Gelfand and Michael P. Bannon et al., *Anatomic Considerations for Central Venous Cannulation*, 4 Risk Mgmt. & Healthcare Pol'y 27 (2011) ("Bannon").
4	Claims 3 and 16 are obvious over Gelfand, Kaiser and Bannon.
5	Claim 15 is obvious over Gelfand and the knowledge of a person of ordinary skill in the art.
6	Claim 15 is obvious over Gelfand, Kaiser and the knowledge of a person of ordinary skill in the art.

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-XII, including identification of supporting evidence to support the challenge and the relevance of the evidence to the challenge.

V. BACKGROUND

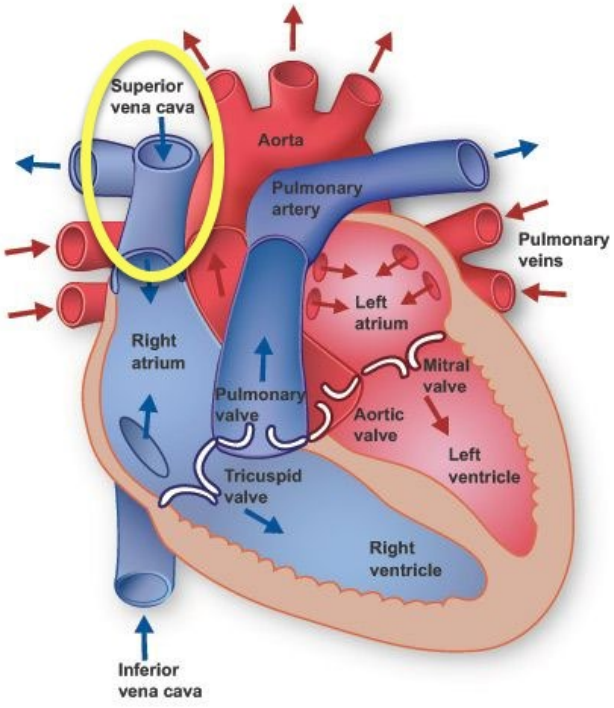
A. Technical Background

The claims of the '871 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,

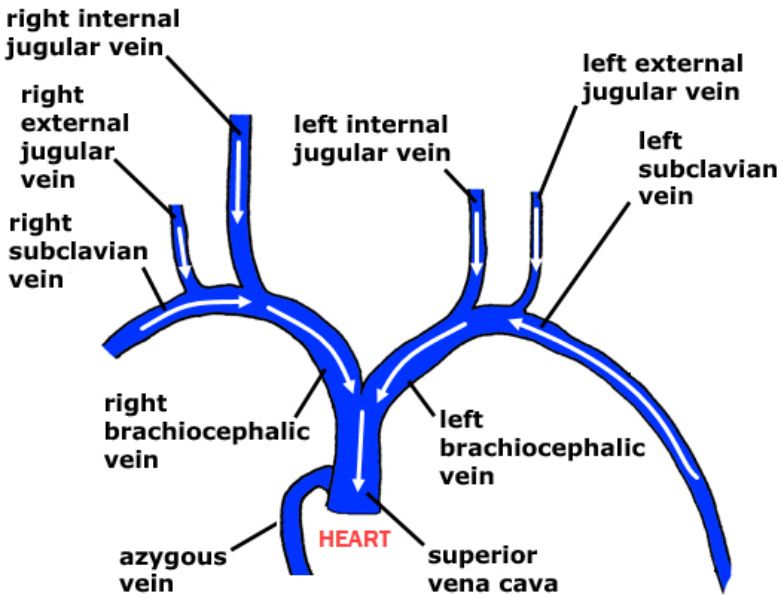
[1] A catheter may use other expandable structures that function like a balloon. The discussion of balloon catheters applies equally to such devices.

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 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.



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 the venous blood returns through the SVC. The figure below shows the relationship of the SVC to other veins mentioned in the '871 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 '871 Patent

According to the '871 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:

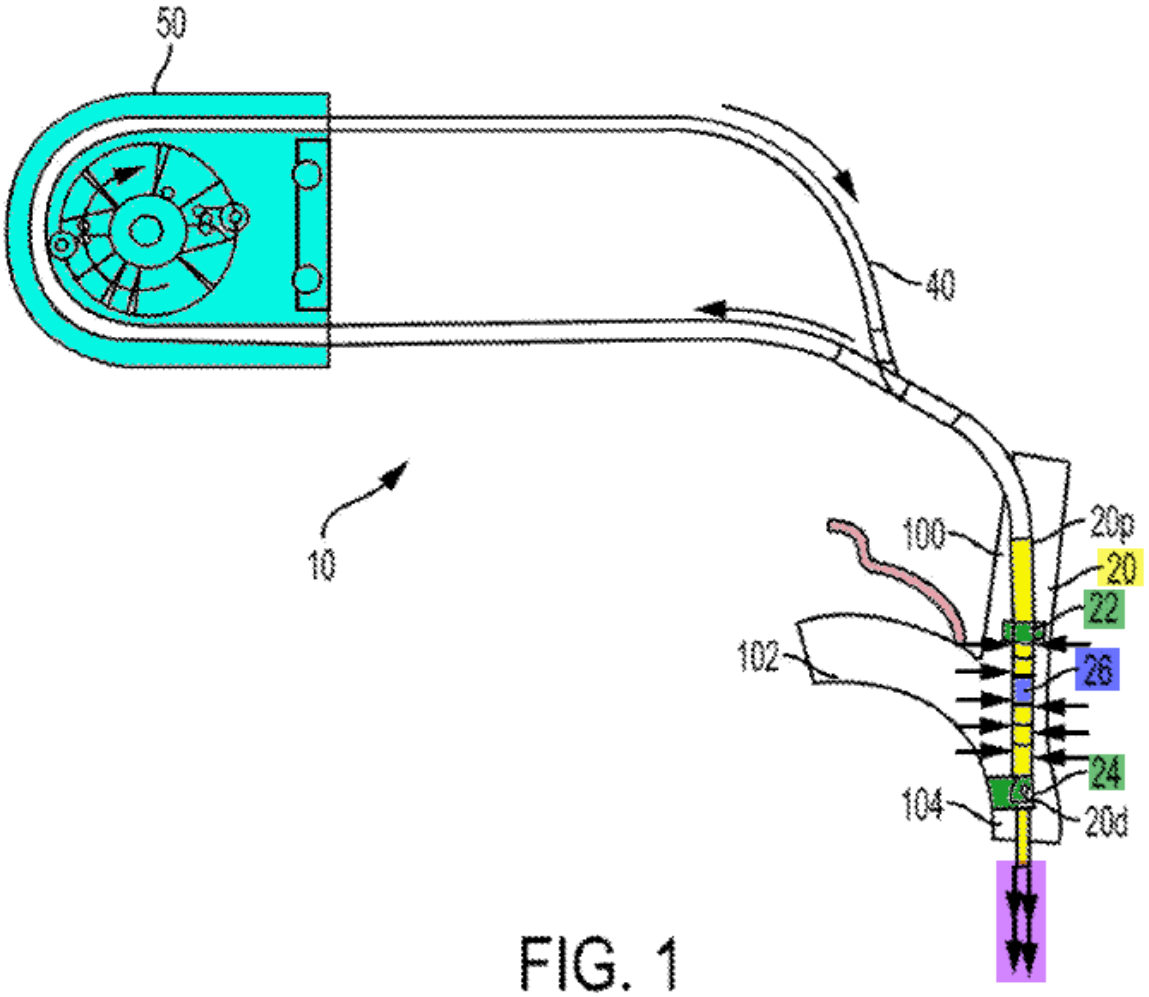


FIG. 1

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

In Figure 1, 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 '871 Patent teaches inserting a catheter (highlighted yellow) with one or more "restrictions"[4] such as inflatable balloons (highlighted green)[5] into the venous system. (Ex. 1001, 4:37-40; 6:61-67.) 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

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

[4] The claims of the '871 Patent use the term "restrictor"; the specification generally uses "restriction" (*See, e.g.*, Ex. 1001, 24:2, 6:64) but also use "restrictor" interchangeably with "restriction" (*e.g.,* 10:23).

[5] The '871 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).

(highlighted blue) and discharges it at a point (highlighted purple) distal[6] 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).

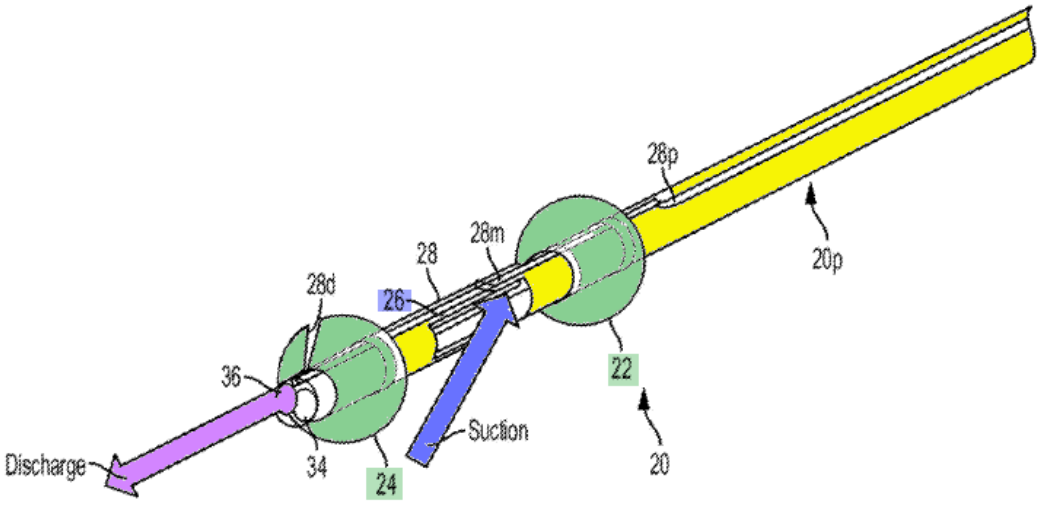


FIG. 3

"[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

[6] 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.

sensors is sent to a control module that can control the pump or alter the volume of the restriction(s). (*See* 15:17-32.)

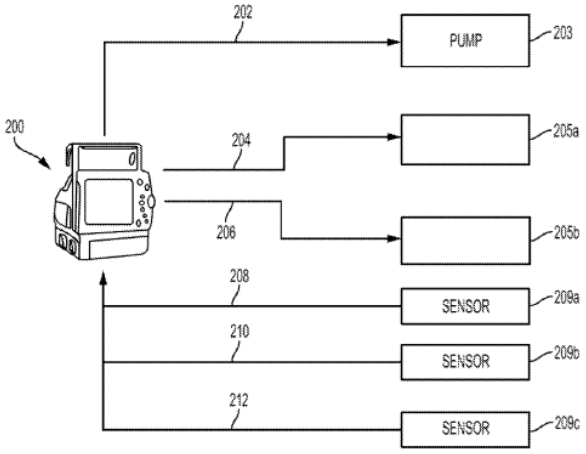


FIG. 10

The only mechanism of action taught in the specification is draining lymph. (Ex. 1002, ¶ 61; Ex. 1004, ¶ 40.) Although all claims of the '871 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, 7:63-65) 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[7] only in the embodiment shown in the annotated version of Figure 27[8] below, which depicts two "restrictions" (*i.e*, the claimed "restrictors") as well as "suction port(s)" between them:

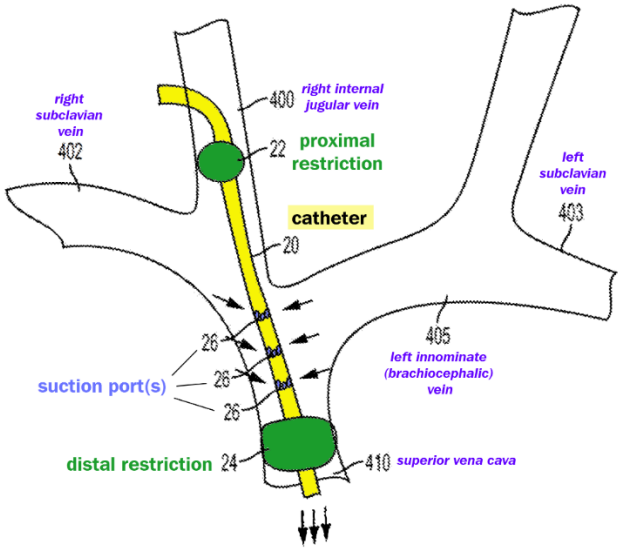


FIG. 27

[7] The specification discloses joining the jugular and SVC with a stent (*e.g.,* Ex. 1001, Fig. 28, 22:22-30), but the stent cannot be adjusted using sensor feedback. (Ex. 1002, ¶ 68.)

[8] 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, ¶ 66.)

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. (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 '871 Patent

As initially filed, the claims were directed to a method of treating edema by enhancing lymph clearance, or an apparatus to create a low-pressure zone downstream of a restrictor. The applicants cancelled all claims in a preliminary amendment and substituted the current method claims.

In the sole office action, the Examiner provisionally rejected all claims for obviousness-type double patenting and two dependent claims for indefiniteness because they recited "the one or more *resistors*," which had no antecedent, instead of "*restrictors.*" (Ex. 1008, p. 97.)

The Examiner issued no rejections based on prior art. The Examiner found that the closest prior art was U.S. Published Patent Application 2009/0131785 ("Lee") and U.S. Published Patent Application 2012/0029466 ("Callaghan"). The Examiner did not consider the references or grounds relied upon in this Petition.

According to the Examiner, although Lee "teaches a balloon catheter for selectively restricting flow through the vena cava . . . . Lee's device is configured to be placed in the inferior vena cava . . . ." (p. 101 (emphasis in original).)[9] The Examiner further found that while Callaghan "teaches a method for treating heart failure [0003] wherein a catheter system is implanted in the superior vena cava [0057] and comprises one or more restrictors for regulating blood flow," "Callaghan does not teach or suggest one or more sensors . . . and adjusting the one or more restrictors based on feedback from one or more sensors." (p. 102 (emphasis in original).)

In response, the applicants filed terminal disclaimers and amended the two dependent claims. The Examiner then allowed the application "for the reasons set forth in the previous office action." (p. 32.)

As demonstrated below, the prior art in this petition teaches the features found missing from Lee and Callaghan, as well as the other limitations of the challenged claims.

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[9] In fact, Lee is not restricted to the IVC and teaches that its "catheter assembly 10 is capable of occluding a variety of vascular and non-vascular lumens, *such as* the IVC." (Ex. 1017, ¶ [0018].)

D. Priority Date

Although the '871 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 claim (Claim 1), it cannot support any of the claims. *See* Ex. 1002, § VI.B.

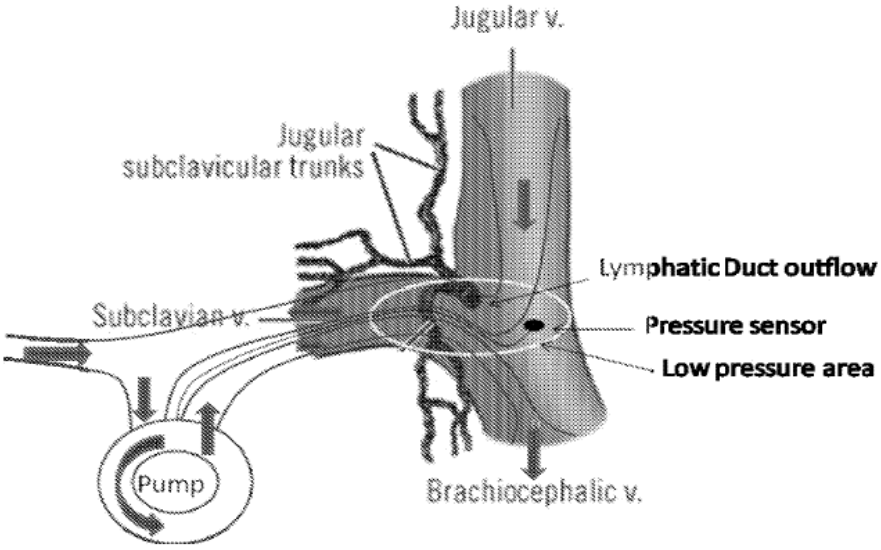
Claim 1 recites a "control module [that] . . . ***controls the one or more restrictors*** based on the feedback from the one or more sensors," as well as "***adjusting the one or more restrictors*** based on [sensor] feedback." (Ex. 1001, 23:40-44, 24:4-5.) However, the provisional does not disclose that sensor data is used to control or adjust a restrictor and thus cannot support the claim. (Ex. 1002, ¶¶ 74-76.)

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.)

Figure 3

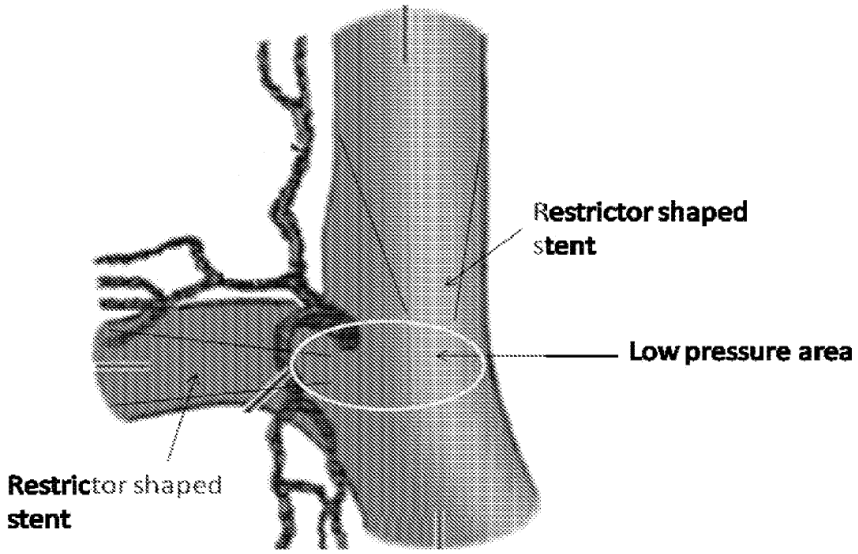
Acute and/or chronic solution with pressure sensor activating the pump



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 limitation "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, ¶¶ 81-83.

Therefore, the earliest possible priority date for any claim is February 19, 2015, the date of filing of the earliest non-provisional application (No. 14/625,930) to which the '871 Patent claims priority.

E. Level of Ordinary Skill in the Art

The claims of the '871 Patents 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 5)

The specification does not use this term, and it was not defined during prosecution of the '871 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" (Claim 14)

Claim 14 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.6), 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.

Claim 14 recites "*one* or more restrictors," 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 only uses "distal restriction" in

describing two-restrictor claim embodiments that have a "proximal restriction" closer to the clinician and a "distal restriction" further away from the clinician (*e.g.*, 3:5-6, 10:18-22, 17:45-52)—including the only SVC embodiment (22:12-20). Given the express definition of "distal" and no indication that its meaning should vary by number of restrictors, the term "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" (Claim 16)

Claim 16 depends from Claim 1, but there is no antecedent for the term "the catheter." However, Claim 1 recites "the catheter apparatus," which is apparently synonymous.

The specification does not define or use the term "extends across a vein wall," and this term was not at issue during prosecution. The only use of "extend" in connection with the catheter are inapposite (*see* Ex. 1001, Abstract, 2:10, 8:14), 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 how the examiner of the '871 Patent read this limitation during prosecution of a related patent: "the catheter is inserted into the vasculature across a vein wall proximal of the superior vena cava." (Ex. 1011, p. 86.)

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

VII. GROUND 1: CLAIMS 1, 3-16 ARE ANTICIPATED BY GELFAND

A. Overview of Gelfand

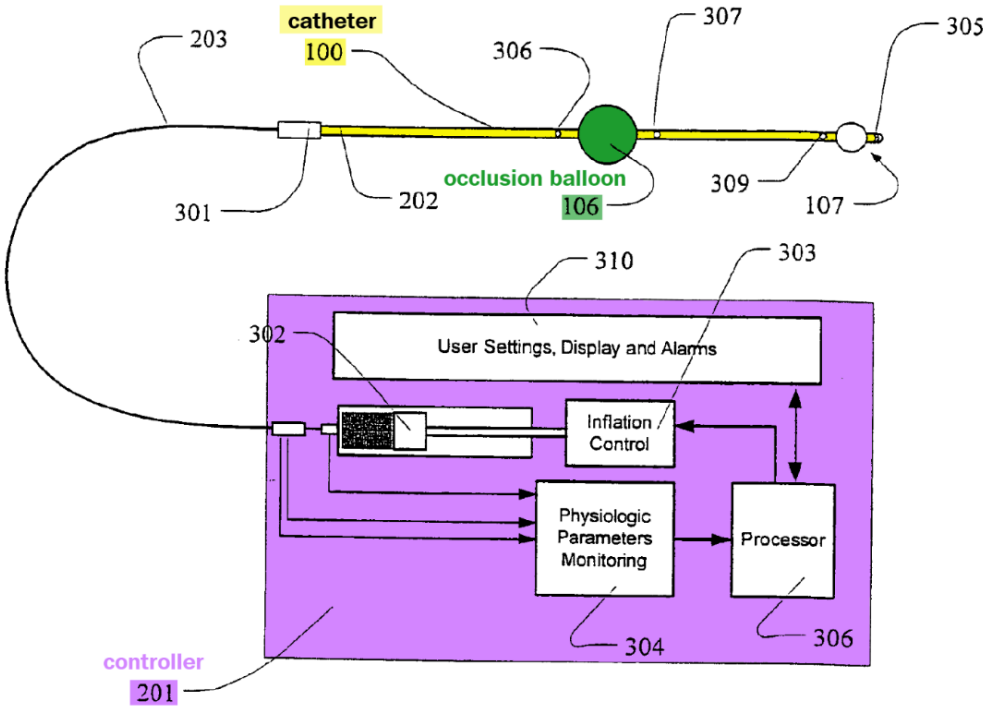
Gelfand was filed on September 21, 2005, and published on March 23, 2006. Gelfand is prior art to the '871 Patent under at least post-AIA 35 U.S.C. § 102(a)(1), but was not of record during the prosecution of the '871 Patent or any of its predecessor applications.

Gelfand is directed to "reduc[ing] the severity and complications of MI [myocardial infarct] 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].) As discussed below (Section VII.B.1), heart failure is among the MI complications treated by Gelfand's method.

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].)

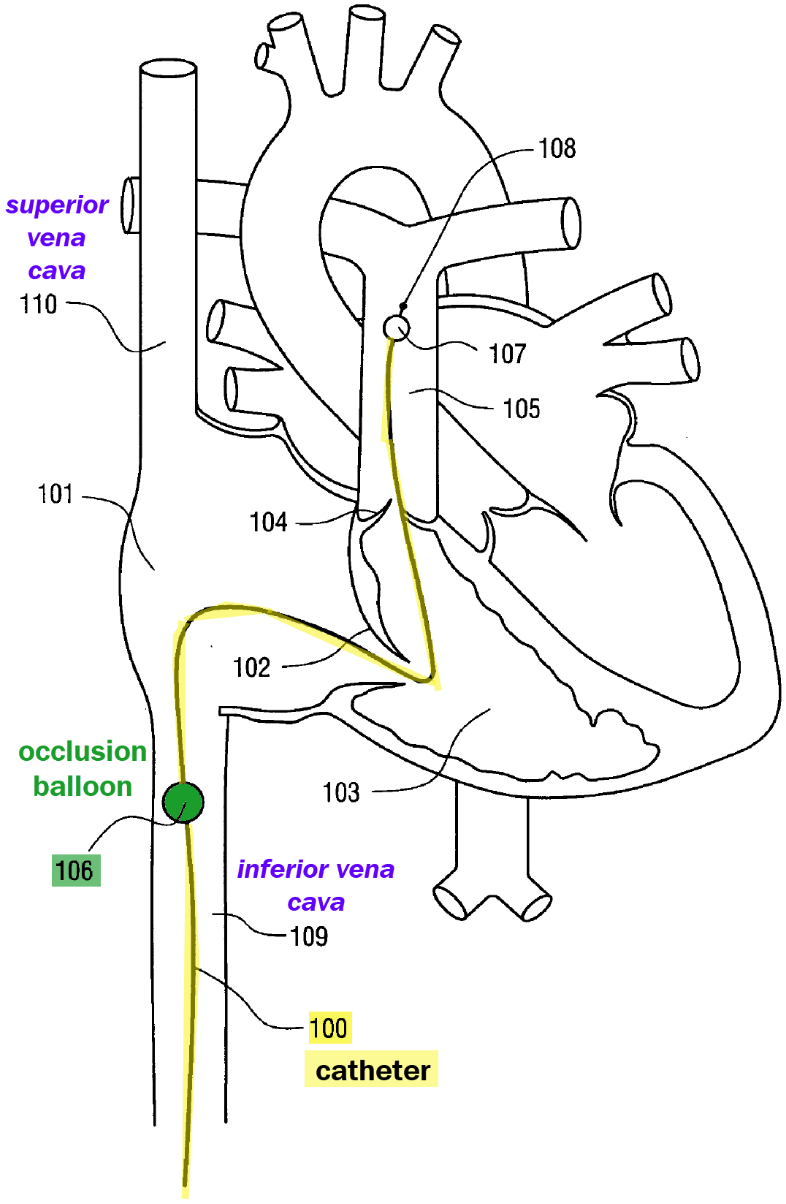
Gelfand explains that "[t]he degree of partial occlusion controls the blood flow." (¶ [0019].) To occlude blood flow, Gelfand discloses a device that "basically consists of the vascular catheter 100, inflatable occlusion balloon 106 proximal to the distal tip 108 of the catheter and the controller 201."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

Figure 3



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

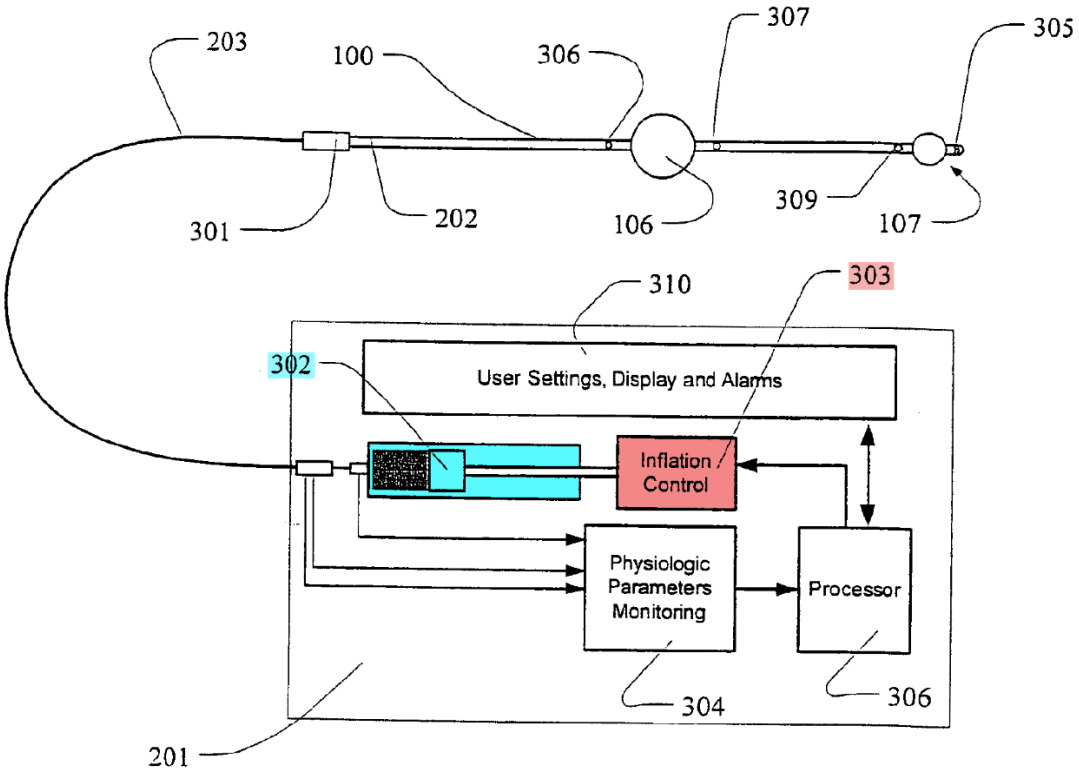
Figure 1



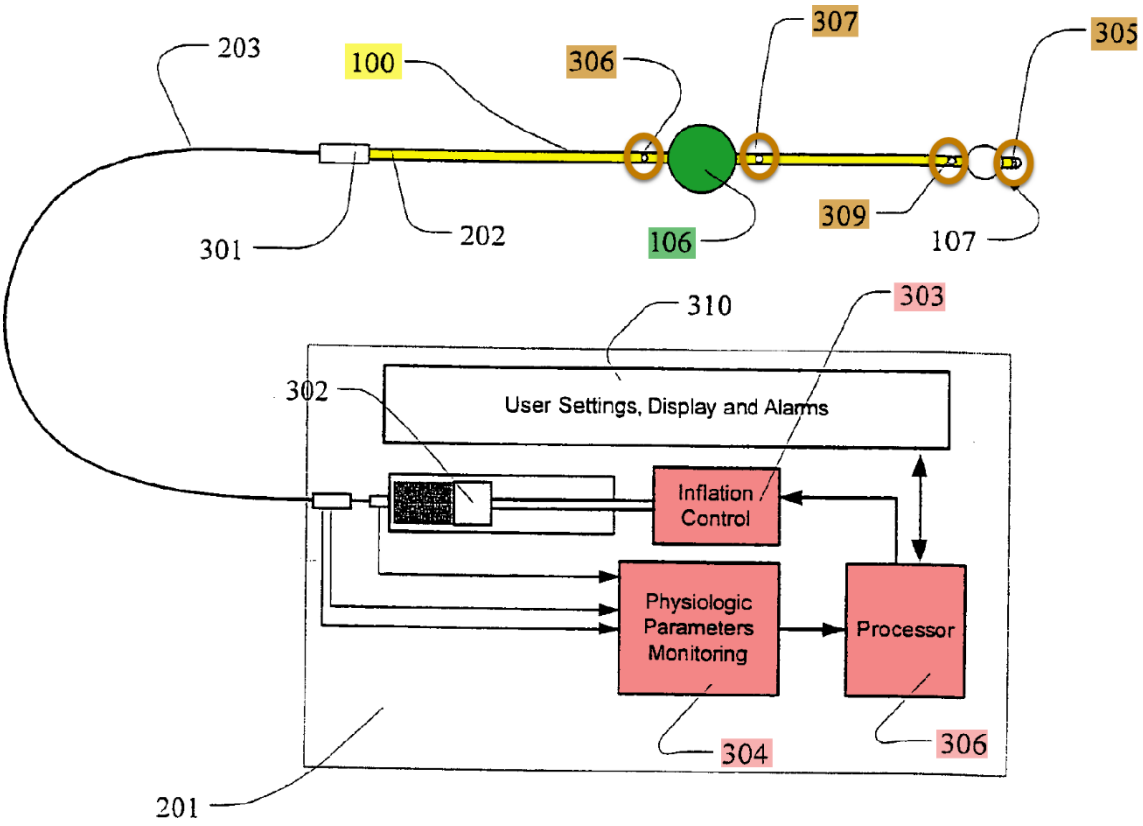
Gelfand expressly teaches that the device can be placed in the SVC to achieve the same blood-flow-limiting objective without "substantially chang[ing] the invented method, system or device." (¶ [0029]; *see also* ¶ [0017].)

As shown in Figure 3 below, a "controller" controls balloon inflation/deflation using a "balloon inflation device" (pump), highlighted turquoise, and "inflation control electronics," highlighted red. (¶¶ [0049]-[0050].)

Figure 3

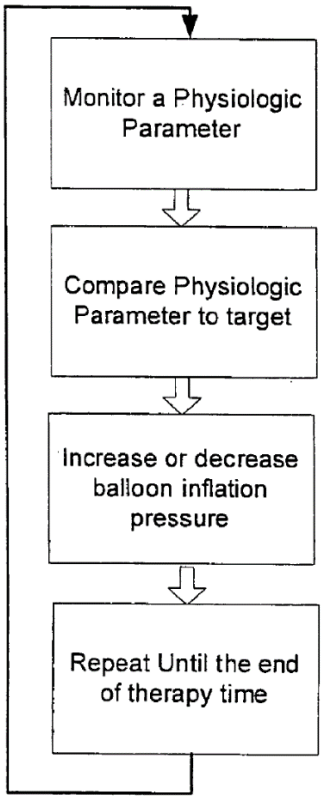


Gelfand teaches that "[a]dvanced micro tip catheter blood pressure transducers . . . can be integrated with the catheter 100 to obtain reliable and accurate measurements of pressure . . . ." (¶ [0051].) Exemplary sensor locations (*see id.*) are shown circled in brown in Figure 3 below:



Gelfand teaches that sensor signals are sent to the controller's "monitoring electronics (sub-system)," highlighted red above. (*Id.*) The controller's "processor" (also highlighted red) uses this sensor feedback 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 VII.B.7.) *See* Ex. 1002, § IX.A.

Figure 4



B. 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.

1. Claim [1p]

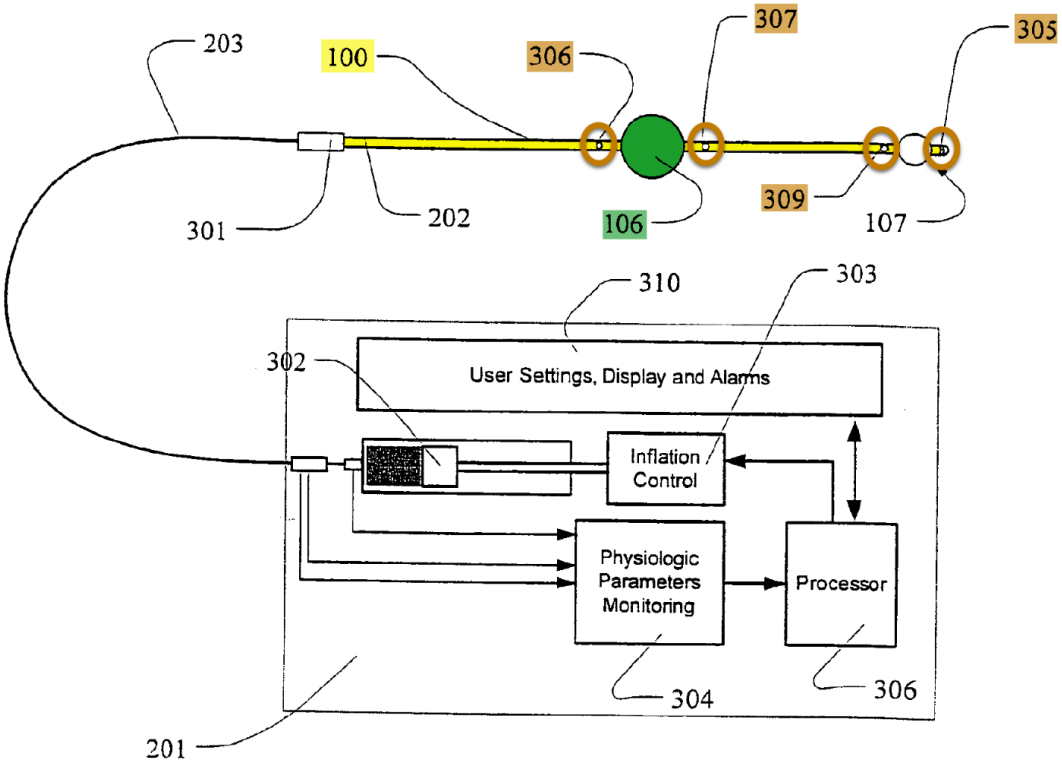
Gelfand discloses a method for treating the adverse consequences of a MI (heart attack), including heart failure, comprising the remaining steps and components of Claim 1. Thus, Gelfand discloses an apparatus that is used to "reduce[] the severity and complications of MI by reducing infarct size and/or 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].) These MI complications include heart failure.

Gelfand teaches that "[t]he total number and incidence of heart failure continues to rise with over 500,000 new cases each year. Approximately 85% of these new cases of ***heart failure are a direct consequence of a large MI***." (¶ [0013].) Gelfand explains that after an MI, oxygen-deprived heart tissue dies, causing high ventricular wall stress. (¶ [0005].) Gelfand teaches that one result of such elevated heart wall stress is "[l]eft ventricular remodeling," which "is defined as changes in shape and size of the Left Ventricle (LV) that can follow a MI." (¶ [0006].) Gelfand further teaches that such remodeling begins shortly after the MI and can result in heart failure. (¶¶ [0006]-[0007].) In reducing heart wall stress, Gelfand's invention treats MI-induced heart failure by arresting or ameliorating such left ventricular remodeling. *See* Ex. 1004, § IX.C.1.

2. Claim [1a]

Gelfand's method provides a system with all the elements of Claim [1a]: a ***catheter*** with an ***occlusion balloon*** (Ex. 1006, Abstract; *see also* ¶¶ [0018], [0026], [0028], [0031], [0048]) and one or more ***sensors.*** (¶¶ [0051], [0036]-[0046].) In Figure 3 below, the catheter is yellow, the balloon is green, and sensor locations are circled in brown:



Gelfand's occlusion balloon performs the same function as the claimed "restrictor" —to occlude the vessel in which it is deployed (¶ [0018])—and therefore corresponds to it. Indeed, the '871 Patent discloses that the "restrictor" may be a balloon. (Ex. 1001, 2:19-21.) *See* Ex. 1002, § IX.B.2.

3. Claim [1b]

It appears that "operable" is intended to mean "operably." (*Compare* Claim 8.)

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, the controller is purple, and the catheter is yellow.

Figure 2

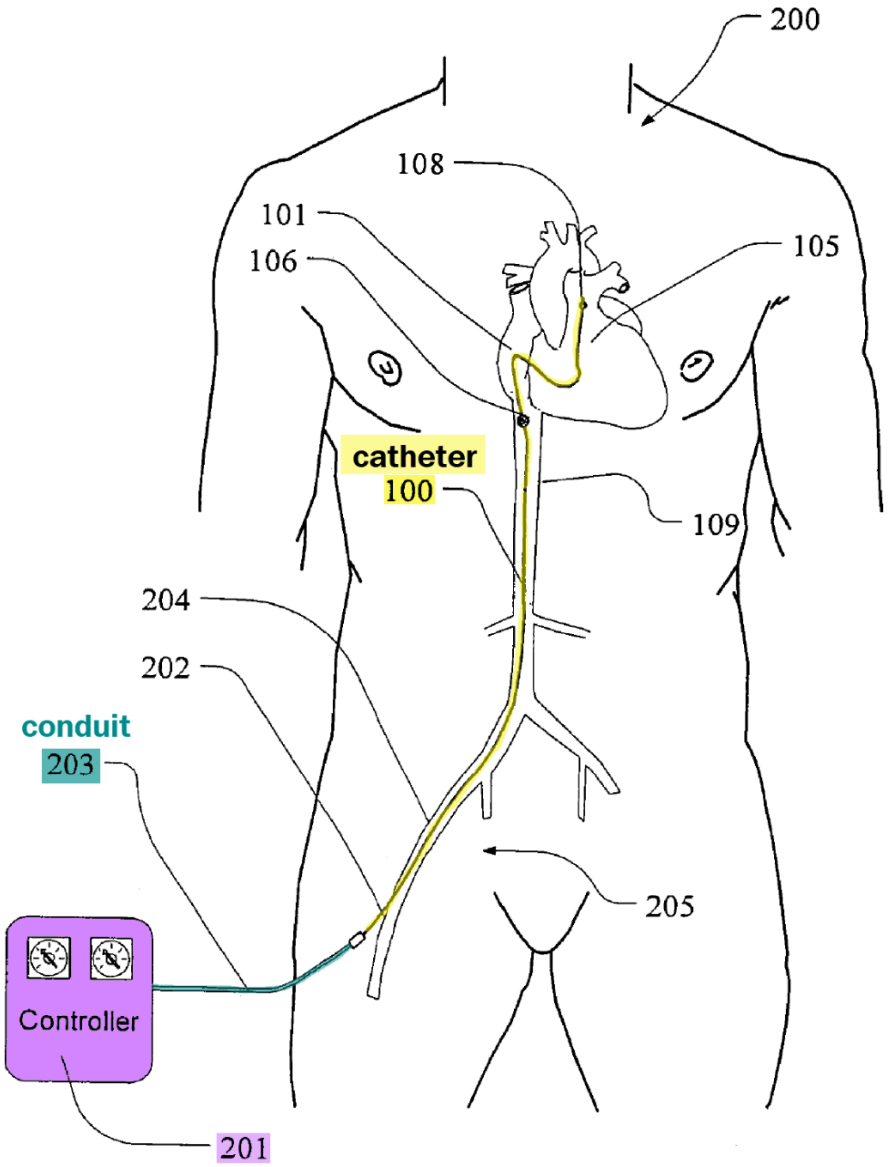
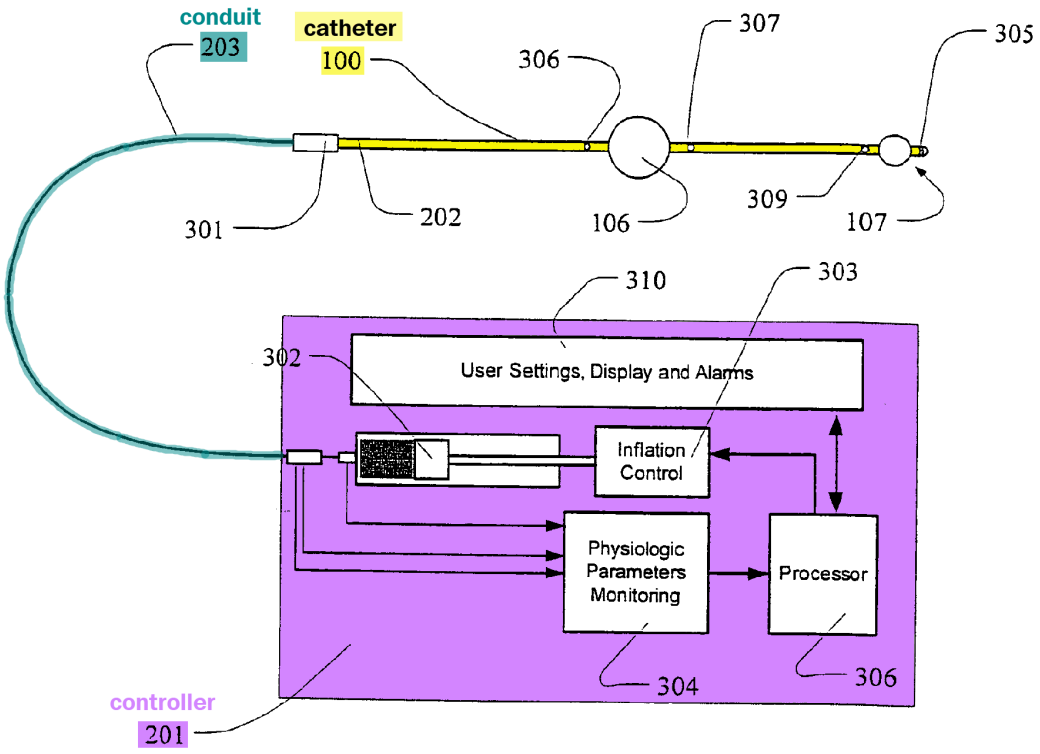


Figure 3



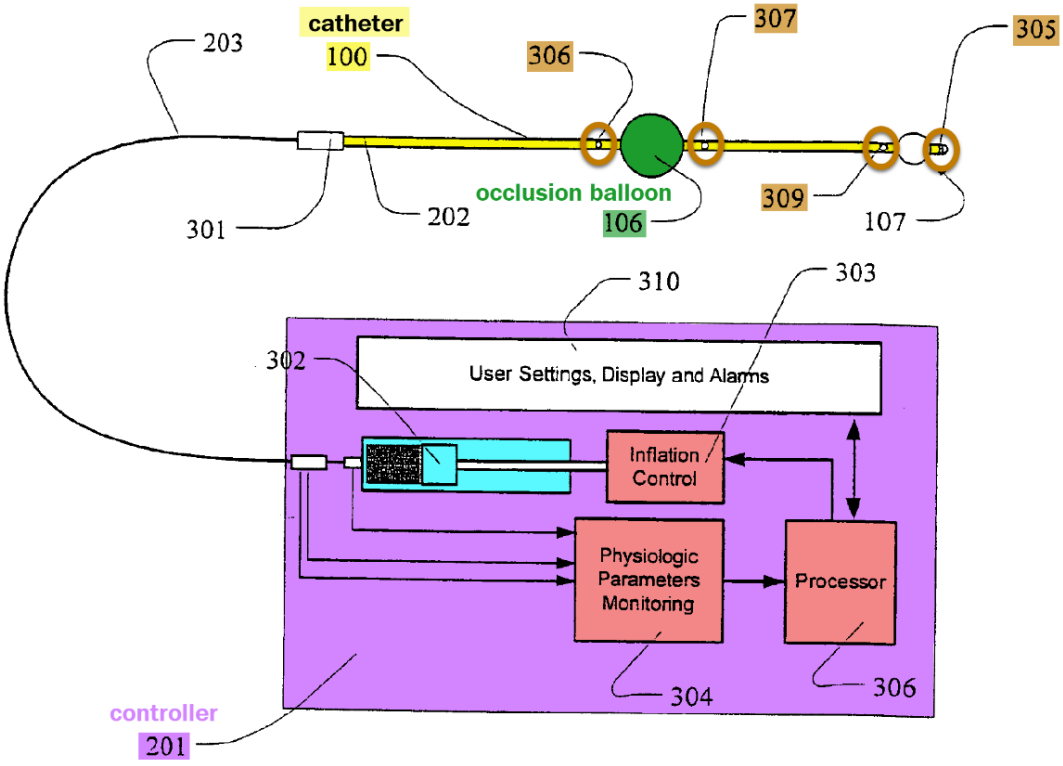
Gelfand teaches that the flexible conduit contains inflation lumens and signal-conducting means used in controller and catheter operation. (¶ [0035]; *see also* ¶ [0048].) For example, the controller controls operation of the catheter balloon via the inflation lumen (¶¶ [0049]-[0050].) Thus, Gelfand discloses that the controller and catheter are "operable coupled." *See* Ex. 1002, § IX.B.3.

4. Claim [1c]

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 balloon (the claimed "restrictor"), specifically to control balloon inflation or deflation. 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 balloon inflation using a balloon inflation device, such as a pump, and inflation control electronics, shown in Figure 3. (¶¶ [0049]-[0050].)

Gelfand specifically teaches the use of physiologic "feedback" from the sensors to control balloon inflation: "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*").) *See* Ex. 1002, § IX.B.4.

5. Claim [1d]

Gelfand discloses that the catheter is inserted 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 specifically teaches that its catheter balloon can also be positioned in the SVC: "it is understood that the occlusion balloon 106, shown in the IVC 109, can be positioned in other places within the right heart and great veins such as . . . **Superior Vena Cava (SVC)** . . . [without] substantially chang[ing] the

invented method, system or device." (¶ [0029]; *see also* Ex. 1002, ¶ 135.) Gelfand thus discloses advancing its catheter into the superior vena cava of a patient. *See* Ex. 1002, § IX.B.5.

6. Claim [1e]

Gelfand discloses operating its catheter to regulate venous blood return to the heart through the SVC by activating (*i.e.*, inflating) the balloon (the claimed "restrictor") to at least partially occlude flow through the SVC. *See* Ex. 1002, § IX.B.6.

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) in the IVC" (¶ [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].) How Gelfand's catheter balloon is inflated ("activat[ed]") and operated is not altered by placement in the SVC. (*Id.*; Ex. 1002, ¶ 140.) Thus, activation and operation of Gelfand's balloon results in

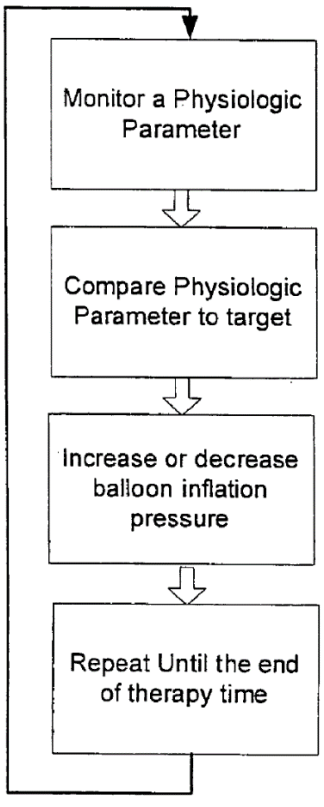
the claimed regulation of venous blood return and at least partial occlusion of blood flow through the SVC.

7. Claim [1f]

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 VII.A, VII.B.2). 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 . . . . Information in digital form is supplied to the processor every 5-10 milliseconds or less frequently if the measurement takes long time. 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 sensor data that blood pressure is too low), [0051], [0054] ("Control signals can be applied continuously or periodically to adjust the size of the balloon."); Claim 9.) *See* Ex. 1002, § IX.B.7.

8. Claim [1g]

The method, components and steps described above are used to treat heart failure. *See* Claim [1p] (Section VII.B.1).

C. Dependent Claims 3-16

1. Claim 3

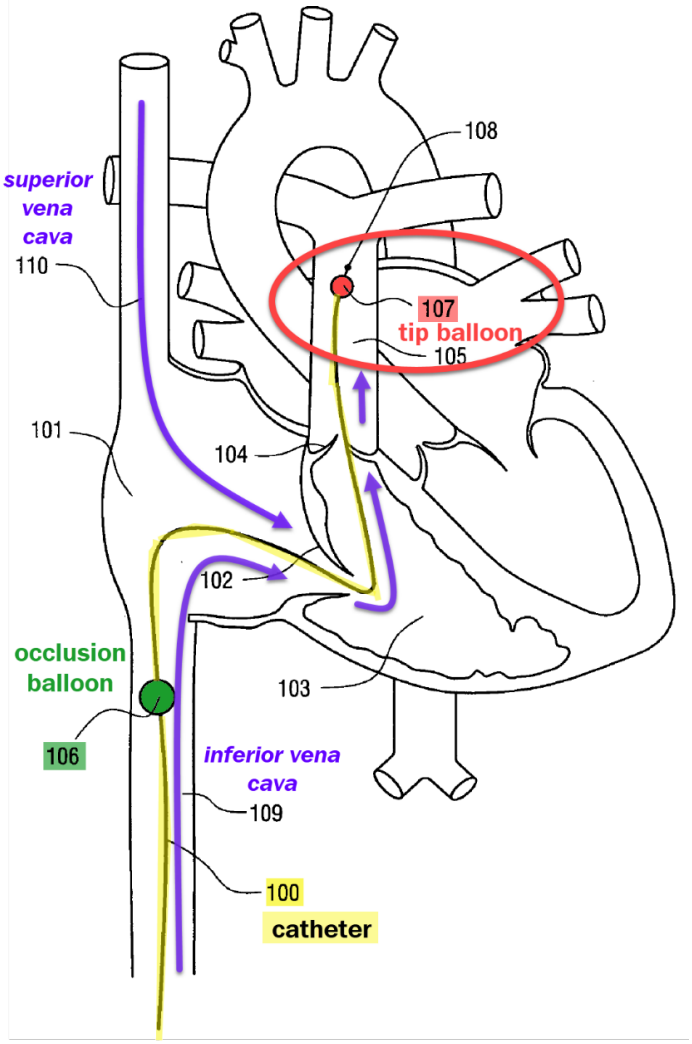
Although, in its exemplary embodiment, Gelfand teaches advancing the catheter through the femoral vein to place its balloon in the IVC (Ex. 1006, ¶¶ [0028], [0032]), Gelfand also expressly teaches positioning the balloon in the SVC (Ex. 1006, ¶ [0029]). Gelfand additionally teaches that insertion via a right-neck vein is typically used to place catheters in or near the heart. (¶¶ [0026]-[0027].)

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 internal and external jugular veins are the only large veins

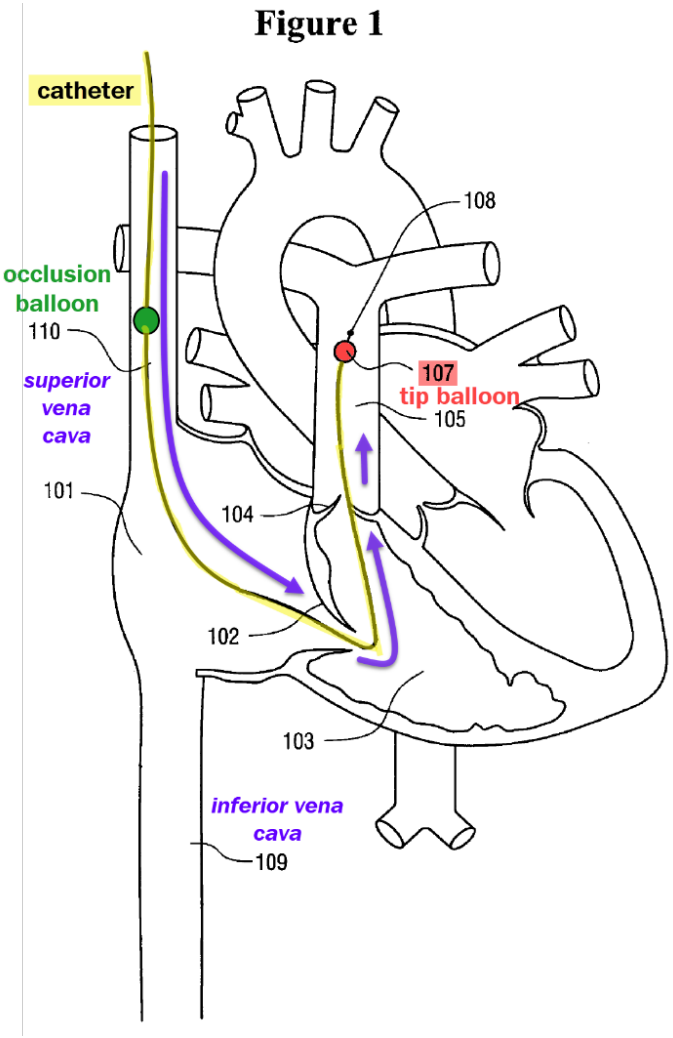
on the right side of the neck, and the right internal jugular vein is commonly used in Swan-Ganz catheterization because it is larger, is easily accessible, and provides the shortest distance to the heart. (Ex. 1012; Ex. 1004, ¶ 77.) From there, a catheter can advance through the SVC to enter the right atrium of the heart and may extend further into the heart and pulmonary artery. (Ex. 1006, ¶ [0027]; Ex. 1004, ¶ 78.)

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 right-neck vein, *i.e.*, a jugular vein. This technique utilizes the conventional placement features included on Gelfand's catheter. (Ex. 1006, ¶¶ [0026]-[0028], [0032].) Gelfand discloses that its catheter, just like the Swan-Ganz, 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 in Figure 1 below, while blood flow direction is shown by arrows. *See* Ex. 1004, ¶¶ 79-80.

Figure 1



If the catheter were inserted upstream of the IVC (*e.g.*, through the femoral vein) and the tip balloon were carried through the heart as intended, the catheter would have to advance partway into the SVC to place the occlusion balloon in 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.



A POSA would also know that jugular insertion provides a shorter, safer and more direct path to the SVC. *See* Ex. 1004, ¶¶ 83-84; Ex. 1012.

Therefore, to position the occlusion balloon inside the SVC as expressly taught by Gelfand (¶ [0029]), a POSA would insert and advance the catheter through a large right-neck vein, *i.e.*, a jugular vein, as described in Gelfand in connection with conventional Swan-Ganz catheterization (¶ [0027].) *See* Ex. 1004, § IX.D.

2. Claim 4

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"), ¶¶ [0036]-[0040], [0043]-[0046] (listing commercially available catheters with pressure sensors), Claims 6, 8.) *See* Ex. 1002, § IX.C.2.

3. Claim 5

"Maintaining intravascular pressure" should be construed to mean "maintaining pressure within blood vessels or a blood vessel." (Section VI.A.)

Gelfand discloses that the algorithm used for controlling its occlusion balloon "can be used to maintain a physiologic parameter or calculated index at the target level." (Ex. 1006, ¶ [0054].) One such "physiologic parameter" that can be "maintained . . . at the target level" is central venous blood pressure (CVP) (¶ [0052]). CVP is blood pressure in the SVC or IVC, so maintaining blood pressure in these blood vessels meets the requirement of "maintaining intravascular pressure." (Ex. 1004, ¶¶ 88-89.)

Gelfand also teaches that prior art treatments suffered from systemic "side effects such as hypotension (pathologically low blood pressure) that can be fatal to

a patient." (¶ [0010].) Gelfand teaches sensor-controlled adjustment of its balloon to prevent such systemic hypotension or undue decrease in the blood flow generated and ejected by the heart, *i.e.*, to maintain overall systemic intravascular pressure within safe limits. (¶ [0019]; Ex. 1004, ¶ 90.) And because the purpose of Gelfand's occlusion of the SVC is to substantially reduce blood flow to the heart (*e.g.*, ¶ [0018]), the inherent result is maintenance of a low-pressure zone downstream of the occlusion. (Ex. 1004, ¶ 91.) Each of these are additional ways in which Gelfand discloses "maintaining intravascular pressure." *See* Ex. 1004, § IX.E.

4. Claim 6

Gelfand discloses an "occlusion balloon" that corresponds to the claimed "restrictor." (Section VII.B.2; *see also* Ex. 1002, § IX.C.4.)

5. Claim 7

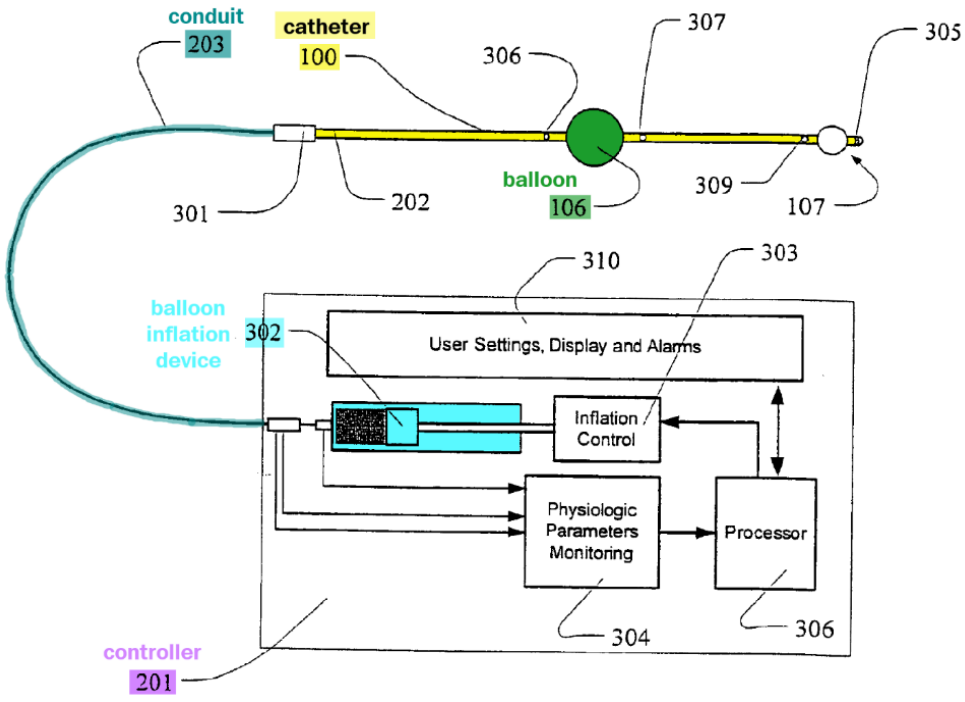
The plain meaning of "compliant" is: "Pliant, yielding to physical pressure". (Ex. 1020; *see also* definition of "compliance" ("the property of a body or material of undergoing elastic deformation . . . when a force is applied").) Because Gelfand discloses that its occlusion balloon (the claimed "restrictor") 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 discloses a "compliant" or "semi-compliant" balloon. *See* Ex. 1002, § IX.C.5.

6. Claim 8

As shown highlighted in turquoise in Figure 3 below, Gelfand discloses that its "[c]ontroller 201 includes the *balloon inflation device* 302. Shown in the preferred embodiment is a syringe pump or piston type apparatus." (Ex. 1006, ¶ [0049]; *see also* ¶ [0050] ("[i]nflation and deflation of the balloon 106 *by the inflation device* 302 is controlled by the inflation control electronics 303").)

Figure 3



The inflation medium can be liquid or gas. (¶ [0049].) The occlusion balloon is operably connected to the inflation device via an inflation lumen in the

catheter and conduit that allows the inflation medium to travel between the inflation device and the balloon: "Proximal end of the catheter 202 is attached to the control and monitoring console 201 by the flexible conduit 203. Conduit 203 can include ***balloon inflation lumens*** . . . ." (¶ [0035]; *see also* ¶ [0032] (catheter has "internal ***lumens for inflation of balloons***").)

Because Gelfand's balloon is connected to the inflation device such that the device can operate (inflate/deflate) it, the balloon is "operably coupled" to the inflation device. *See* Ex. 1002, § IX.C.6.

7. Claim 9

Gelfand's balloon (the claimed "restrictor") is adjusted based on feedback from the sensors. (Section VII.B.7.) Whenever balloon inflation is adjusted inside a blood vessel, a new pressure gradient is created. If the balloon becomes larger, blood pressure upstream of the balloon increases because less blood flows through the occlusion while pressure downstream of the balloon decreases. If the balloon becomes smaller, the opposite occurs, with pressure upstream of the balloon decreasing and pressure downstream of the balloon increasing. The resulting difference between upstream and downstream pressures is the pressure gradient created by adjusting the balloon. *See* Ex. 1002, ¶¶ 166-167.

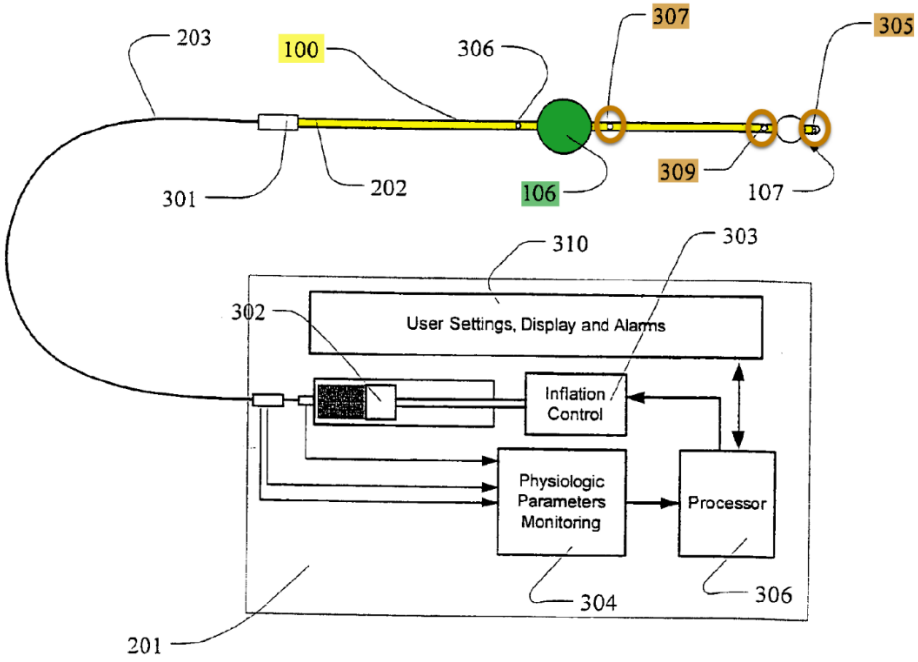
Gelfand provides an example of creating a new pressure gradient by adjusting the balloon based on sensor feedback:

> sensors . . . can measure pressure . . . to avoid reducing the blood flow too much. Excessive obstruction of IVC can lead to hypotension (dangerously low blood pressure). Based on these frequent or continuous physiologic measurements the occlusion can be reduced promptly . . . by an electronic controller mechanism.

(Ex. 1006, ¶ [0019].) In other words, if downstream pressure is too low, balloon size is decreased to reduce occlusion of the blood vessel with the objective of increasing blood flow past the balloon, thereby raising downstream pressure and creating a new pressure gradient across the balloon. *See* Ex. 1002, ¶ 168.

8. Claim 10

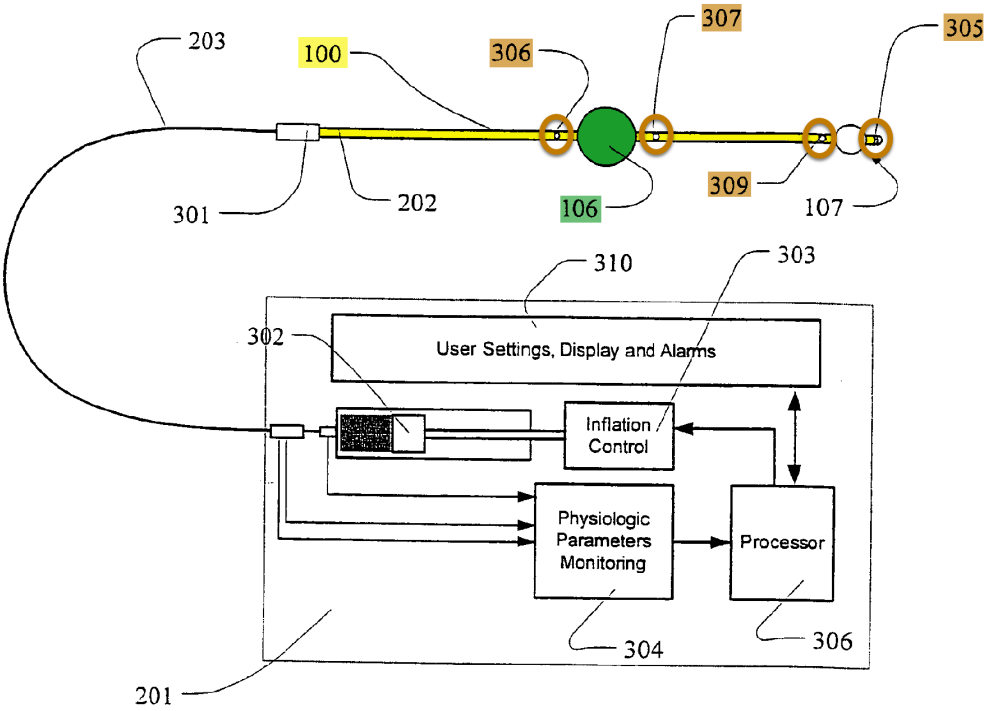
The catheter 100 used in Gelfand's method has at least three sensors—identified by reference numbers 305, 307 and 309 and circled in brown below —that are located distal to occlusion balloon 106 (the claimed "restrictor"):



(*See* Ex. 1006, ¶ [0051]; *see also id*., Claim 6 ("at least one physiologic sensor mounted *distal* to the expandable balloon").) *See* Ex. 1002, § IX.C.8.

9. Claim 11

The catheter 100 used in Gelfand's method has at least four sensors—identified by reference numbers 305, 306, 307 and 309 and circled in brown — that are spaced apart from occlusion balloon 106 (the claimed "restrictor"):



(*See* Ex. 1006, ¶ [0051]; *see also* ¶ [0046] (describing sensor 305).) *See* Ex. 1002, § IX.C.9.

10. Claim 12

As discussed above (Sections VII.B.2, VII.B.6), Gelfand teaches that the purpose of inflating ("activating") its occlusion balloon (the claimed "restrictor") is

to reduce blood flow through the veins leading to the heart: "the amount of venous blood returning to the heart (filling the heart) is reduced by creating a partial temporary obstruction (occlusion) in the IVC . . . ." (Ex. 1006, ¶ [0018].) As noted above, IVC teachings apply to the SVC. (¶ [0029].) Thus, "[t]he degree of partial occlusion controls the blood flow" (*id*.) through veins like the IVC or SVC.

As further discussed above (Section VII.B.7), the result of expanding Gelfand's balloon in a vein to reduce blood flow is a pressure drop in that vein. This is confirmed by Gelfand's teaching that "[e]xcessive obstruction of IVC can lead to hypotension (dangerously low blood pressure)." (¶ [0019].) *See* Ex. 1002, § IX.C.10.

11. Claim 13

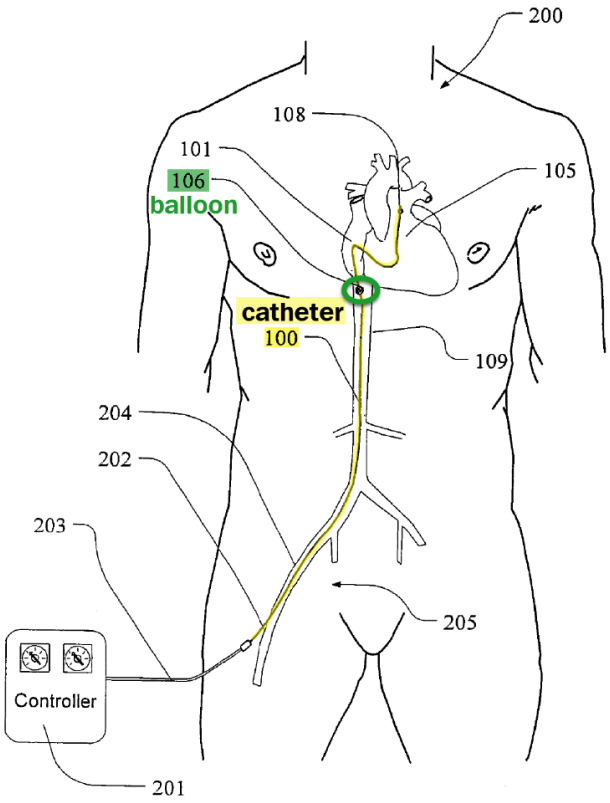
Gelfand teaches that its method includes detecting a pressure drop indicative of dangerously low blood pressure and compensating for that drop by decreasing balloon size. (Ex. 1006, ¶¶ [0019], [0056].) Gelfand further teaches that blood pressure, and hence these or other blood pressure drops, can be detected in the IVC or SVC: "The physiologic measurements can include . . . Central Venous Blood Pressure (CVP). Each one of these parameters can be used as a feedback to control the inflation of the occlusion balloon . . . ." (¶ [0052].) As noted earlier, CVP refers to blood pressure in the IVC or SVC. *See* Ex. 1002, § IX.C.11.

12. Claim 14

"Distal restrictor" should be construed to mean **"the restrictor that is located furthest from the clinician."** (Section VI.B.)

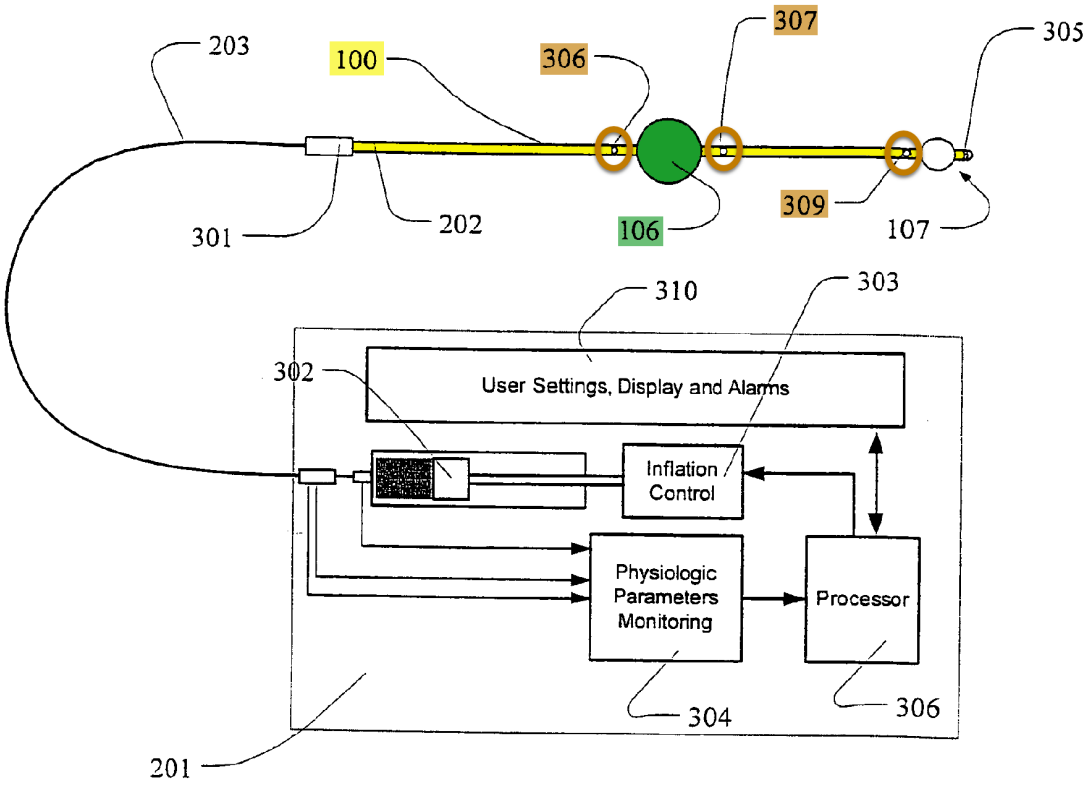
As shown in Figure 2, Gelfand's balloon 106 (highlighted green) is a "distal restrictor" because it is the only "restrictor" and thus furthest away from the clinician.

Figure 2



Gelfand's tip balloon 107 is not a claimed "restrictor"—it is used for catheter placement, not occlusion, and is not sensor-controlled. *See* Ex. 1002, ¶ 186.

Gelfand's Figure 3 discloses sensors (circled brown) both proximal and distal to the occlusion balloon.



Each of these proximal and distal sensors measures blood pressure: "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].) Signals from these sensors are sent to the controller, which uses them to control balloon inflation or deflation as part of Gelfand's method. (*Id.*) *See* Ex. 1002, ¶ 188.

Accordingly, Gelfand discloses "measuring a pressure distal of and proximal of the distal restrictor," *i.e.*, the balloon.

13. Claim 15

Gelfand discloses that its catheter "has multiple internal lumens for," among other things, "monitoring of blood pressure." (Ex. 1006, ¶ [0032].) A POSA knows that to be used for monitoring blood pressure, an internal catheter lumen must be connected to an opening on the wall of the catheter that is in contact with the blood whose pressure is measured. *See* Ex. 1002, § IX.C.13.

14. Claim 16

"Catheter extends across a vein wall" should be construed as "catheter extends through a vein wall." (Section VI.C.) Gelfand discloses positioning the catheter occlusion balloon in the SVC, and a POSA knows this would be accomplished by inserting the catheter through a neck vein, such as the jugular vein, using the conventional Swan-Ganz catheterization technique taught by Gelfand. (*See* Section VII.C.1.) A catheter inserted through the jugular vein—or indeed any vein except the SVC itself, which requires unnecessary surgery—necessarily extends through a vein wall "proximal" of the SVC by definition (*see* Section V.B, n.6) because the insertion site is closer to the clinician than the SVC. *See* Ex. 1004, § IX.F.

VIII. GROUND 2: CLAIMS 1-16 ARE OBVIOUS OVER GELFAND AND KAISER

Kaiser discloses a method of treating heart failure by partially or fully occluding the SVC using a catheter with an adjustable, expandable component whose operation is controlled by sensor readings—in other words, a device virtually identical in structure and operation to Gelfand's device. Given Kaiser's teachings, it would have been obvious to use Gelfand's device to treat heart failure in the manner recited by each of the claims of the '871 Patent.

A. Overview of Kaiser

Kaiser is prior art to the '871 Patent under at least post-AIA 35 U.S.C. § 102(a)(2), but was not of record during the prosecution of the '871 Patent or any of its predecessor applications.

The application for Kaiser was filed on January 14, 2015, and claims priority to a provisional application filed on January 12, 2014. The priority date of the '871 Patent is no earlier than February 19, 2015, because the June 1, 2014 provisional application does not support any of its claims. (*See* Section V.D.) But even if the '871 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.[10]

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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[10] 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 6.)

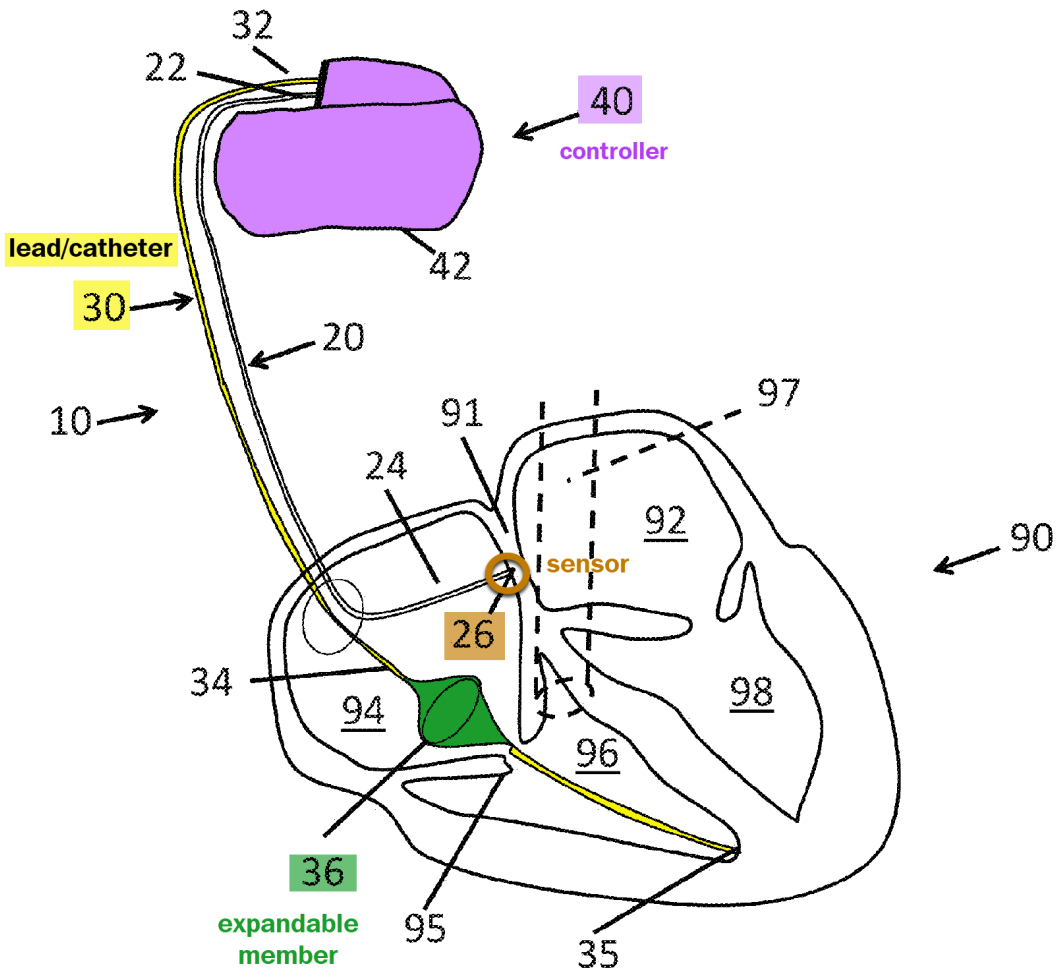


FIG. 1

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.

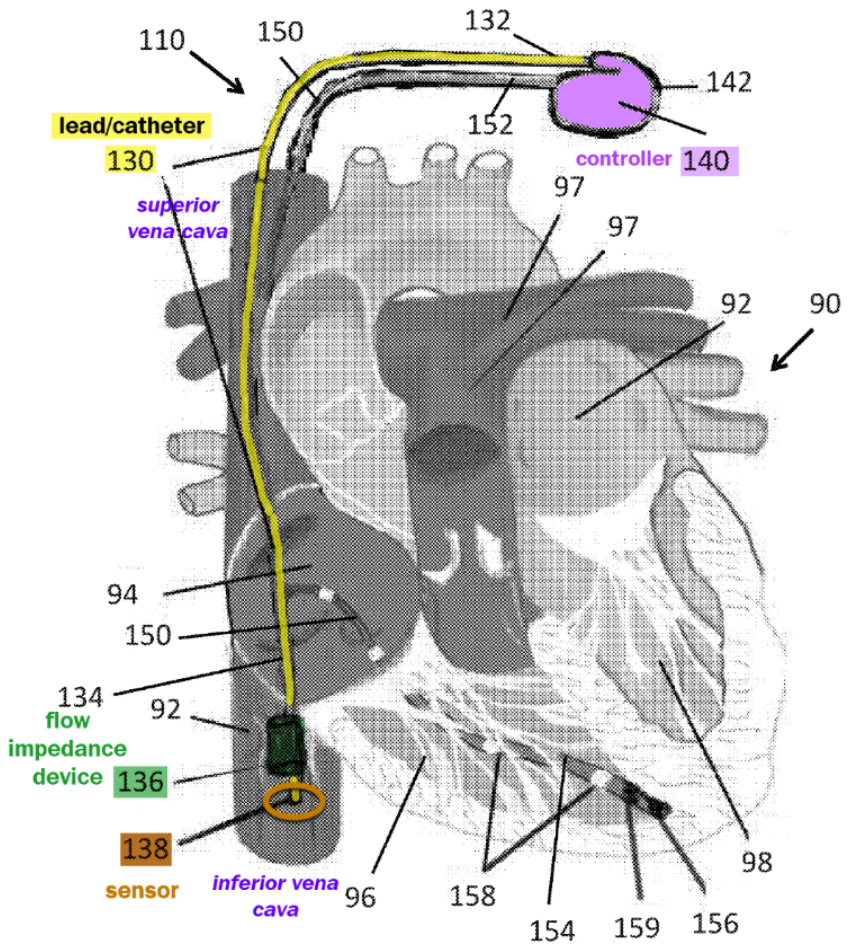


FIG. 2

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 that may be a ***"catheter"*** (*e.g.*, 7:59-64, 10:26-29).[11]

[11] 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.) 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."[12] (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 can control 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, § X.A.1; Ex. 1004, § X.A.

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

B. Application of the *Graham* Factors

The analysis in this and subsequent obviousness grounds 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 1-16, and by the motivations 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

Each of Kaiser and Gelfand teaches methods of treating heart disease by using a device to occlude the SVC, and both teach 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. In each device, the catheter is connected to a computerized controller that

controls occlusion using data obtained from catheter sensors. 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, the controller adjusts the size of the balloon, and with it the degree of blood occlusion, based on feedback from the sensors. While Gelfand aims to reduce heart wall stress and Kaiser aims to optimize intracardiac pressures and induce "mechanical diuresis," 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 according to Gelfand's method, but also heart failure according to Kaiser's method, *i.e.*, by controllably reducing venous blood return to the heart to regulate intracardiac filling pressure and induce "mechanical diuresis." A POSA would be motivated to use Gelfand's device because it uses conventional, off-the-shelf components familiar to clinicians—catheters, balloon pumps and sensors (Ex. 1006, ¶¶ [0026]-[0028], [0030], [0036]-[0045], [0049])—and describes features such as sensor operation or balloon operation in greater detail, making Gelfand's device potentially easier to implement and use. *See generally* Ex. 1002, ¶ 248; Ex. 1004, ¶¶ 97-98, 110-12. 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 placement and computerized sensor-controlled occlusion of the SVC. Additional discussion of motivation to combine and expectation of success is found below.

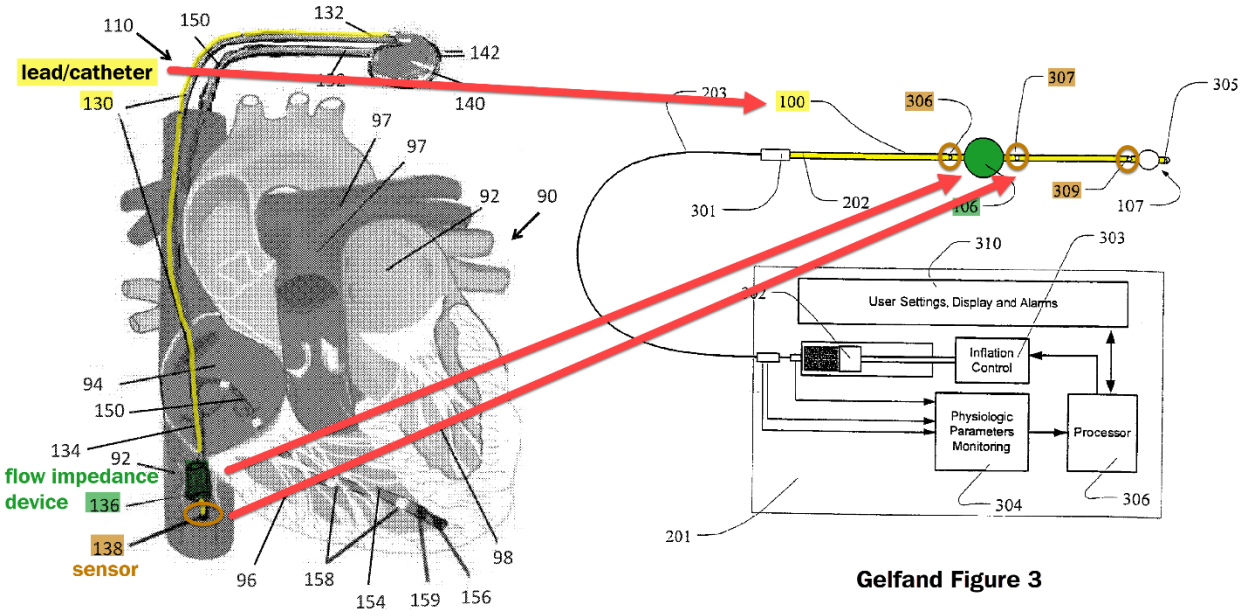
D. Independent Claim 1

1. 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 above (Section VIII.C), Kaiser discloses treating heart failure using a sensor-controlled balloon-catheter-type device essentially the same as Gelfand's in essentially the same way—to occlude the SVC—so it would have been obvious and easy to use Gelfand's device for that purpose. *See* Ex. 1004, § X.B; Ex. 1002, § X.C.1.

2. Claim [1a]

Claim 1[a] requires providing (1) a catheter apparatus with (2) at least one restrictor and (3) at least one sensor. Both Gelfand and Kaiser provide a system with these components and, as demonstrated above, they have the same purpose.



Kaiser FIG. 2

Gelfand Figure 3

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.)

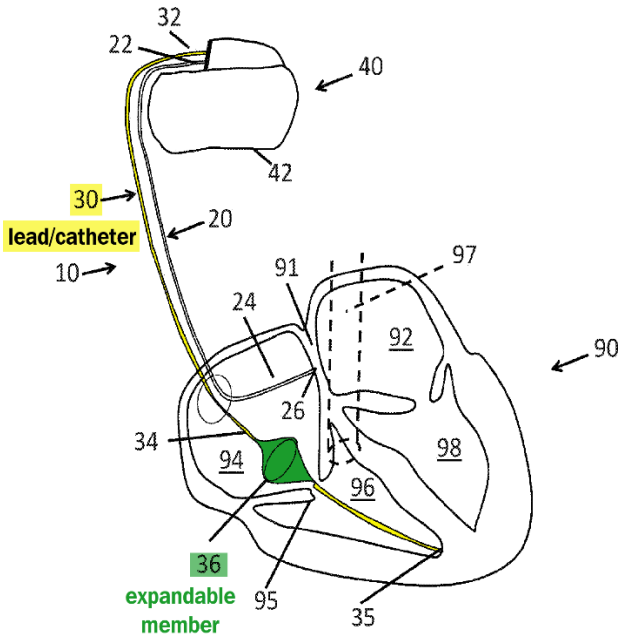


FIG. 1

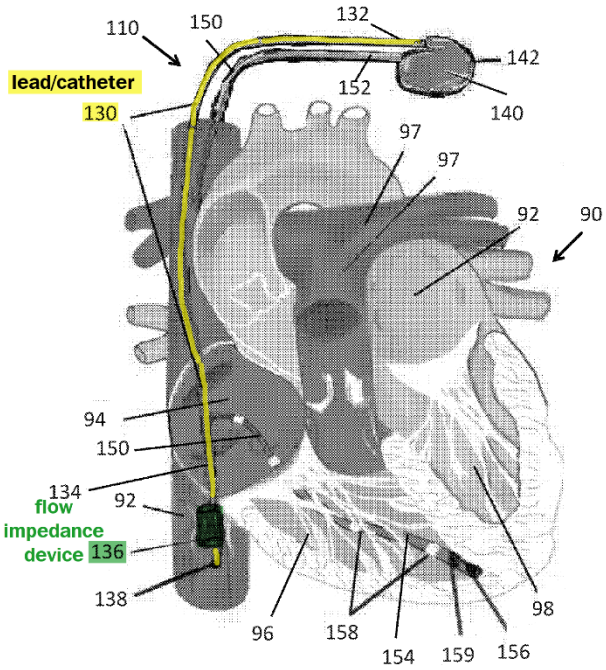


FIG. 2

Gelfand, too, discloses using a catheter (the claimed "catheter apparatus"). (Section VII.B.2.)

Kaiser further discloses using an Adjustable Component, 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.) Gelfand also discloses the use of a balloon (the claimed "restrictor") to occlude blood flow (Section VII.B.2).

Kaiser's catheter includes sensors to measure blood pressure (Ex. 1007, 7:60-8:2, 6:31-36, 12:65-13:2; Ex. 1010, 10:12-14, 15:3-4), examples of which are circled in brown below.

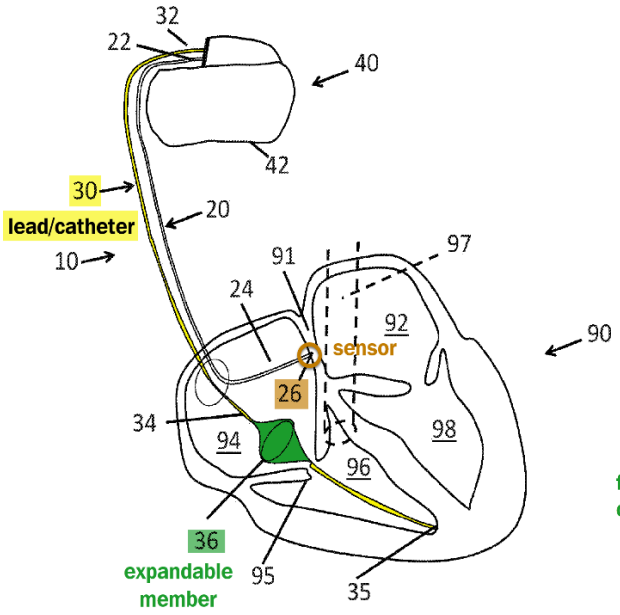


FIG. 1

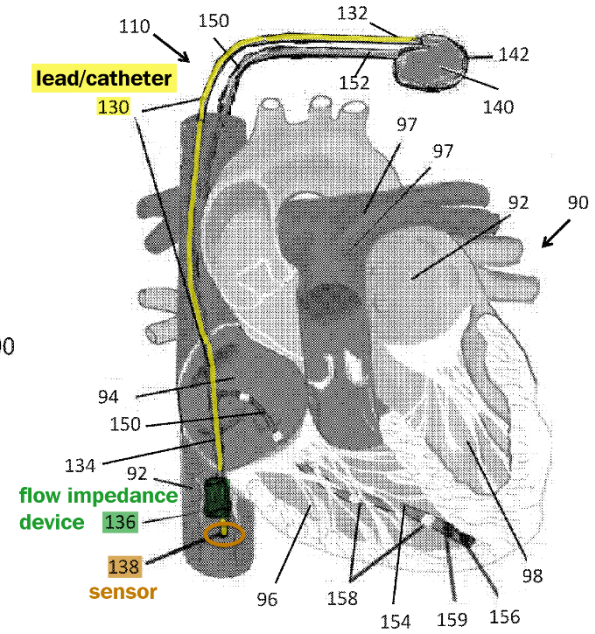
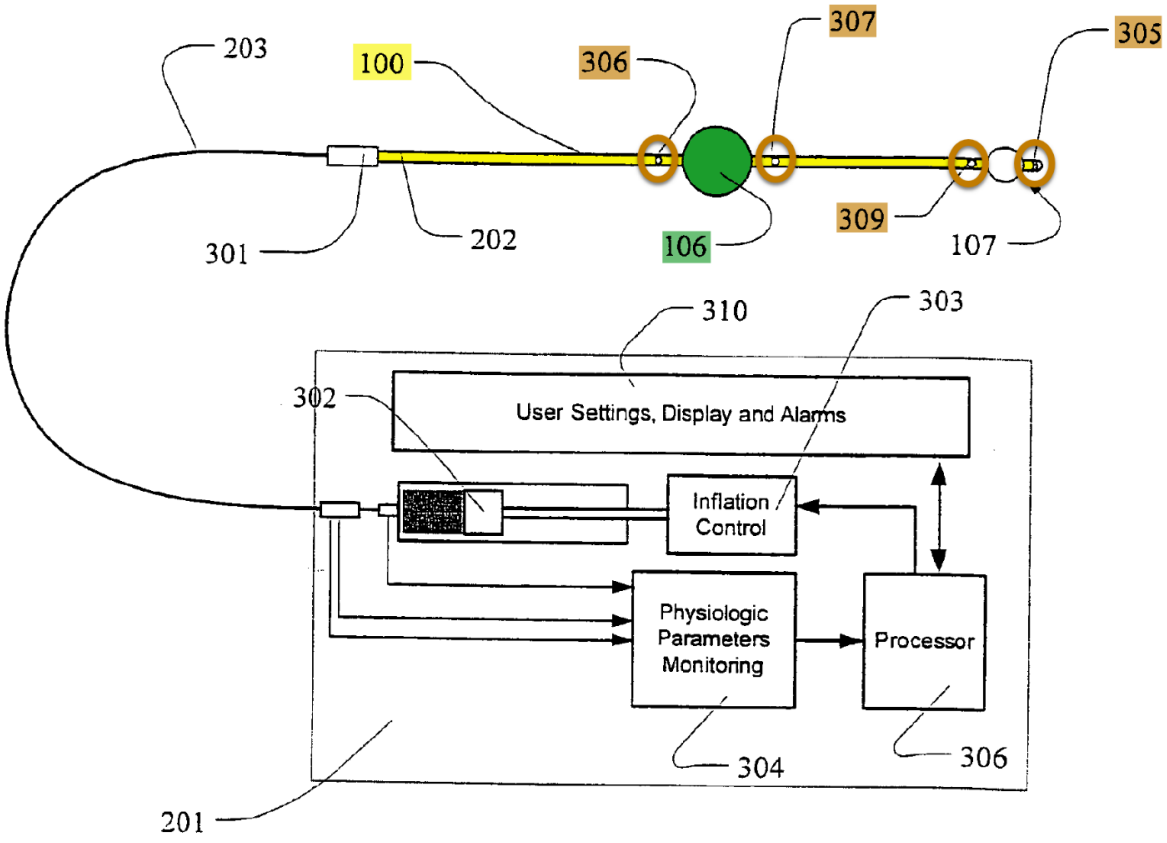


FIG. 2

(*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.) Gelfand's device also has blood pressure sensors, including in the locations used by Kaiser's method (*e.g.*, in the right atrium or SVC, or upstream). (*See* Sections VII.B.2, VII.C.2.)



See generally Ex. 1002, § X.C.2

3. Claim [1b]

Kaiser discloses providing and using a "controller" that is operably coupled to the lead/catheter. (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:

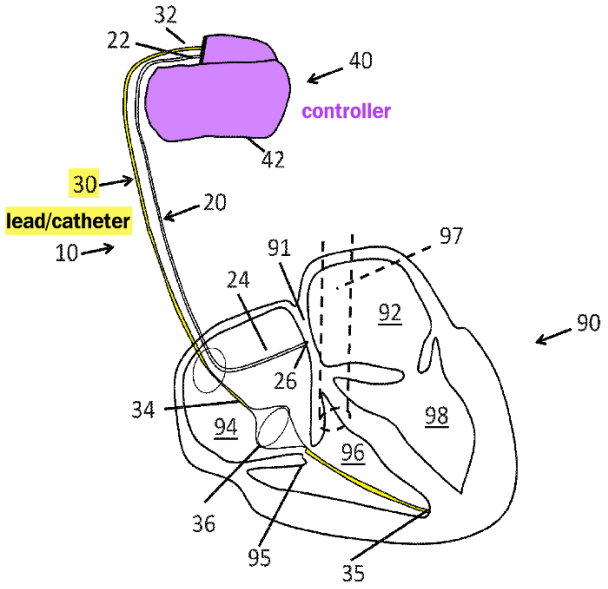


FIG. 1

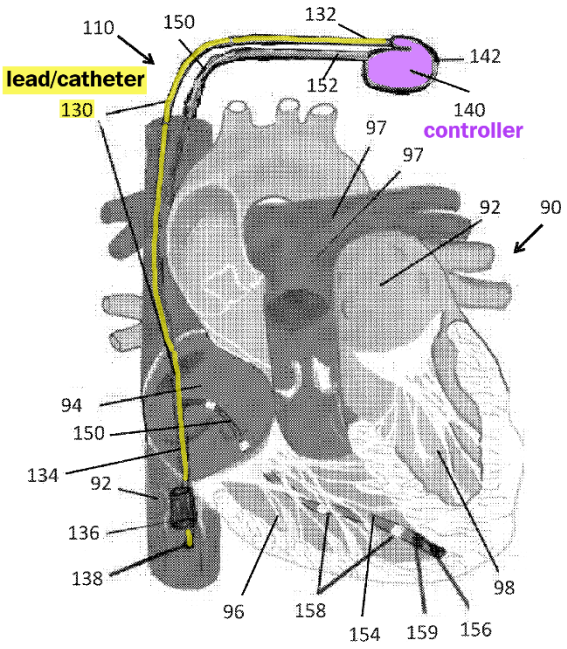


FIG. 2

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.) Likewise, Gelfand's catheter is operably coupled to a controller (the claimed "control module") that inflates the occlusion balloon via an inflation lumen. (Section VII.B.3.) *See* Ex. 1002, § X.C.3.

4. Claim [1c]

Kaiser discloses that its controller receives signals or data from sensors (*i.e.*, "feedback") and uses them to control the Adjustable Component. (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, "[t]he 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, can be used in algorithms that control the pressure differential created by the flow impedance device. (*See* 15:45-16:17, 8:61-62.)

The analogous components on Gelfand's device can perform the same functions: Gelfand's controller (the claimed "control module") receives feedback from the catheter's sensors and uses that data to control the occlusion balloon (Section VII.B.4), and its processor could execute any of Kaiser's occlusion algorithms. *See* Ex. 1002, § X.C.4.

5. Claim [1d]

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 can be placed in the SVC (Section VIII.A; Ex. 1007, 5:64-6:1; Ex. 1010, 6:1-3).

Gelfand also discloses percutaneous placement of the balloon on its catheter in the SVC. (Section VII.B.5.) *See* Ex. 1002, § X.C.5.

6. Claim [1e]

Kaiser discloses that its "*adjustable component 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.

Like Kaiser, Gelfand teaches that its occlusion balloon may be inflated (the claimed "activating") to regulate and at least partially occlude blood flow in the SVC. (Section VII.B.6.) *See* Ex. 1002, § X.C.6.

7. Claim [1f]

Kaiser discloses that its Adjustable Component 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 cardiac output trends and/or *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.)

Gelfand's device has the same capability of adjusting its occlusion balloon based on sensor feedback (Section VII.B.7) and could thus execute Kaiser's adjustment algorithms. *See* Ex. 1002, § X.C.7.

8. Claim [1g]

Kaiser's invention is directed to the treatment of heart disease, including congestive heart failure. (Sections VIII.A, VII.D.1.) As discussed above (Section VII.B.1), Gelfand's device can be used for the same purpose. But to the extent the Board concludes that a POSA would not understand from Gelfand's disclosure that Gelfand's device treats heart failure, a POSA would understand that it could successfully be used for that purpose in view of Kaiser's disclosures. (Ex. 1004, § X.B; Ex. 1002, § X.C.8.)

9. Motivation to Combine and Reasonable Expectation of Success

As discussed above (Section VIII.C), a POSA would be motivated to use Gelfand's device in practicing Kaiser's method and have a reasonable expectation

of success. In the resulting combination, Kaiser discloses Claim [1p] and [1g] while Gelfand discloses the remaining limitations, thus rendering Claim 1 obvious. (Ex. 1002, ¶ 284.)

E. Obviousness of Dependent Claims 2-16

1. Claim 2

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 "at least partially" occluded, Kaiser discloses that the Adjustable Component can be used for full filling/occlusion, which fully restricts 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 blood flow.

Kaiser expressly teaches that its device may be used in the SVC (*see* Section VII.D.5) 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* Ex. 1010, 1:4-6, 5:9-28, 11:1-4.)

A POSA using Gelfand's device to practice Kaiser's method of treating heart failure would 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 Claim 2, rendering it obvious. *See* Ex. 1004, § X.C; Ex. 1002, § X.D.1.

2. Claim 3

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 the placement method taught by Gelfand (Sections VII.B.5, VII.C.1): inserting the 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 using Gelfand's device in the SVC to practice Kaiser's method would thus be motivated to follow Gelfand's teachings for placing the device, *i.e.*, through a large right-neck vein like a jugular vein. The POSA would have a reasonable expectation of success for the reasons set forth in Sections VII.C.1 and IX, including because this vein "is often the access site of choice for central venous cannulation" (Ex. 1012, p.4), *i.e.*, catheterization, which is what Kaiser's method entails. The resulting combination of using Gelfand's placement method to advance Gelfand's device into the SVC to practice Kaiser's occlusion method discloses every element of Claim 3, rendering it obvious. *See* Ex. 1004, § X.D; Ex. 1002, § X.D.2.

3. Claim 4

As discussed in Section VIII.D.2, Kaiser discloses that its lead/catheter may contain one or more pressure sensors. (*See* Ex. 1007 at 7:66-8:2 (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.) The pressure sensor locations shown in Figures 1 and 2 are circled in brown below.

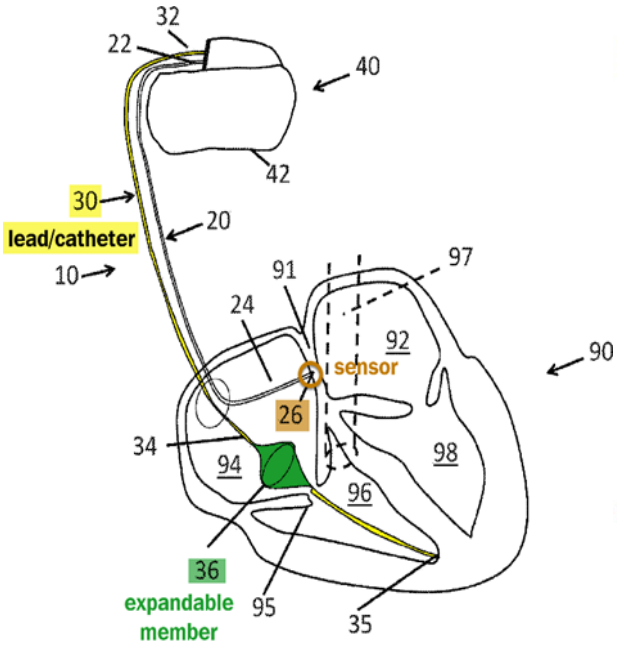


FIG. 1

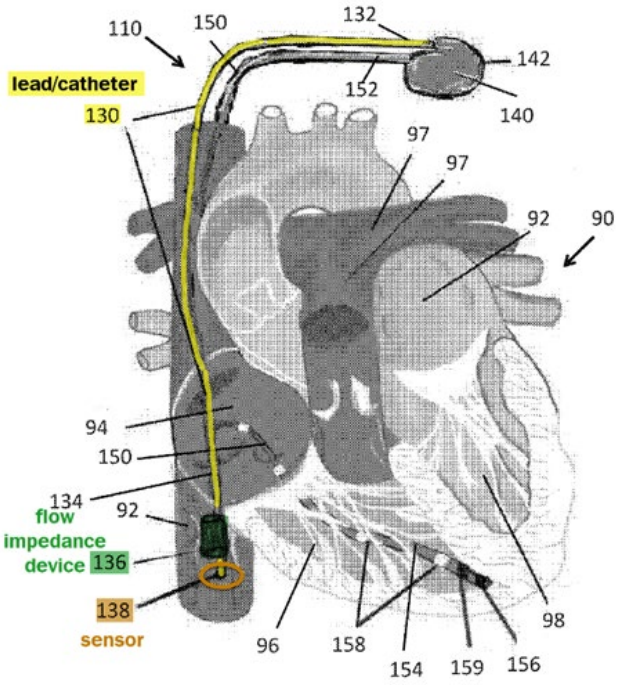
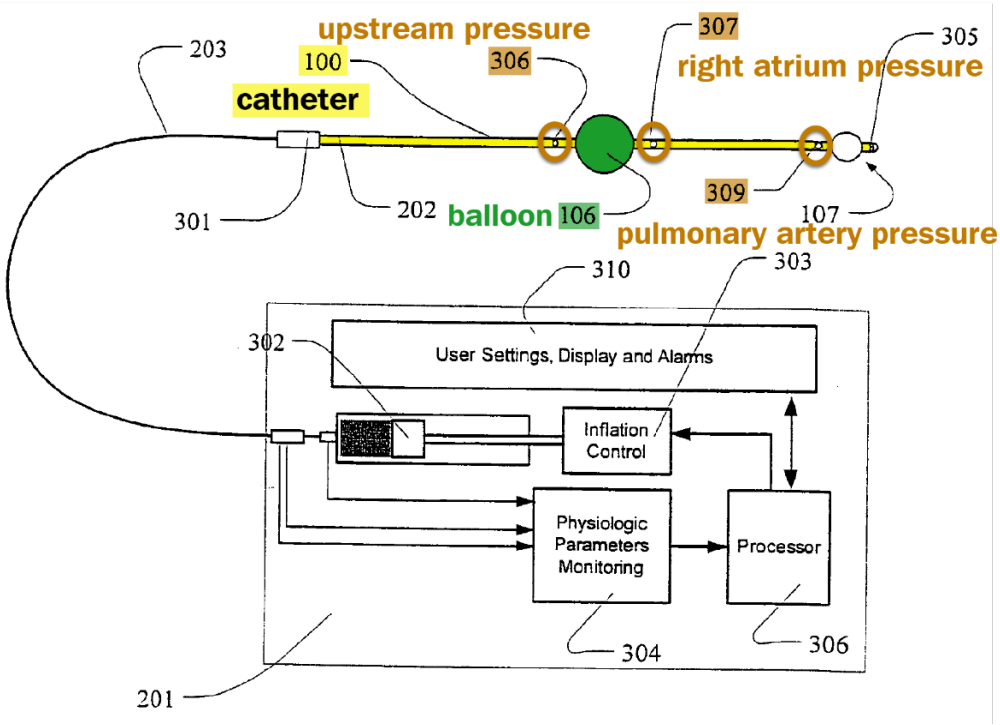


FIG. 2

Kaiser teaches that additional sensors can be placed in locations such as the SVC, right atrium or pulmonary artery. (Ex. 1007, 6:31-35; Ex. 1010, 10:12-14.)

Gelfand's catheter has pressure sensors placed in the same locations, and that are connected to Gelfand's controller for the same purposes taught by Kaiser, *i.e.*, to control occlusion (Sections VII.A, VII.B.4, VII.C.12):



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. The resulting combination of using pressure sensors on Gelfand's device to practice Kaiser's method discloses every element of Claim 4, rendering it obvious. *See* Ex. 1002, § X.D.3.

4. Claim 5

"Maintaining intravascular pressure" should be construed to mean "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. (Ex. 1004, § X.E.)

Second, as discussed above (Sections VIII.D.4, VIII.D.7), 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.)

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. The resulting combination discloses every element of Claim 5, rendering it obvious. *See* Ex. 1004, § X.E; Ex. 1002, § X.D.4.

5. Claim 6

Kaiser discloses that "the adjustable component 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.) Gelfand's device comprises a balloon, so a POSA motivated to use the device to practice Kaiser's method would be motivated to retain Gelfand's balloon. 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 that purpose. The resulting combination discloses every element of Claim 6, rendering it obvious. *See* Ex. 1002, § X.D.5.

6. Claim 7

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.) Gelfand also discloses a compliant (inflatable) balloon. (Section VII.C.5.)

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 Claim 7, rendering it obvious. *See* Ex. 1002, § X.D.6.

7. Claim 8

Kaiser discloses that when the Adjustable Component is a balloon, an inflation source, such as a pump, can be coupled to the balloon to operate (inflate or deflate) it. (Ex. 1007 at 10:26-34; *see also* 8:19-36; Ex. 1010, 8:7-11.) Gelfand also discloses that its catheter balloon is operably coupled to an inflation source such as a pump. (Section VII.B.2.) Such pumps are conventional in the art, as confirmed by Gelfand's disclosure of commercial pumps. (Ex. 1006, ¶ [0049].)

Accordingly, a POSA would be motivated to retain the operable coupling of a balloon with an inflation source when Gelfand's device is used in Kaiser's method and would have a reasonable expectation of success. The resulting combination discloses every element of Claim 8, rendering it obvious. *See* Ex. 1002, § X.D.7.

8. Claim 9

Kaiser discloses that adjustment of its Adjustable Component creates a pressure gradient across that component in the SVC: "the adjustable component

may ***create a pressure gradient*** by . . . adjusting blood flow impedance through the superior vena cava." (Ex. 1007, 6:60-64; *see also* 11:5-11, 12:55-58, Claim 10; Ex. 1010, 8:30-9:5.) Because Gelfand's device operates exactly like Kaiser's to adjust flow impedance through the SVC—by adjusting balloon size—it can create the pressure gradient taught by Kaiser. (Section VII.C.7.) 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") by adjusting its size. The resulting combination discloses every element of Claim 9, rendering it obvious. *See* Ex. 1002, § X.D.8.

9. Claim 10

Kaiser discloses that sensors on its lead/catheter may be distal to the Adjustable Component: "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.) Distal placement of the sensor 138 is illustrated in Figure 2, where it measures upstream pressure in the IVC:

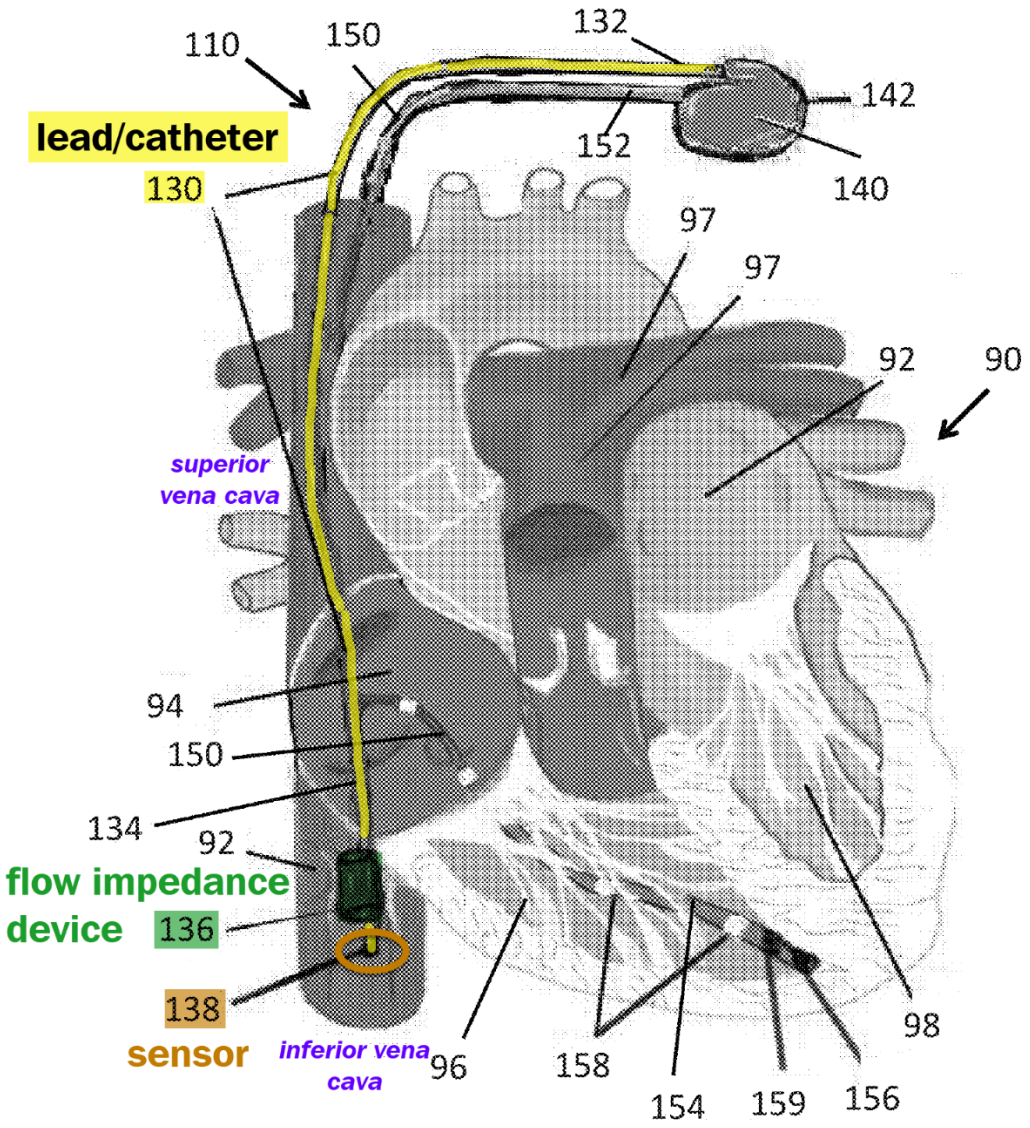
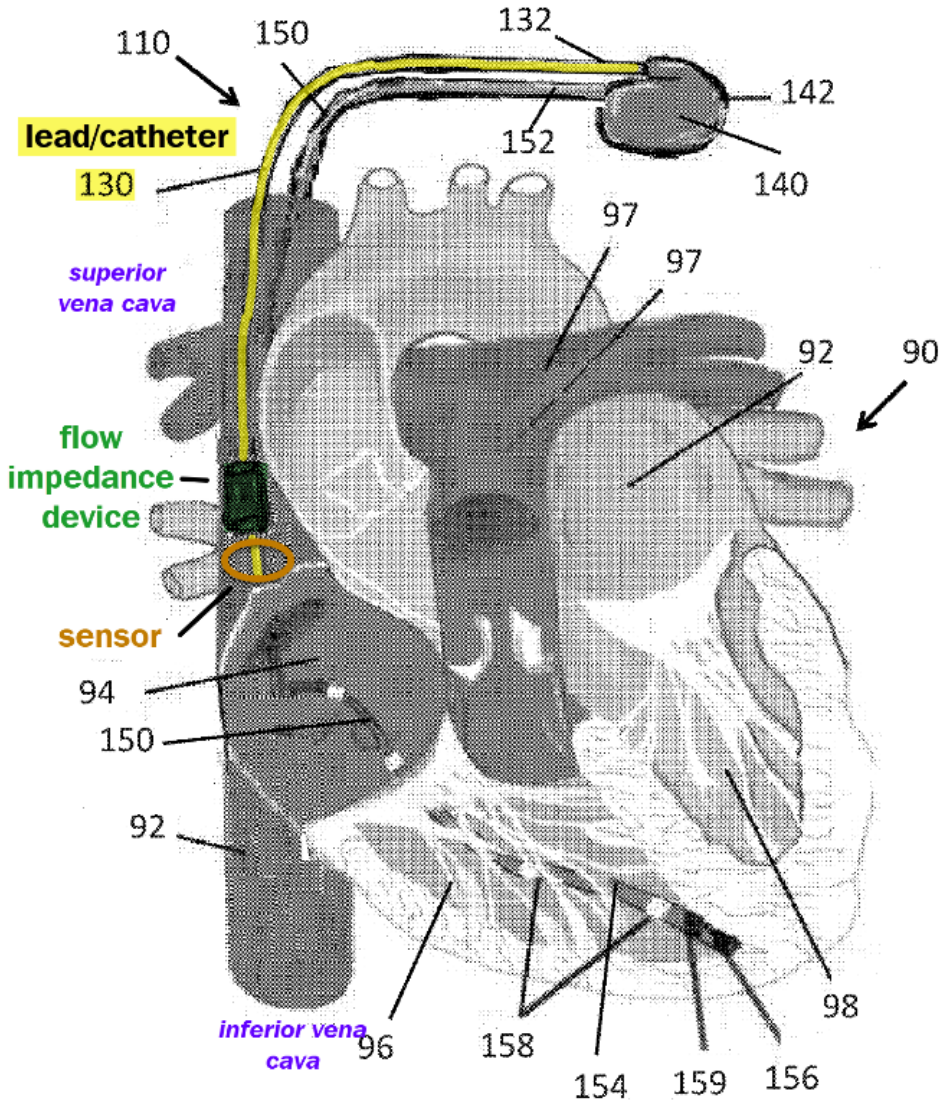


FIG. 2

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.

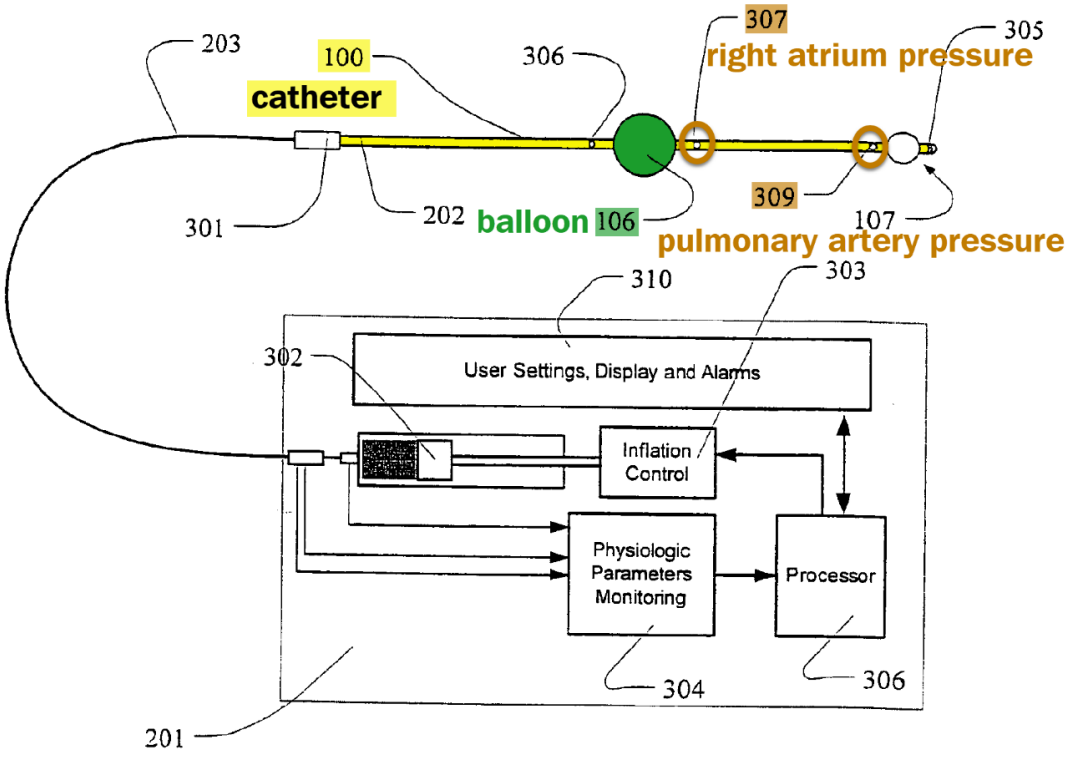


MODIFIED FIG. 2

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.

Gelfand discloses sensors distal to the balloon (the claimed "restrictor"), which measure pressure in distal locations (Ex. 1006, ¶ [0051]) taught by Kaiser,

i.e., in the right atrium and pulmonary artery (Ex. 1007, 6:31-36; Ex. 1010, 5:29-6:1, 14:23-25), and it would be easy to add another "miniature" sensor (Ex. 1006, ¶ [0046]) to measure downstream SVC pressure as well.



Consequently, a POSA using Gelfand's device for Kaiser's method would be motivated to retain or augment, and then use, Gelfand's distal sensors and have a reasonable expectation of success. The resulting combination discloses every element of Claim 10, rendering it obvious. *See* Ex. 1002, § X.D.9.

10. Claim 11

Kaiser discloses that its system may have an Adjustable Component placed in the SVC (Section VIII.D.6) and 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 Figure 2 shows the upstream sensor "spaced apart from" an Adjustable Component.

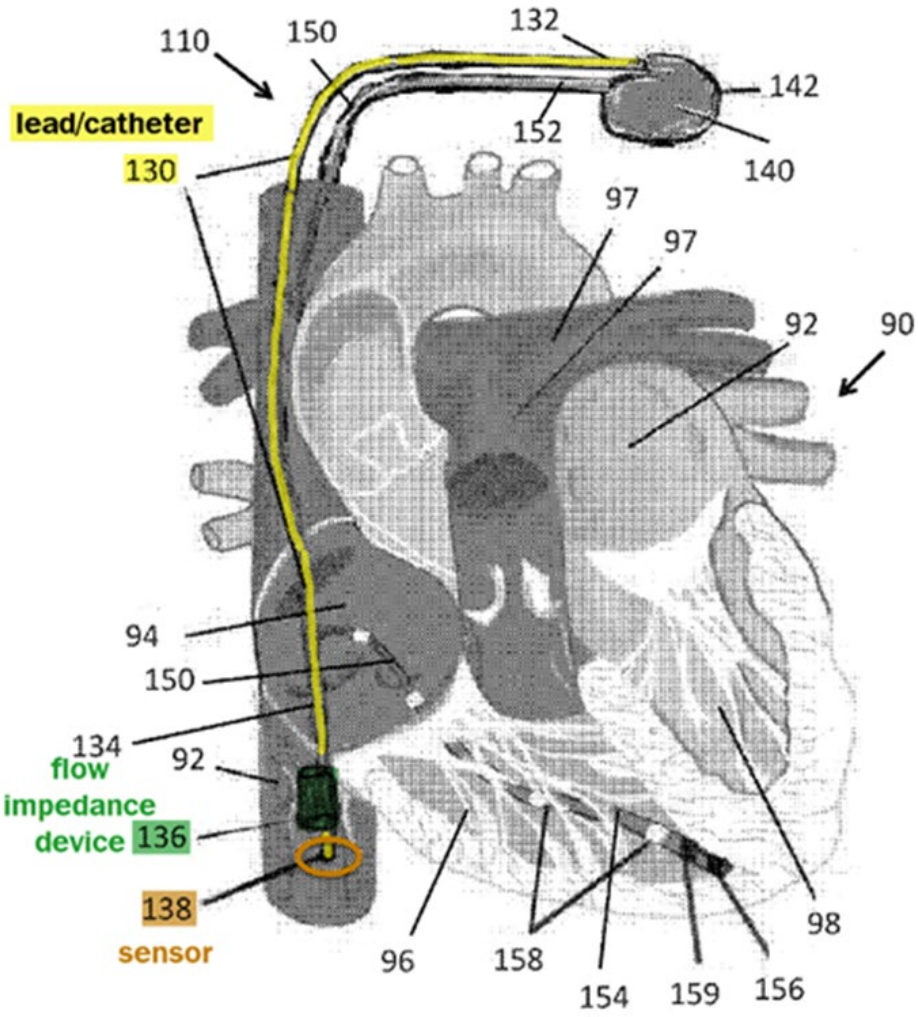
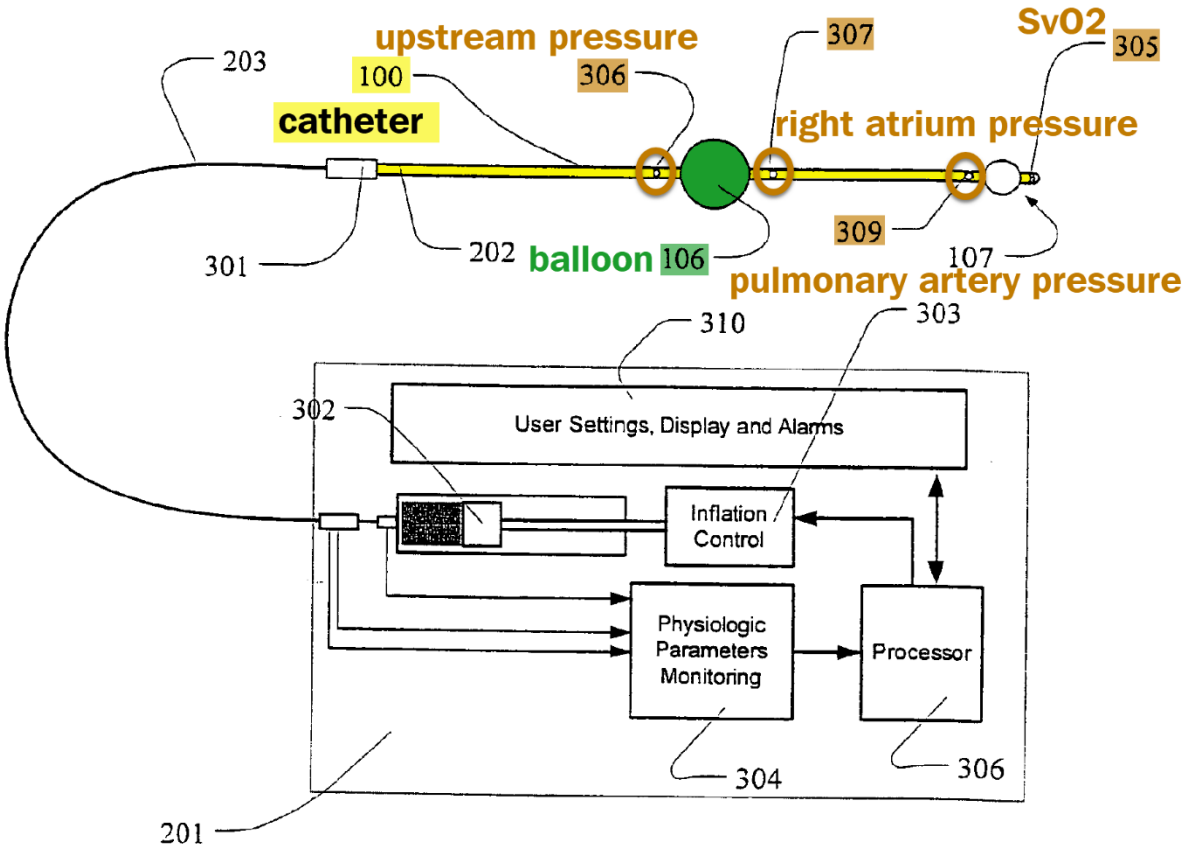


FIG. 2

Gelfand's catheter also has sensors spaced apart from its balloon, including in locations disclosed by Kaiser:



(*See* Ex. 1006, ¶ [0051].) A POSA could easily add any other sensors taught by Kaiser.

Consequently, a POSA using Gelfand's device for Kaiser's method would be motivated to retain or augment, and then use, the spatial configuration of Gelfand's sensors and would have a reasonable expectation of success. The resulting combination discloses every element of Claim 11, rendering it obvious. *See* Ex. 1002, § X.D.10.

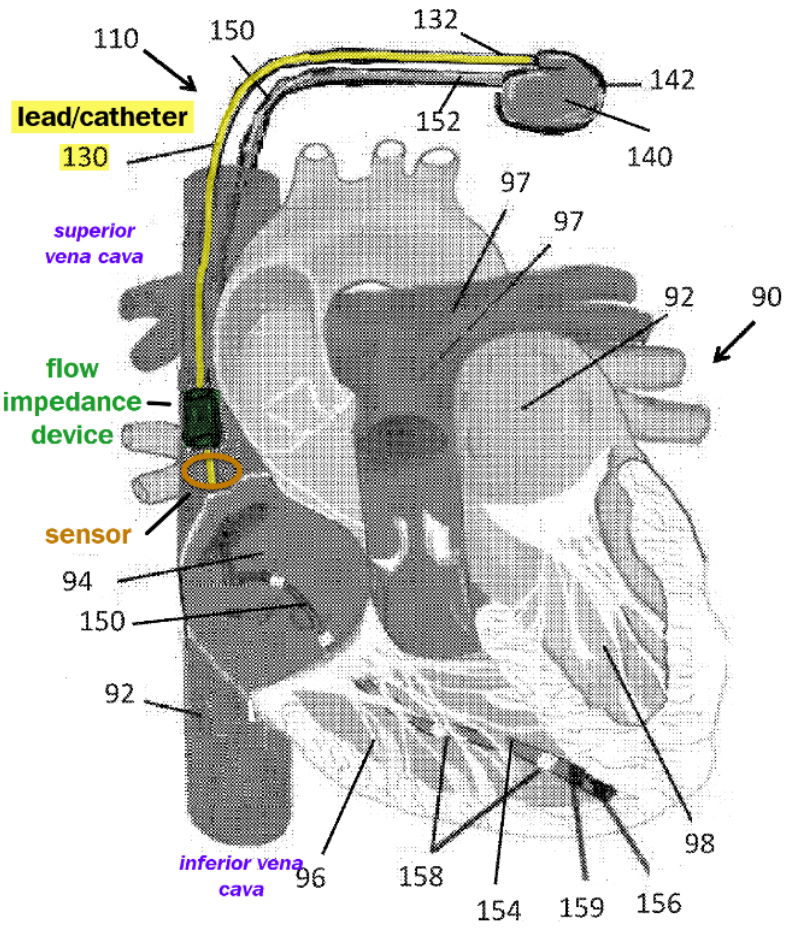
11. Claim 12

Kaiser teaches 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 an Adjustable Component to create a pressure gradient, which concomitantly creates a downstream pressure drop. (Section VIII.E.8.) 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 VII.C.10.) The resulting combination discloses every element of Claim 12, rendering it obvious. *See* Ex. 1002, § X.D.11.

12. Claim 13

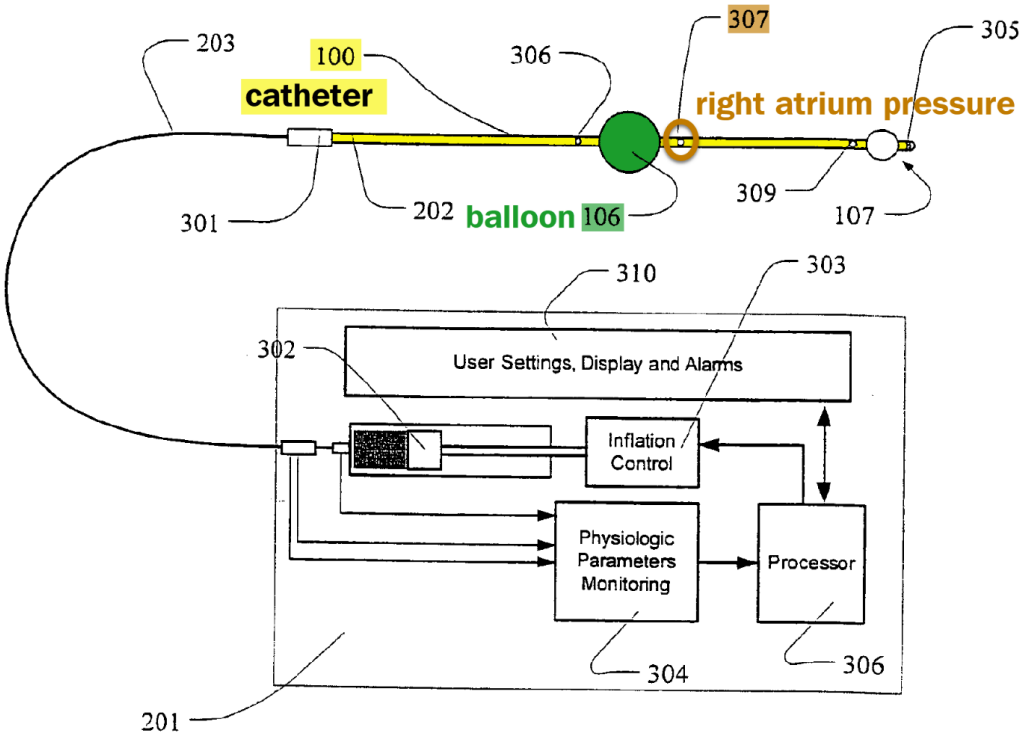
Kaiser discloses placing downstream sensors in either the SVC or right atrium to facilitate adjusting the pressure gradient. Specifically, Kaiser teaches that "pressure gradient and heart rate may be adjusted to optimize the filling pressures inside of the heart" (Ex. 1007, 5:31-32), that "[m]onitoring 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 filling pressure because there is no valve between the SVC or right atrium. As noted above (Section VIII.E.9),

Kaiser's Figure 2 sensor (138) would monitor downstream pressure if the Adjustable Component were moved to the SVC.



MODIFIED FIG. 2

Kaiser specifically 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 VIII.E.11.) This pressure drop would be detected by either a right-atrium or SVC sensor and could be used to adjust the pressure gradient to optimize filling pressure.



Gelfand's device measures pressure in the right atrium and could easily be modified to add a downstream SVC sensor. (Section VIII.E.9.) Accordingly, a POSA using Gelfand's device would be motivated to use its sensors to monitor 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 could cause excessively low downstream pressure, which sensor detection can prevent by deflating the balloon. (Section VII.C.11.) The POSA would have a reasonable expectation of success in detecting such pressure drops because Gelfand's device is used for this purpose.

The resulting combination discloses every element of Claim 13, rendering it obvious. *See* Ex. 1002, § X.D.12.

13. Claim 14

"Distal restrictor" should be constructed to mean "**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 VIII.E.12). Kaiser also discloses measuring pressure distal to the Adjustable Component, *i.e.,* upstream in the IVC (Ex. 1007, 12:65-13:2), which a POSA would know would be useful to ensure pressure does not get too high.

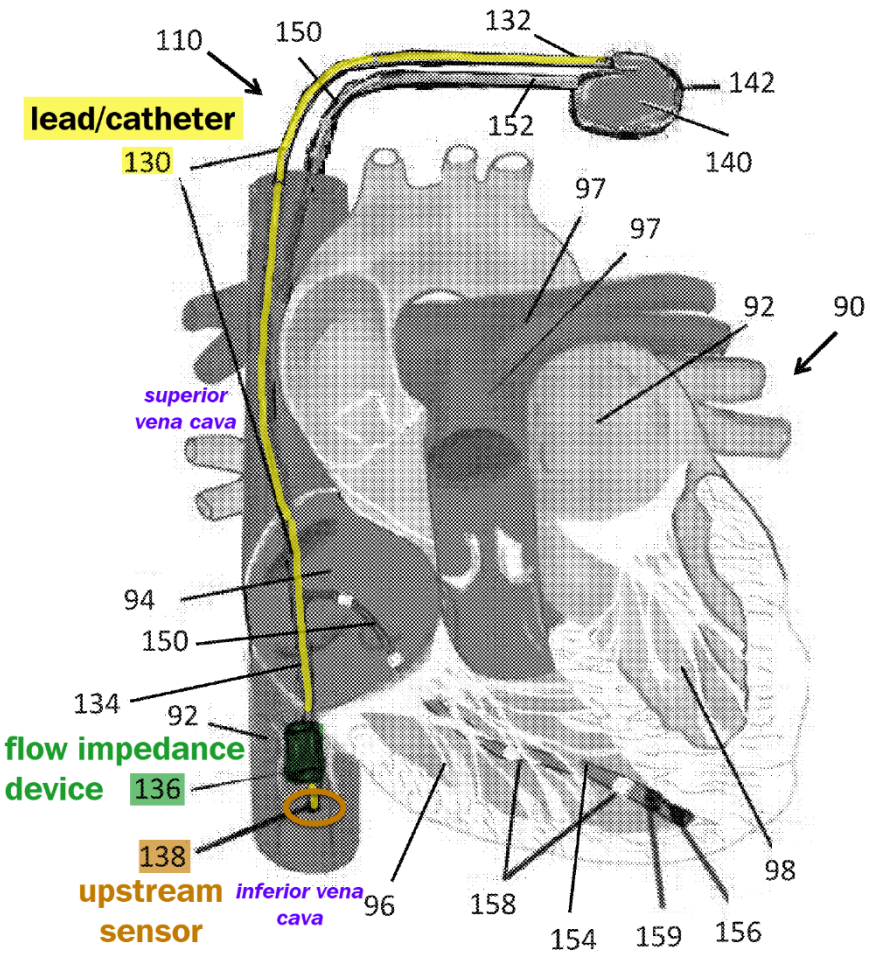
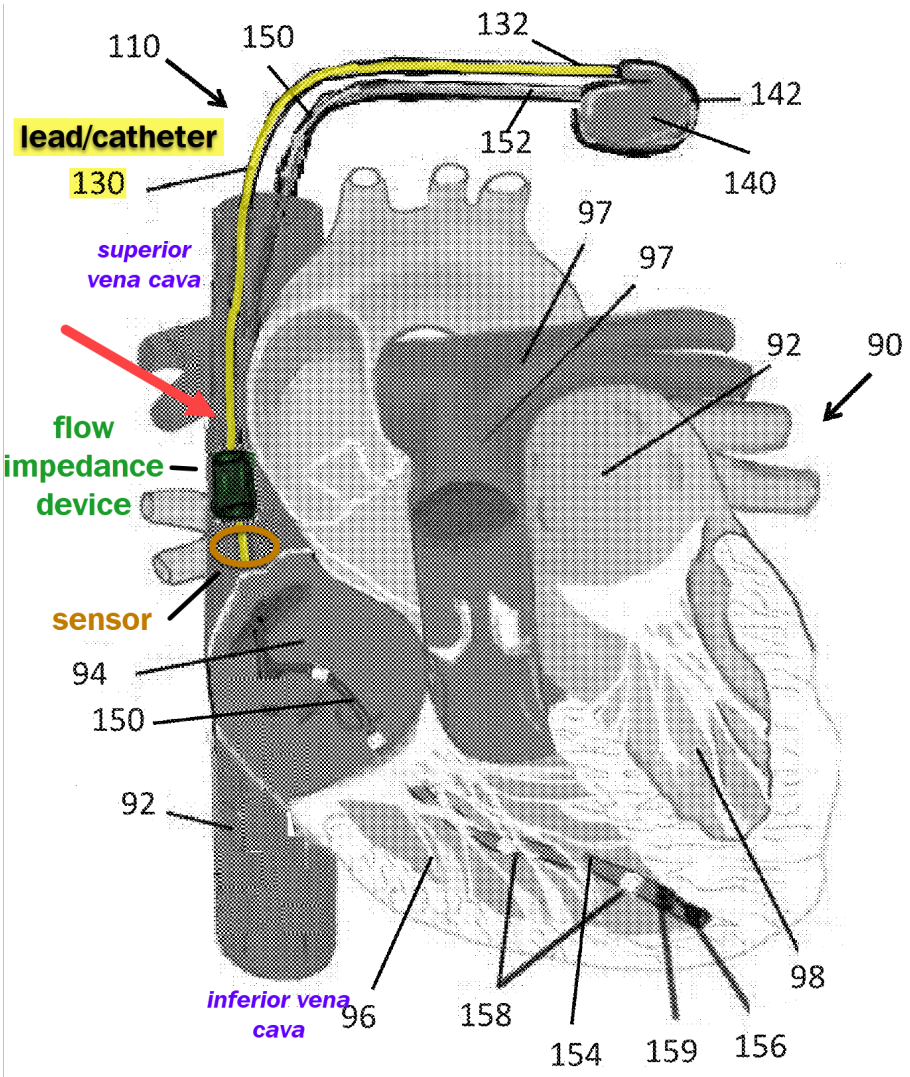


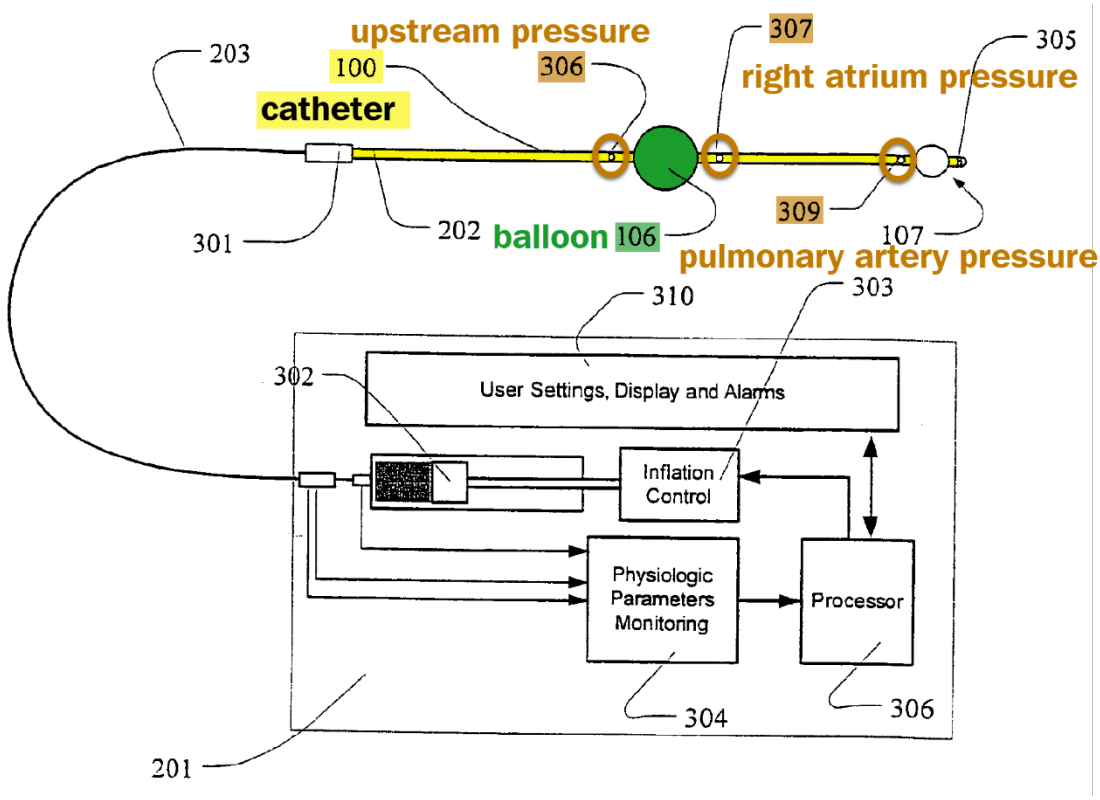
FIG. 2

If the Adjustable Component is in the SVC, as taught by Kaiser (Section VIII.C.6), a right-atrium sensor, pulmonary-artery sensor, or upstream sensor (138) would be distal to the Adjustable Component, while an upstream sensor would be proximal *i.e.*, in the location shown by the red arrow below:



MODIFIED FIG. 2

As discussed above, Gelfand's device has sensors that measure pressure in these locations, (Sections VII.C.2, VIII.E.9, VIII.E.11), and it would be easy to add a downstream SVC sensor.



Consequently, a POSA using Gelfand's device for Kaiser's method would have been motivated to measure pressure proximal and distal to the balloon (the claimed "distal restrictor") (Section VII.C.8), and would have had a reasonable expectation of success because Gelfand's device discloses the necessary sensors. The resulting combination discloses every element of Claim 14, rendering it obvious. *See* Ex. 1002, § X.D.13.

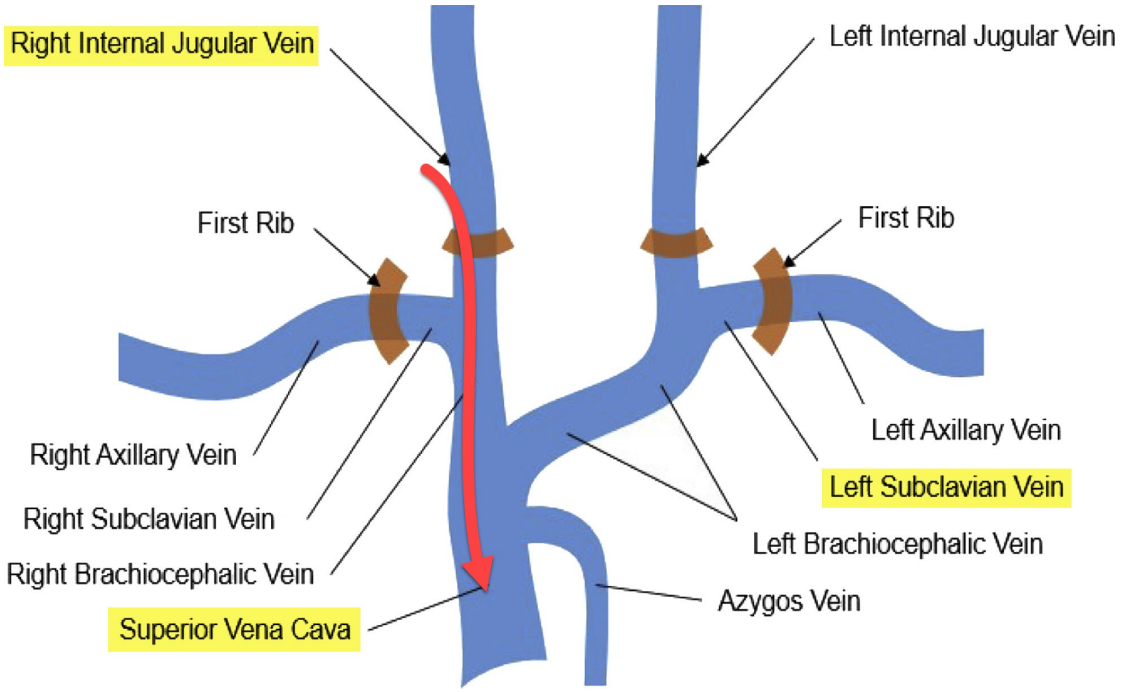
14. Claim 15

A POSA motivated to use Gelfand's device for Kaiser's method would measure blood pressure with that device. (*E.g.*, Sections VIII.D.4, VIII.D.7.) Gelfand teaches that its catheter "has multiple internal lumens for," among other

things, "monitoring of blood pressure," and a POSA would know that these lumens are connected to an opening on the catheter that is in contact with blood. (Section VII.C.13.) Accordingly, a POSA would be motivated to use these lumens and their associated openings for Kaiser's method and would have a reasonable expectation of success because they would function the same way they do in Gelfand's method. The resulting combination discloses every element of Claim 15, rendering it obvious. *See* Ex. 1002, § X.D.14.

15. Claim 16

"Catheter extends across a vein wall" should be construed as "catheter extends through a vein wall." (Section VI.C.) A POSA practicing Kaiser's method would be motivated to percutaneously insert Gelfand's device through at least a jugular vein, as taught by Gelfand and as illustrated below, and would have a reasonable expectation of success for the reasons discussed above (Sections VII.C.1, VIII.E.2; s*ee also* Section XI.) Following insertion, Gelfand's catheter would extend through a vein wall that is closer to the clinician (*i.e.,* "proximal") than the SVC. The resulting combination discloses every element of Claim 16, rendering it obvious. *See* Ex. 1004, § X.F; Ex. 1002, § X.D.15.



IX. GROUND 3: CLAIMS 3 AND 16 ARE OBVIOUS OVER GELFAND 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. 1014.

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.

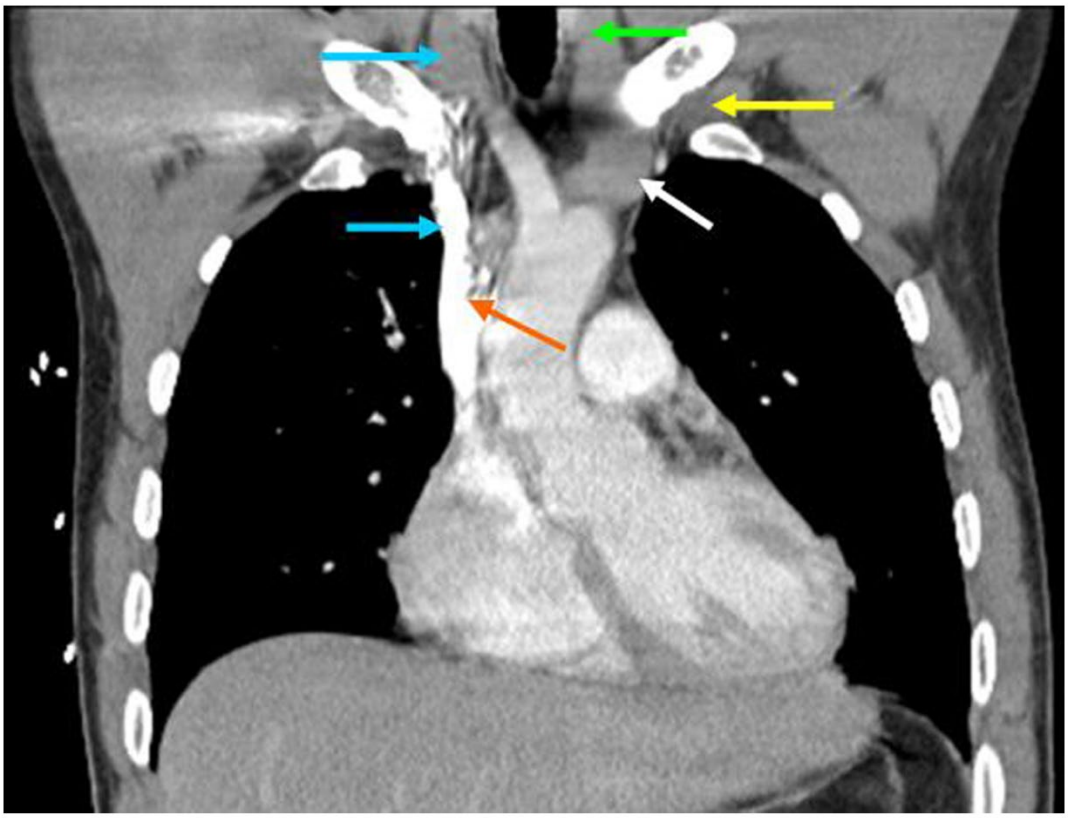
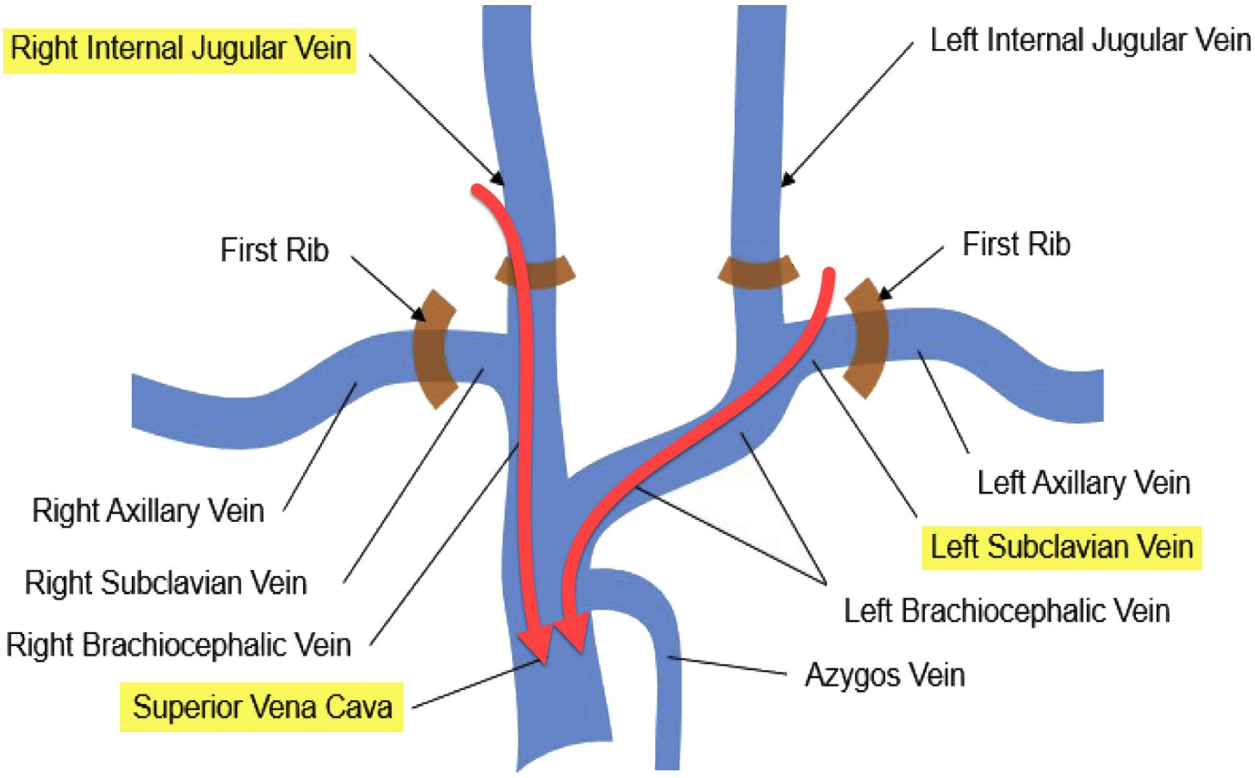


Figure 2 Computed tomography scan showing venous course from right internal jugular vein (blue arrows) and venous course from left subclavian vein (yellow arrow) through the innominate vein (white arrow) to superior vena cava (orange arrow); course from left internal jugular vein (green arrow) with turns 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. Claim 3

In Gelfand's exemplary embodiment, the catheter is inserted through the femoral vein to place the occlusion balloon in the IVC, but Gelfand also expressly

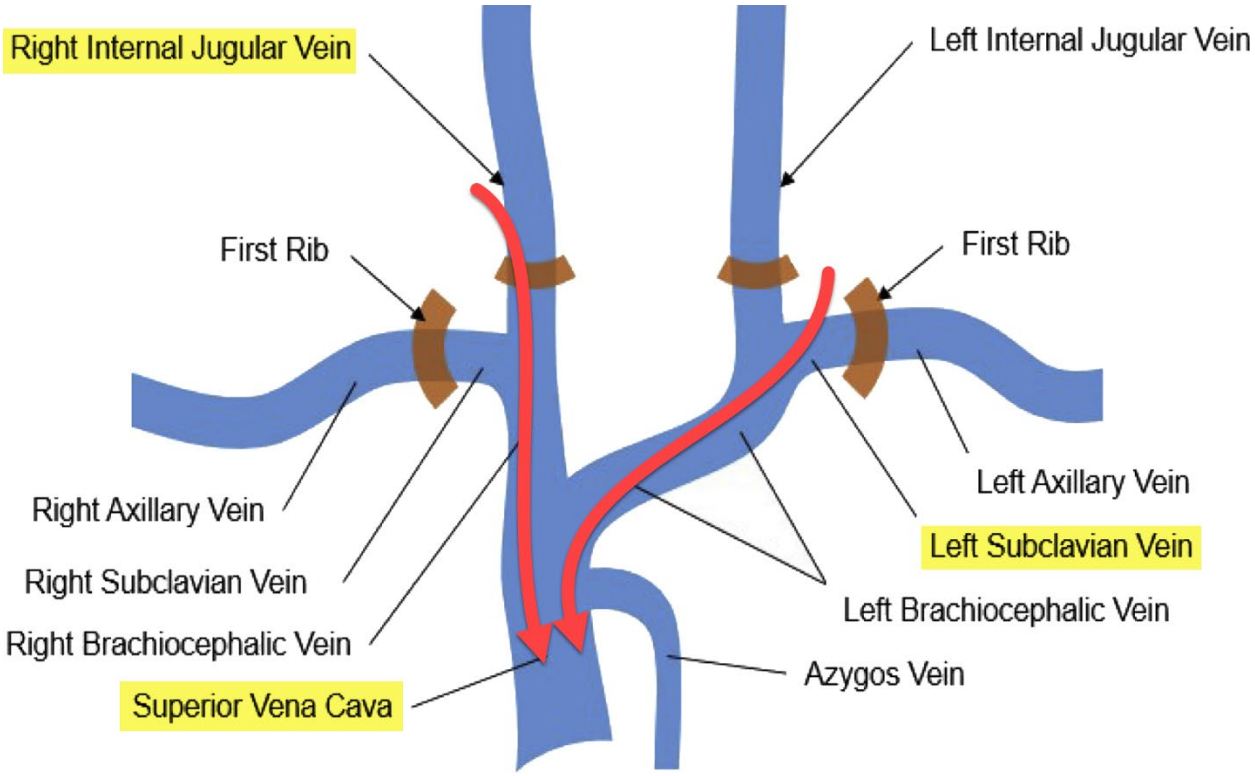
teaches placing the balloon in the SVC. (Section VII.B.6.) If Gelfand's teaching that Swan-Ganz catheters (like Gelfand's) are conventionally inserted through a right-neck vein (*i.e*, the jugular) is found not to disclose Claim 3, it would have been obvious over Bannon.

Because placement of Gelfand's catheter involves 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. He/she would have had a reasonable expectation of success in doing so because of the advantages of such insertion, including over femoral-vein insertion. Indeed, Bannon's jugular vein teachings mirror Gelfand's disclosure of catheter insertion into large right-neck veins.

The resulting combination of inserting and advancing Gelfand's catheter as taught by Bannon discloses every element of Claim 3, rendering it obvious. *See* Ex. 1004, § XI.B.

C. Claim 16

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



X. GROUND 4: CLAIMS 3 AND 16 ARE OBVIOUS OVER GELFAND, KAISER AND BANNON

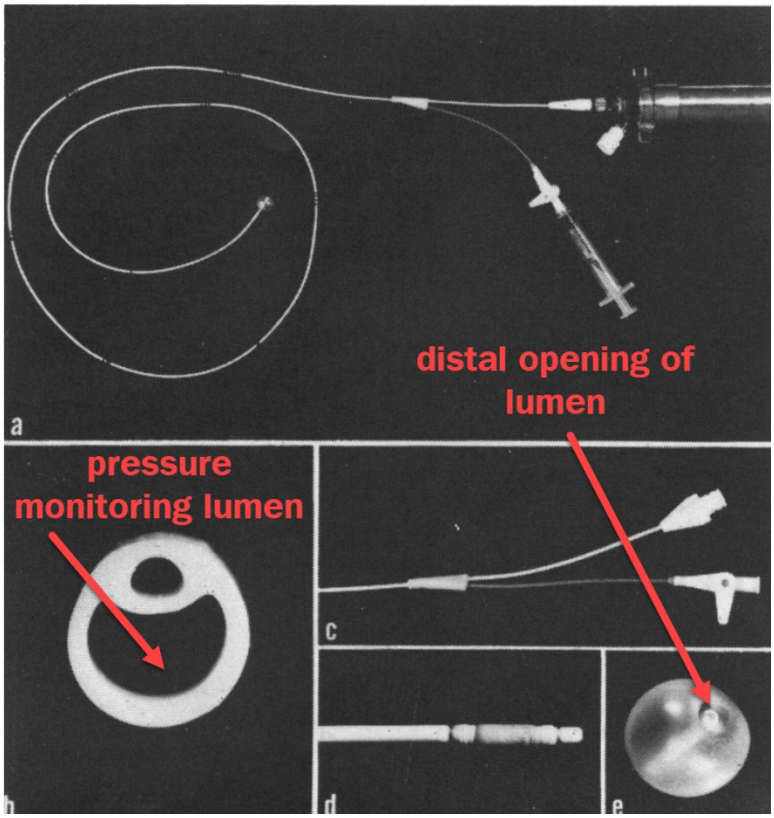
As discussed above (Section VIII), it would have been obvious to use Gelfand's device in practicing Kaiser's method of treating heart failure. Doing so entails inserting Gelfand's catheter in the same way as for Gelfand's method. Because Claims 3 and 16 would be obvious over Gelfand and the insertion locations taught by Bannon (Section IX), they would also be obvious over Gelfand, Kaiser and Bannon. *See* Ex. 1004, § XII.

XI. GROUND 5: CLAIM 15 IS OBVIOUS OVER GELFAND AND THE KNOWLEDGE OF A PERSON OF ORDINARY SKILL IN THE ART

If the Board finds that Gelfand does not disclose a catheter with an "opening that is configured to facilitate pressure monitoring," using such an opening 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 through 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, 447-48); was described as prior art by the 1980s (*e.g*, Ex. 1021, 1:41-2:5); and is still widely used in right-heart catheterization (Ex. 1023, p. 230-31).



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. 1024, 21:31; Ex. 1002, ¶¶ 365-67). *See* Ex. 1002, § XI.A.

B. Obviousness of Claim 15

Gelfand's catheter "has multiple internal lumens for," among other things, "monitoring of blood pressure." (Ex. 1006, ¶ [0032].) For the advantages listed above, a POSA would be motivated to modify Gelfand's device to implement a fluid-lumen pressure sensing system by adding an opening on the catheter wall to Gelfand's internal lumen. 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 Gelfand's device would be minor and within the skill of a POSA. Gelfand's catheter already contains internal lumens, so the POSA would simply need to add the opening on one end, and a sensor in the lumen or on the other end, then connect the sensor to the controller. *See* Ex. 1002, § XI.A.

XII. GROUND 6: CLAIM 15 IS OBVIOUS OVER GELFAND, KAISER AND THE KNOWLEDGE OF A PERSON OF ORDINARY SKILL IN THE ART

As discussed above (Section VIII), it would have been obvious to use Gelfand's device in practicing Kaiser's method of treating heart failure. Doing so

entails using the pressure sensing capabilities of Gelfand's catheter in the same way as in Gelfand's method. To the extent 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 elements of Claims 3 and 16, Bannon supplies them. (Section IX.A.) Viewed in light of Bannon's teachings, Gelfand's disclosure would have motivated a POSA practicing Kaiser's method to insert and advance Gelfand's catheter at least through the right internal jugular vein with a reasonable expectation of success, resulting in the catheter extending through a vein wall proximal of the SVC. *See* Ex. 1004, § XII.

XIII. 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 1-16 of the '871 Patent be cancelled.

Date: September 22, 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][13]	Ex. 1010, 5:9-11, 7:5-7; Ex. 1002, ¶¶ 218-19.
[1a]	Ex. 1010, 8:25-28; Ex. 1002, ¶ 220.
[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, ¶¶ 221-22.
[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, ¶¶ 223-26.
[1d]	Kaiser Provisional discloses a pacing component (pacing electrodes on a lead) to pace the heart. *See* Ex. 1010, 8:19-24; Ex. 1002, ¶ 227.
[1e]	Ex. 1010, 7:5-7; Ex. 1002, ¶ 228.

[13] The claim text is in Appendix B.

Claim 1 Element	Supporting Disclosure in Kaiser Provisional Application
[1f]	Ex. 1010, 7:5-7; Ex. 1002, ¶ 229.
[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, ¶¶ 230-32.
[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, ¶¶ 233-36.

APPENDIX B

Claim Listings

U.S. Patent No. 10,653,871

Claim Number	Claim Language
[1p]	A method for treating heart failure in a patient, the method comprising:
[1a]	providing a system comprising: a catheter apparatus comprising one or more restrictors and one or more sensors;
[1b]	and a control module operable coupled to the catheter apparatus,
[1c]	wherein the control module receives feedback from the one or more sensors and controls the one or more restrictors based on the feedback from the one or more sensors;
[1d]	advancing the catheter apparatus into a superior vena cava of a patient; 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]	and adjusting the one or more restrictors based on feedback from the one or more sensors,
[1g]	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 catheter apparatus is advanced through a subclavian or jugular vein.
4	The method of claim 1, wherein the one or more sensors are one or more pressure sensors.

Claim Number	Claim Language
5	The method of claim 1, wherein the method is performed while maintaining intravascular pressure.
6	The method of claim 1, wherein the one or more restrictors are one or more balloons.
7	The method of claim 6, wherein the one or more balloons are one or more compliant or semi-compliant balloons.
8	The method of claim 6, wherein the one or more balloons are operably coupled to one or more inflation sources.
9	The method of claim 1, wherein the adjustment of the one or more restrictors comprises creating a pressure gradient across at least one of the one or more restrictors.
10	The method of claim 1, wherein at least one of the one or more sensors is distal to at least one of the one or more restrictors.
11	The method of claim 1, wherein at least one of the one or more sensors is spaced apart from at least one of the one or more restrictors.
12	The method of claim 1, wherein activating the one or more restrictors creates a pressure drop in a vein.
13	The method of claim 12, wherein the method further comprises detecting a pressure drop in the vein via the one or more sensors.
14	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.
15	The method of claim 1, wherein the catheter comprises an opening that is configured to facilitate pressure monitoring.
16	The method of claim 1, 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 22, 2021, at the correspondence address of record for the '871 Patent:

Brown Rudnick LLP
One Financial Center
Boston, MA 02111

Date: September 22, 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 13,999 words according to the word processing program used to prepare it.

Date: September 22, 2021

/Sharonmoyee Goswami/
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