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Paper 13
Date: April 12, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABIOMED, INC.,
Petitioner,

v.

WHITE SWELL MEDICAL LTD.,
Patent Owner.

IPR2021-01565
Patent 10,639,460 B2

Before ROBERT A. POLLOCK, TIMOTHY G. MAJORS, and DAVID COTTA, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Abiomed, Inc. ("Petitioner") filed a Petition for *inter partes* review of claims 1–24 of U.S. Patent No. 10,639,460 B2 (Ex. 1001, "the '460 Patent"). Paper 5 ("Pet."). White Swell Medical Ltd. ("Patent Owner") timely filed a Preliminary Response to the Petition. Paper 12 ("Prelim. Resp.").

For the reasons provided below, we determine that Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has demonstrated a reasonable likelihood that at least one claim of the '460 Patent is unpatentable, we institute an *inter partes* review of all challenged claims on each of the Grounds raised in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *see also* Guidance on the Impact of SAS on AIA Trial Proceedings (April 26, 2018).[1]

A. Real Parties-in-Interest

Petitioner identifies itself as the real party-in-interest. Pet. 8. Patent Owner identifies itself as the real party-in-interest. Paper 3, 1.

B. Related Matters

In its Mandatory Notice, Patent Owner stated that it "is not aware of any judicial or administrative matters that could affect, or could be affected by, a decision in this proceeding." Paper 3, 1. Petitioner has, however, filed IPR2021-01564, challenging claims 1–24 of the '460 Patent on different grounds; PGR2021-00107, challenging claims of U.S. Patent No. 10,926,069 ("the '069 Patent"); and IPR2021-01477 and IPR2021-01478, both challenging claims of U.S. Patent No. 10,653,871 ("the '871 Patent").

[1] Available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial ("Guidance").

The ’460, ’069, and ’871 Patents issued from a series of continuations first filed as U.S. Application No. 14/625,930 (“the ’930 Application”), on February 19, 2015, which claims priority to Provisional Application No. 62/006,206 (“the ’206 Provisional Application”), filed on June 1, 2014.

C. The ’460 Patent and Relevant Background

The ’460 Patent is directed to “Systems and Methods for Treatment of Pulmonary Edema” and describes “a method for implanting an indwelling catheter within a vein of patient” to create “a localized low pressure zone . . . within a portion of the vein housing the catheter,” and adjacent to an outflow port. Ex. 1001, code (54), Abstr.

According to the ’460 Patent, under normal circulatory conditions of the arterial and venous systems, “the lymph fluid is cleared back through the lymphatic system.” Ex. 1001, 1:34–37. However, in pathological conditions, a pressure gradient is reduced such that the lymphatic system cannot clear additional fluid. *Id.* at 1:37–41. In acute cardiogenic pulmonary edema, for example, “the capillary hydrostatic pressure and the venous pulmonary pressure can become elevated and fluid flows excessively out of the blood vessels and into the interstitial and alveolar spaces.” *Id.* at 1:42–46. Accumulation of this excess fluid in the air spaces of the lungs may lead to respiratory failure. *Id.* at 1:46–48.

The ’460 Patent explains that current treatments for pulmonary edema employ loop diuretics or vasodilators, but these treatments are not ideal because the “edema is not always alleviated rapidly enough and for many patients renal function is adversely affected.” *Id.* at 1:49–55. The ’460 Patent purports to resolve this problem by providing a system for treating edema using an implanted “indwelling catheter within a vein of a patient” with a

"first restriction." *Id.* at 2:6–14. The first restriction is used to localize a low pressure zone within a portion of the vein to enable fluid to pass from a lymph duct outflow port into the vein, in which the first restriction can be an "expandable balloon formed on an outer wall of the catheter." *Id.* at 2:12–22.

Figure 1 of the '460 Patent, reproduced below, shows such a system.

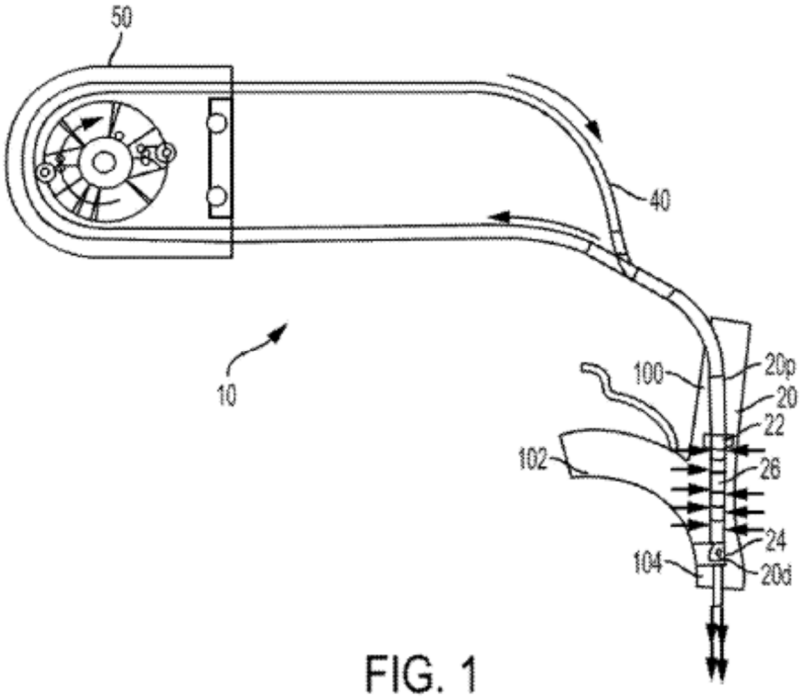


FIG. 1

Figure 1 is a schematic view of a system 10 for treating pulmonary edema. *Id.* at 4:37–38. System 10 includes indwelling catheter 20 implanted within a vein of a patient and pump 50 for removing lymphatic fluid, external to the patient but connected to catheter 20 via drainage tubing 40. *Id.* at 7:17–21, 58–65. Catheter 20 has suction port 26 for withdrawing fluid from the vein and a discharge port which can be at the distal end of catheter 20 for discharge of fluid back to the vein. *Id.* at 7:31–36. Catheter 20 "can also include pressure sensors and one or more selectively deployable restrictions (such as a first restriction 22, a second restriction 24) and the control lumens that communicate with the pressure sensors and restrictions." *Id.* at 7:36–40.

Figure 2 of the ’460 Patent is reproduced below.

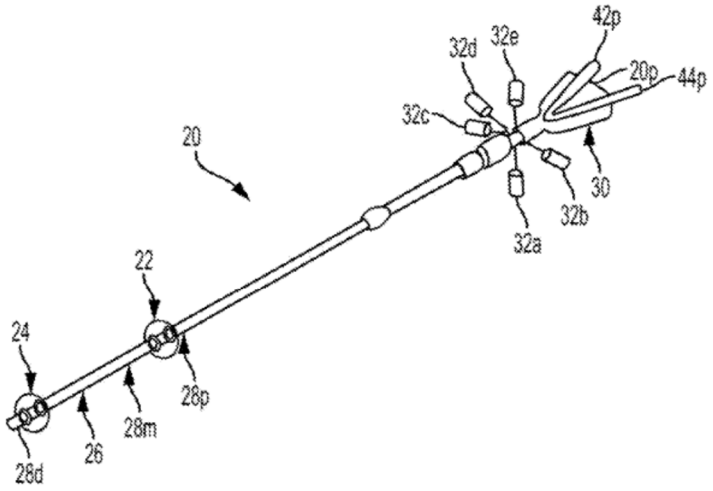
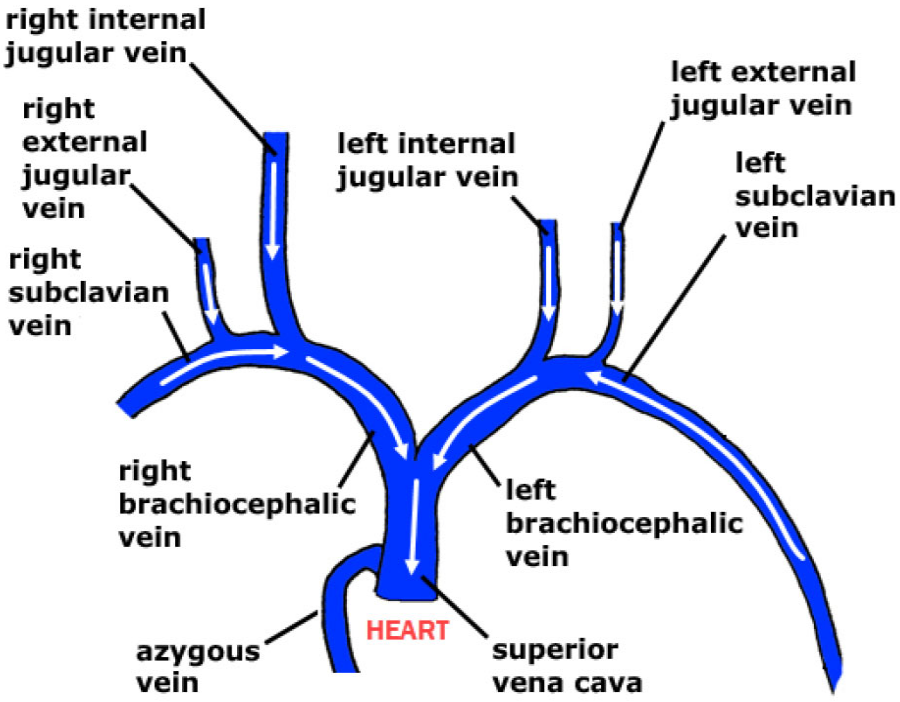


FIG. 2

Figure 2 is a perspective view of the indwelling catheter of Figure 1. *Id.* at 4:39–40. Port 32d is used to deliver fluid to restriction 22 and port 32a is used to deliver fluid to restriction 24. *Id.* at 9:7–15. Within lumens inside catheter 20, pressure sensors can be positioned “to be used for sensing pressure at various locations along the vein in which the catheter is implanted.” *Id.* at 9:15–20.

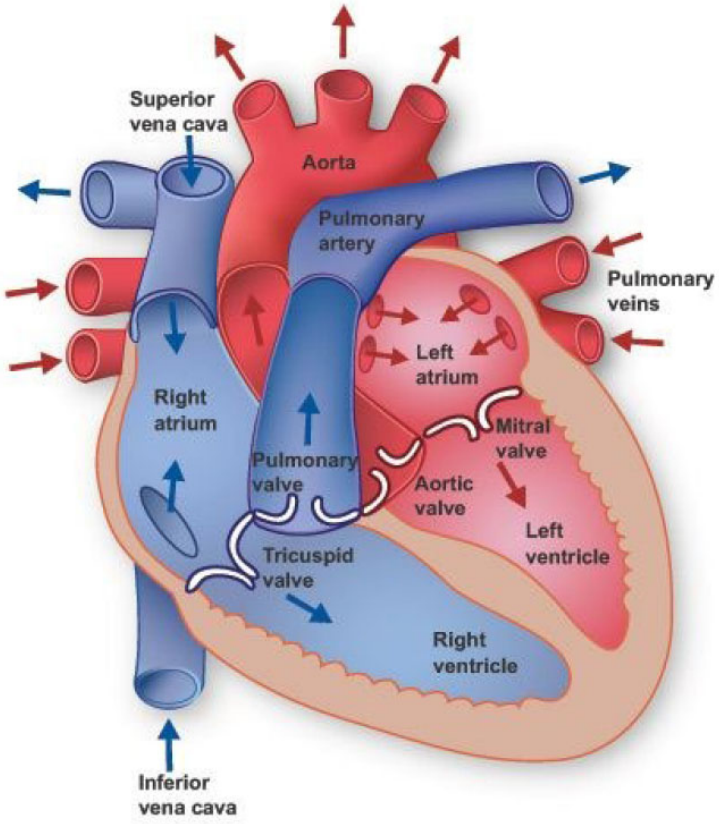
According to the ’460 Patent, the system “can further include a control module to receive information from the sensors, activate the restrictions, and adjust flow rate of the pump.” *Id.* at 15:17–19. Control module 200 (shown in Figure 10) receives information regarding the pressure from various locations with the veins. *Id.* at 15:20–26. Upon receiving this information, “the control module can be configured to actuate the pump function” and alter “the first or second restriction volume.” *Id.* at 15:20–32.

A catheter such as illustrated in Figure 1 may be placed, for example, in a jugular, subclavian, or innominate vein using a "placement technique . . . well known to those skilled in the art." *See, e.g.*, *id.* at 8:3–15, 10:1–11, 12:50–54, 13:39–43, 17:36–42. As explained by Petitioner's declarant, Dr. Day, the jugular, subclavian, and innominate (a.k.a "brachiocephalic") veins drain venous blood into the heart via the superior vena cava. *See* Ex. 1002 ¶¶ 41–46. Dr. Day illustrates the relationship between these elements in the following diagram.



Id. ¶ 42.

The above diagram depicts the major veins that feed directly or indirectly into the superior vena cava (SVC). *Id.* ¶¶ 41–46. In addition to placement in various jugular, subclavian, and auxiliary veins, the '460 Patent discloses methods of advancing the catheter into the SVC. *See, e.g.*, Ex. 1001, 17:36–44, 18:35–46, 22:13–21, Figs 15–17, 27. For context, we reproduce below Dr. Day's color illustration of the heart, labeled to show the direction of blood flow through major heart structures.



Ex. 1002 ¶ 36. The above figure illustrates the major veins and chambers of a human heart, including the direction of venous blood flow into the right atrium via the superior vena cava (top left) and inferior vena cava (bottom left). *See generally id.* ¶¶ 35–46.

Figure 27 of the ’460 Patent is reproduced below.

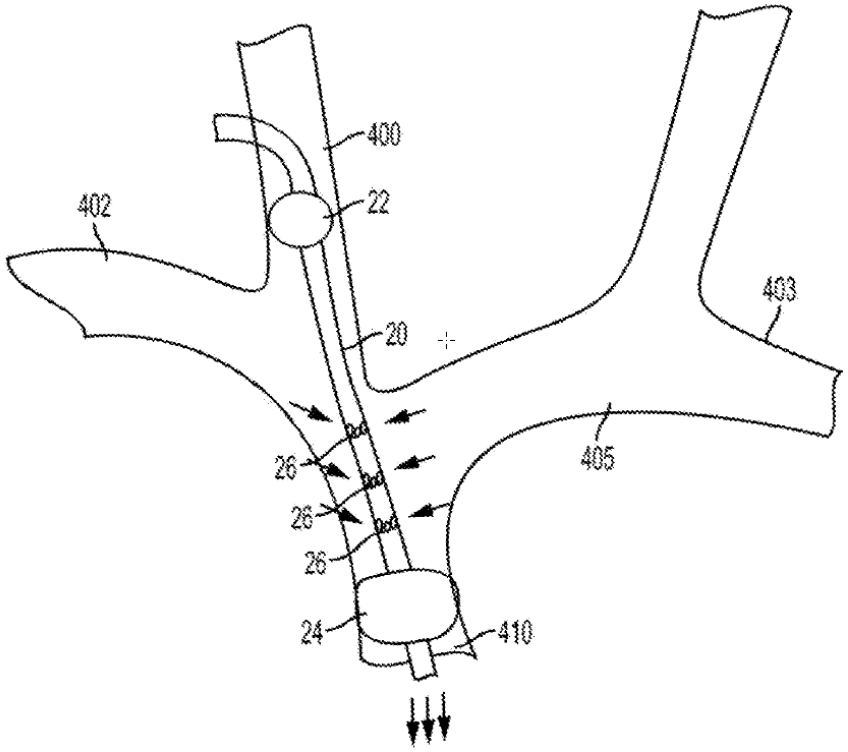


FIG. 27

Figure 27 shows a catheter positioned, in part, at the superior vena cava.

With reference to Figure 27, the ’460 Patent states that

> catheter 20 can be positioned such that the distal restriction 24 is positioned within the superior vena cava (SVC) 410 and the proximal restriction is within the right internal jugular vein 400. The positioning of the suction port(s) 26 between the proximal and distal restrictions is such that blood can be withdrawn from the right subclavian vein 402, and from the left innominate vein 403. This arrangement enables drainage of both the right lymphatic duct and the thoracic duct.

Id. at 22:13–31.

D. Relevant Prosecution History of the ’460 Patent

The ’460 Patent issued from Application No. 16/592,996 (“the ’996 Application”). Ex. 1001, code (21). The ’996 Application was filed with a preliminary amendment canceling all claims in lieu of claims similar to those at issue here. *See* Ex. 1008, 696–701.

The Examiner provisionally rejected the newly-added claims for obviousness-type double patenting, and rejected most claims as anticipated by Callaghan, or obvious in view of Callaghan and Fulton. *Id.* at. 85–90. According to the Examiner, “Callaghan’s balloons . . . are designed to be fully inflated when in use. It is unclear why one of ordinary skill in the art at the time of the invention would have modified Callahgan’s system to adjust the degree of balloon inflation in response to a sensed pressure.” *Id.* The Examiner further stated that “[t]he prior art does not teach or suggest the method of [dependent] Claims 21 and 23, wherein the restrictors are adjusted/controlled based on feedback from the pressure sensors.” *Id.* at 91. The Examiner further objected to claims 22 and 24 “as being dependent upon a rejected base claim,” indicating that they “would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.” *Id.*

In response, the Applicants filed terminal disclaimers, and redrafted the claims to require sensor feedback control of the restrictors. *Id.* at 52–57. The Examiner allowed the claims “for the reasons set forth in the previous office action.” *Id.* at 13.

E. Priority date of the ’460 Patent

The ’460 Patent, on its face, claims benefit of priority to the ’206 Provisional Application, filed on June 1, 2014, and a series of non-

provisional continuation applications first filed on February 19, 2015, as the '930 Application. Ex. 1001, codes (21), (60), (63); *see* section I.B, above. Petitioner argues that multiple elements of independent claims 1 and 13 are not supported in the '206 Provisional Application, such that the earliest possible priority date for any claim challenged here is the February 19, 2015, filing of the '930 Application. Pet. 21–24.

Patent Owner declines to address whether the challenged claims are supported in the '206 Provisional Application, and argues that we need not reach the issue "[b]ecause the references relied on by the Petition are each dated before the June 1, 2014 filing date of the provisional application" and, thus, necessarily predate the filing date of the '206 Provisional Application. *See* Prelim. Resp. 10–11.

As the parties agree, at least implicitly, that the asserted references are prior art with respect to the challenged claims, we need not presently consider whether the '460 Patent is entitled to the priority date of the '206 Provisional Application. Based on the present record, it is not apparent that there is any material difference between a POSA's skill level or understanding whether June 1, 2014, or February 19, 2015, is the applicable priority date. To the extent either party contests the understanding of one of ordinary skill as of a specific critical date, the parties are welcome to revisit the priority issue at trial.

F. Challenged Claims

Petitioner challenges claims 1–24 of the '460 Patent, of which claims 1 and 13 are independent. Pet. 10; Ex. 1001, 23:37–24:64. Illustrative claim 1 is reproduced below:

[1p] A method for treating heart failure in a patient, the method comprising:

[1a] advancing a catheter apparatus comprising one or more restrictors

[1b] through a subclavian or jugular vein and

[1c] into a superior vena cava of a patient,

[1d] wherein the catheter apparatus further comprises one or more pressure sensors; and

[1e] operating the catheter apparatus to regulate venous blood return through the superior vena cava, wherein operating at least comprises activating the one or more restrictors within the superior vena cava to at least partially occlude flow through the superior vena cava

[1f] while maintaining intravascular pressure,

[1g] wherein the one or more restrictors are adjusted based on feedback from the one or more pressure sensors,

[1h] thereby treating heart failure in the patient.

Ex. 1001, 23:36–51; Pet. 106 (paragraphing and labeling as added in Petitioner's claim listing).

G. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–24 of the '460 Patent on the following grounds (Pet. 10):

Ground	Claims Challenged	35 U.S.C §	Reference(s)/Basis
1	1–10, 12–22, 24	102	Kaiser[2]
2	1–24	103	Kaiser, Gelfand[3]
3	1–10, 12–22, 24	103	Kaiser, Bannon[4]

[2] Kaiser et al., US 9,878,080 B2, issued Jan. 30, 2018 (Ex. 1007).
[3] Gelfand and Levin, US 2006/0064059 A1, publ. Mar. 23, 2006 (Ex. 1006).
[4] Bannon et al., "*Anatomic considerations for central venous cannulation*," 4 RISK MANAGEMENT AND HEALTHCARE POLICY 27–39 (2011) (Ex. 1012).

Ground	Claims Challenged	35 U.S.C §	Reference(s)/Basis
4	1–24	103	Kaiser, Gelfand, Bannon
5	11, 23	103	Kaiser, knowledge of person of ordinary skill in the art
6	11, 23	103	Kaiser, Bannon, knowledge of person of ordinary skill in the art
7	11, 23	103	Kaiser, Gelfand, knowledge of person of ordinary skill in the art
8	11, 23	103	Kaiser, Gelfand, Bannon, knowledge of person of ordinary skill in the art

With respect to Petitioner's reliance on the "knowledge of a person of ordinary skill in the art" in obviousness Grounds 5–8, we note that an analysis of whether claims would have been obvious and whether it would have been obvious to combine or modify prior art, must *always* be from the perspective of one of ordinary skill in the art and in view of the knowledge generally available to the skilled artisan. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (one must consider "the background knowledge possessed by a person having ordinary skill in the art").

Because "knowledge of a person of ordinary skill in the art" is always a consideration, and not an independent basis for an obviousness challenge, Petitioner's express recitations of "knowledge of a person of ordinary skill in the art" in its summaries of Grounds 5–8, collapse into obviousness in view of Kaiser (Ground 5), Kaiser and Bannon (Ground 3/6), Kaiser and Gelfand (Ground 2/7), and Kaiser, Gelfand, and Bannon (Ground 4/8).

In addition to Petitioner's reliance on Kaiser, Gelfand, and Bannon, Petitioner further relies, *inter alia*, on the Declarations of Dr. Steven W.

Day, Ph.D. (Ex. 1002) and Dr. Lawrence Alexander Garcia, M.D. (Ex. 1004). Considering the record before us, we determine that Drs. Day and Garcia are qualified to offer testimony on the knowledge of one of ordinary skill in the art at the time of the invention. *See* Ex. 1002 ¶¶ 3–15, 27–46, 97–100 (Dr. Day's statements as to his background and qualifications, background on the relevant technology, and definition of the person of ordinary skill in the art); Ex. 1003 (Dr. Day's *curriculum vitae*); Ex. 1004 ¶¶ 4–15, 28–32, 54–57 (Dr. Garcia's statements as to his background and qualifications, background on the relevant technology, and definition of the person of ordinary skill in the art); Ex. 1005 (Dr. Garcia's *curriculum vitae*); section II.B, below (provisionally adopting Petitioner's definition of one of ordinary skill in the art).

H. Overview of Asserted References

1. Overview of Kaiser (Ex. 1007)

Kaiser is directed, *inter alia*, to "methods for prevention and/or remediation of heart disease, e.g., for optimizing intra-cardiac filling pressures," including for "patients suffering from . . . congestive heart failure." Ex. 1007, 1:15–20. According to Kaiser, the primary treatment for congestive heart failure is to reduce total body fluid volume with diuretics. *Id.* at 2:54–59. Kaiser postulates that a device that can "induce 'mechanical diuresis' where excess fluid is sequestered elsewhere in a patient's body may be able to optimize cardiac pressures and cardiac output similarly to diuretics." *Id.* at 2:59–63. Accordingly, Kaiser discloses apparatus and systems including a controller-actuated flow impedance device to "control the intra - cardiac filling pressures by creating a pressure differential in a vessel such as the inferior vena cava." *Id.* at 4:56–59, 6:49–59. Kaiser

teaches that this "pressure differential may sequester extraneous blood to . . . the venous system . . . [and] manifest an effective 'mechanical diuresis.'" *Id.* at 4:59–62. Kaiser teaches additional benefits of reducing cardiac pressure including as an aid in "remodeling that improves myocardial function and hemodynamics." *Id*. at 5:8–25.

Kaiser discloses an exemplary embodiment comprising a "catheter, lead, or elongate member"[5] and at least one adjustable component[6] (e.g., an inflatable balloon) "placed percutaneously and selectively expanded in the vena cava with a mechanism to induce a pressure gradient." *Id.* at 6:37–43. Figure 1, reproduced below, shows an exemplary embodiment of Kaiser's system implanted within a patient's body such that a flow impedance device (e.g., inflatable balloon) is within the right atrium.

[5] Kaiser appears to use the terms catheter, lead, and elongate member as interchangeable. Ex. 1007, 6:23–25, 7, 59–66, 8:2–5. To the extent they are not, Kaiser expressly discloses embodiments where the elongate member "is a catheter including . . . inflation[] lumen[s]," or where a lead "may be a catheter including an inflation lumen." *Id.* at 8:26–36, 10:26–29. In light of Kaiser's nomenclature, we adopt Petitioner's "lead/catheter" notation as appropriate. *See* Pet. 33, n.9; Ex. 1002 ¶¶ 113, 149, 229.

[6] Kaiser variously uses "adjustable component," "expandable member," "balloon" and "flow impedance device" in reference to catheter flow restriction elements. We note Dr. Day's umbrella terms "expandable member" or "adjustable component" as referring to any or all of these terms. *See* Ex. 1002 ¶¶ 107, 231.

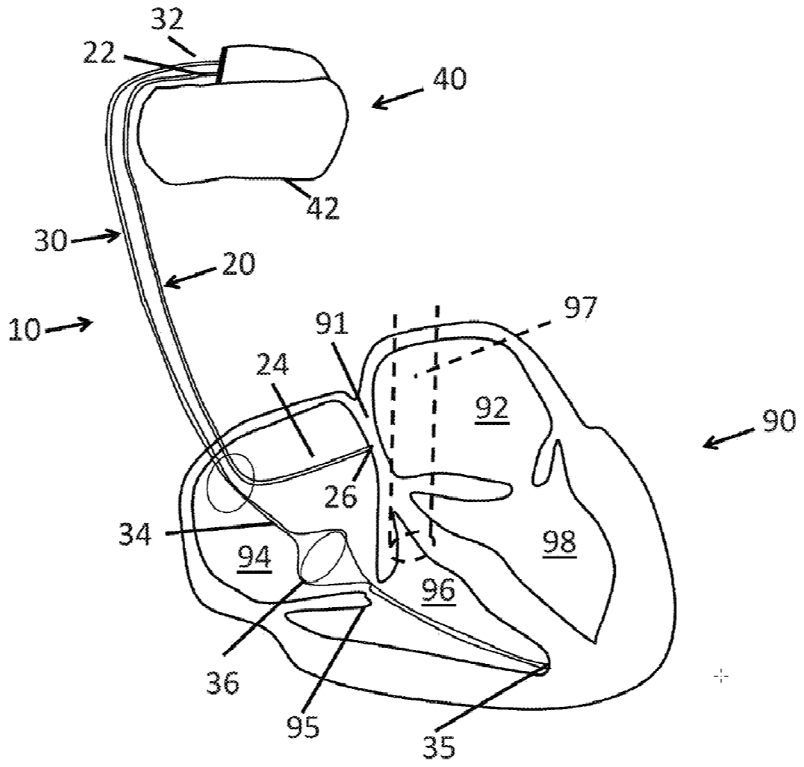


FIG. 1

Id. at 8:57–58.

Figure 1 shows a two-lead system including leads/catheters 10 and 20 connected to controller 40 at their proximal ends. Lead/catheter 30 "includes an expandable member 36 on the distal end 34, e.g., offset proximally by a predetermined distance from distal tip 35 . . . such that the expandable member 36 is located within the right atrium 94 and /or the tricuspid valve 95." *Id.* at 9:53–62; *see id.* at 10:26–29 (defining "lead 30" as a "catheter including an inflation lumen"). Kaiser teaches "expandable member 36 may be a compliant balloon configured to . . . at least partially fill right atrium 94 (or other body lumen) and/or occlude flow into or through a body lumen within or adjacent the heart." *Id.* at 10:10–15. In other embodiments, the inflatable device may be positioned to cause a pressure drop in, for example, the pulmonary artery, IVC, or SVC. *Id.* at 6:60–64, 5:64–6:1, claim 5

(reciting a "flow impedance device implantable within a patient's inferior vena cava"), claim 17 ("The method of claim 10, wherein the body lumen within which the adjustable component is positioned is one of an inferior vena cava, a superior vena cava, a right atrium, and a right ventricle of the patient's heart.").

Kaiser's Figure 2, reproduced below, illustrates a flow impedance device implanted in the IVC.

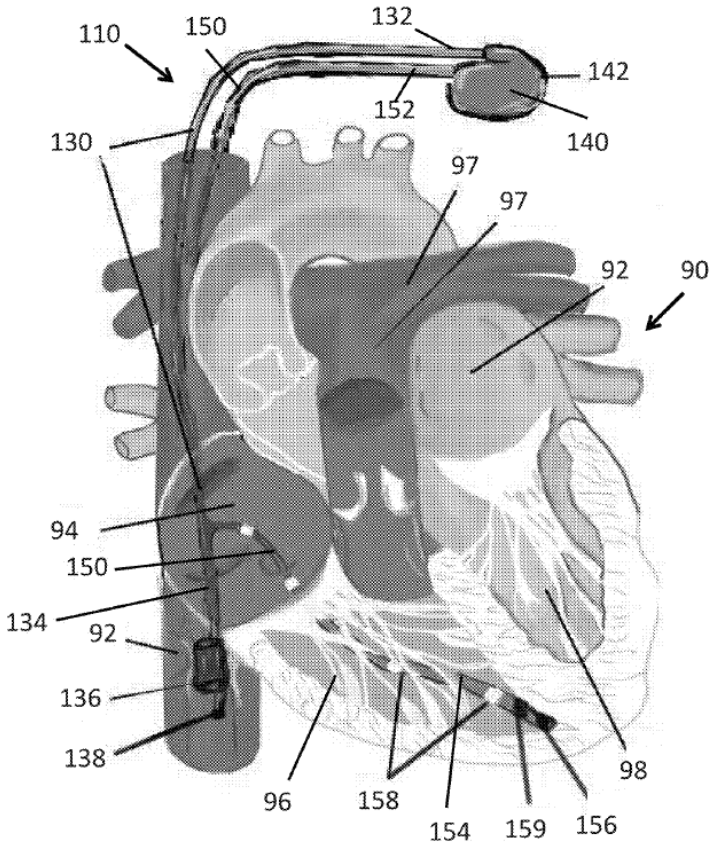


FIG. 2

Figure 2 shows an embodiment of a two-lead system similar to that depicted in Figure 1. *See generally id.* at 8:59–60, 12:7–15. In this embodiment, lead/catheter 130 includes impedance flow device 136 positioned in the inferior vena cava 92. *Id.* at 12:52–64. Figure 2 further shows sensor 138 on the distal end of lead/catheter 130, "coupled to

controller 140 to measure the pressure of blood beyond the flow impedance device 136." *Id.* at 12:65–13:2. Using estimates of intracardiac filling pressures derived from catheter sensor data, "[c]ontroller 140 may adjust the pressure differential from the flow impedance device 136." *Id.* at 13:14–21.

2. Overview of Gelfand (Ex. 1006)

According to Gelfand, "[a] Myocardial Infarction (MI), or heart attack, starts when a coronary artery suddenly becomes occluded and can no longer supply blood to the myocardial tissue," resulting in a localized infarct. Ex. 1006, ¶ 5. In other words, "myocardial tissue that is no longer receiving adequate blood flow dies and causes biochemical and structural changes in that tissue." *Id.* "The area of actual destruction, or necrosis, of myocardial tissue is called the infarct size." *Id.* ¶ 7.

"Infarct healing is a complex process of biochemical and physical changes that occurs to replace or compensate for the loss of muscle cells from the infarction." *Id.* Gelfand teaches that for up to two weeks after the initiation of an MI event, "collagen and other tissues within the infarcted and adjacent regions are particularly vulnerable to distorting forces caused by increased wall stress. This period of remodeling is called infarct expansion." *Id.* According to Gelfand,

> pharmaceuticals such as ACE inhibitors, beta-blockers, diuretics, and calcium channel antagonists have the ability to reduce aortic pressure and heart muscle contractility leading to a mild decrease in wall stress. . . . these agents have also been shown to slow the ventricular remodeling process. Nevertheless, . . . their ability to reduce the infarct expansion is limited by side effects such as hypotension (pathologically low blood pressure) that can be fatal to a patient.

Id. ¶ 10. Gelfand instead discloses "[a] method and apparatus for prevention and reduction of myocardial infarct size and/or expansion and heart remodeling by partial, controllable and reversible obstruction of the venous blood flow to the heart." *Id.*, Abstr.

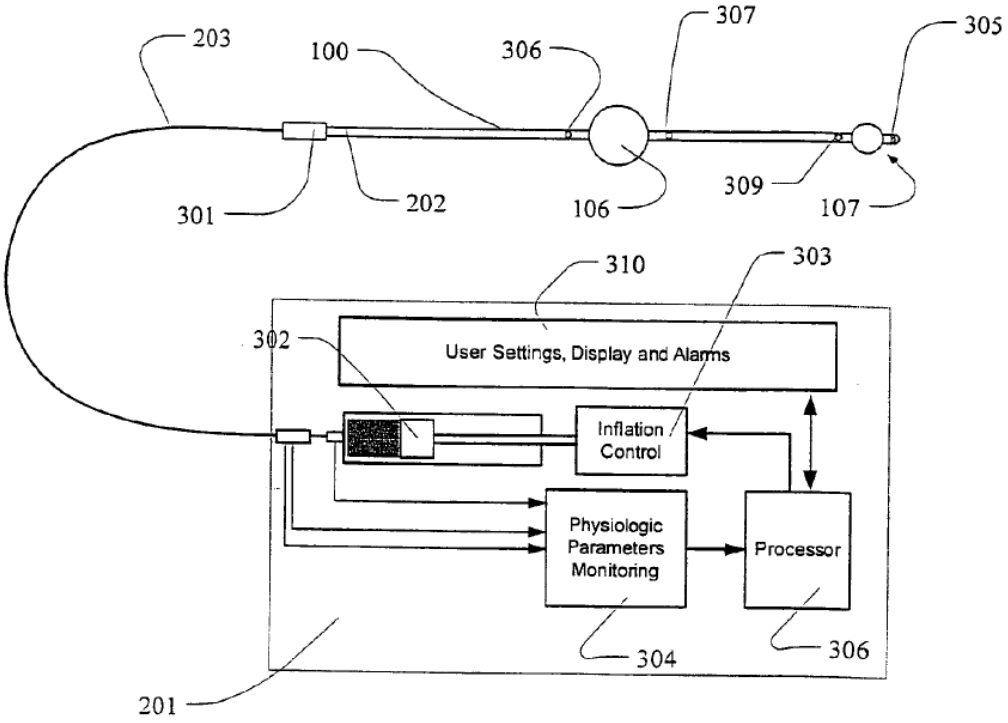
> Gelfand explains that venous blood returns to the heart
>
> predominantly via the Inferior Vena Cava (IVC) and to lesser extent via the Superior Vena Cav[a] (SVC) and coronary veins. IVC and SVC converge into the Right Atrium (RA) of the heart. If the amount of venous blood returning to the heart is reduced for example by 10%, the volume and wall stress of the ventricles of the heart, and specifically the left ventricle, will be temporarily reduced allowing heart to heal better and limiting the MI expansion.

Id. ¶ 17. Gelfand thus discloses 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." *Id.* ¶ 14. In particular, "[t]he invention limits infarct size and/or expansion by 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." *Id.* ¶ 16; *see also id.* at code (54) ("Treatment of Infarct Expansion by Partially Occluding Vena Cava").

Gelfand states that in some embodiments, "the amount of venous blood returning to the heart (filling the heart) is reduced by creating a partial temporary obstruction (occlusion) in the IVC or RA," where "[t]he degree of partial occlusion controls the blood flow." *Id.* ¶¶ 18–19. Gelfand notes that the use of catheters to partially occlude blood vessels such as the aorta is known in the field of medical devices. *Id.* ¶ 30. To occlude venous blood flow, Gelfand employs a catheter similar to a standard Swan-Ganz catheter,

but equipped with an additional inflatable occlusion balloon proximal to the conventional distal PA (pulmonary artery) balloon. *See id.* ¶¶ 26–28.[7] According to Gelfand, the catheter "basically consists of the vascular catheter 100, inflatable occlusion balloon 106 proximal to the distal tip 108 of the catheter and the controller 201." *Id.* ¶ 31. Figure 3, reproduced below, shows Gelfand's catheter and associated hardware.

Figure 3



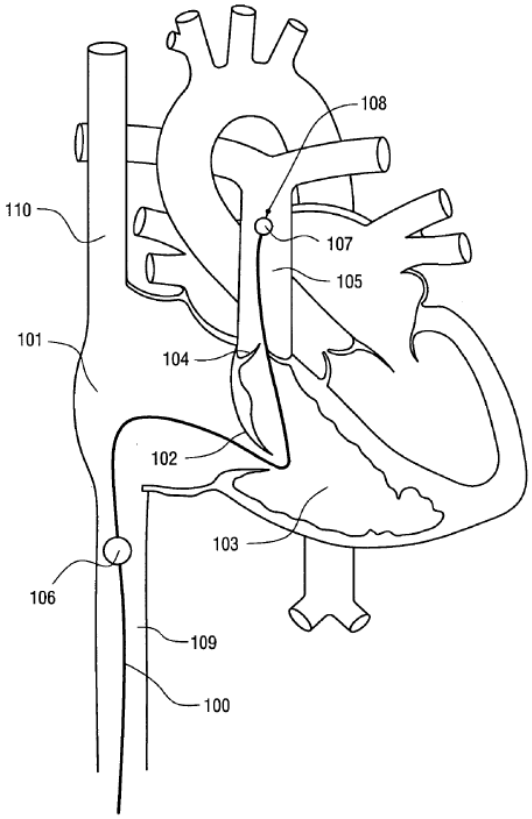
Id. ¶ 23, Fig. 3. Figure 3 shows catheter 100 including oxygen sensor 305 and blood pressure sensors 306 and 309, in communication with electronic subsystem 304 of controller 201. *Id.* ¶ 51; *see generally id.* ¶¶ 23, 43–51.

[7] Gelfand states: "It is understood that while the preferred embodiment of this invention uses an inflatable balloon to partially occlude a great vein, other expandable mechanical devices can be envisioned that can be mounted on a catheter and perform the same function." Ex. 1006 ¶ 30.

"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 b[]y controlling the inflation control system 302." *Id.* ¶ 51. Figure 4 (not shown) further illustrates an algorithm embedded in the software of processor 306 that uses catheter sensor information to automatically control and adjust balloon inflation to keep physiologic parameters such as blood pressure within safe limits. *See id.* ¶¶ 24, 53–54, Fig. 4.

Figure 1, reproduced below, illustrates the placement of catheter 100 "in the IVC to reduce filling of the heart."

Figure 1



Id. ¶ 21.

Figure 1 shows catheter 100 threaded through the right atrium 101 with a distal PA balloon 107 positioned in the pulmonary artery and

occlusion balloon 106 positioned in the inferior vena cava 109. *See id.* ¶¶ 28–29. Gelfand indicates that the orientation shown in Figure 1 is a preferred embodiment, but expressly teaches that

> occlusion balloon 106, shown in the IVC 109, *can be positioned in other places within the right heart and great veins such as* in the RA101, *Superior Vena Cava (SVC) 110*, right ventricle 103 or pulmonary artery 105 with the similar effect of reducing the filling of the heart. These modifications will not substantially change the invented method, system or device.

Id. ¶ 29 (emphasis added).

3. Overview of Bannon (Ex. 1012)

Bannon discusses procedures for central venous cannulation including the "use of surface landmarks to facilitate safe placement of internal jugular, subclavian and femoral venous catheters." Ex. 1012, Abstr. According to Bannon,

> The right internal jugular vein and the left subclavian vein are the preferred sites for cannulation with catheters requiring introducer sheaths to avoid kinking of the sheath at the turns associated with the right subclavian and left internal jugular approaches. The right internal jugular and left subclavian veins are also the preferred approaches for wide-bore stiff dialysis catheters that carry a greater risk of venous injury in the alternative positions for the same anatomic reasons.

Id. at 29.

Further comparing these two preferred procedures, Bannon states that "[t]he internal jugular vein is often the access site of choice for central venous cannulation. Advantages include a superficial location, easy ultrasonic visualization, and a straight course to the superior vena cava (on the right)." *Id.* at 30. Alternatively, Bannon states that "[t]he subclavian vein, long favored by surgeons, offers an alternative to the internal jugular

vein for central venous access. It may be associated with fewer infectious complications than the internal jugular vein, and will remain accessible after localized thrombosis of the internal jugular vein." *Id.* at 33 (internal footnote numbering omitted).

In contrast, Bannon teaches that "[f]emoral vein catheters are associated with higher rates of infection and thrombosis than subclavian catheters or internal jugular vein catheters. Therefore, the femoral vein is considered the third choice for catheterization and is used only when subclavian and internal jugular approaches are not feasible." *Id.* at 37 (internal footnote numbering omitted).

II. ANALYSIS

A. Legal Standards

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (2012) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

To show anticipation under 35 U.S.C. § 102, each and every claim element, arranged as in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008). The prior art need not, however, use the same words as the claims to find anticipation. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). In

evaluating anticipation, it is permissible to take into account not only the literal teachings of the prior art reference, but also the inferences the skilled artisan would draw from it. *Eli Lilly and Co. v. Los Angeles Biomedical Res. Inst. at Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017) (holding that the "dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer from a prior art reference that every claim element is disclosed in that reference"); *In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995) ("A reference anticipates a claim if it discloses the claimed invention 'such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention.'") (quoting *In re LeGrice*, 301 F.2d 929 (CCPA 1962)) (emphasis omitted). Moreover, "a reference can anticipate a claim even if it does not expressly spell out all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would at once envisage the claimed arrangement or combination." *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (internal quotation marks and alterations omitted). However, a patent claim "cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003); *see also Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001) ("[A]nticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabling to one of skill in the art."). However, a patent claim "cannot be anticipated by a prior art reference if the

allegedly anticipatory disclosures cited as prior art are not enabled." *Amgen,* 314 F.3d at 1354.

"While a reference must enable someone to practice the invention in order to anticipate under § 102(b), a non-enabling reference may qualify as prior art for the purpose of determining obviousness." *Beckman Instruments Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989). With respect to obviousness, our reviewing court explains that, "a reference that does not provide an enabling disclosure for a particular claim limitation may nonetheless furnish the motivation to combine, and be combined with, another reference in which that limitation is enabled. Alternatively, such a reference may be used to supply claim elements enabled by other prior art or evidence of record." *Raytheon Techs. Corp. v. Gen. Elec. Co.*, 993 F.3d 1374, 1380 (Fed. Cir. 2021) (citation omitted).

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill

in the art "to combine . . . known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotations omitted).

We address Petitioner's challenges with these standards in mind, and in view of the definition of the skilled artisan and the claim constructions discussed below.

B. Person of Ordinary Skill in the Art

Factual indicators of the level of ordinary skill in the art include "the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field." *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros*).

Petitioner proposes two highly similar and interrelated versions of a person of ordinary skill in the art. The first comprises

> 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").

Pet. 24–25; Ex. 1002 ¶¶ 97–98; Ex. 1004 ¶¶ 54–55. In the second, Petitioner recasts the above team as a collection of skilled artisans in complementary fields, specifically,

> 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.

Pet. 25; Ex. 1002 ¶ 99; Ex. 1004 ¶ 56. However phrased, Petitioner's proposed definition indicates a high level of skill in the relevant art.

Patent Owner does not presently contest the above definitions, but argues that we need not address them "[b]ecause no issue that must be decided by the Board depends on the level of ordinary skill." Prelim. Resp. 11–12. We do not agree with Patent Owner's reasoning insofar as the perspective of one of ordinary skill in the art is critical to our patentability analyses. Our reviewing court has made clear that an understanding of a patent's claims, the teachings of the prior art, and whether a claim would have been obvious in light of those references, are all determined from the perspective of one of ordinary skill in the relevant art. *See, e.g.*, *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1360, 1361, n.3 (Fed. Cir. 2008).

Whether expressed as "a multidisciplinary team," or as a set of one or more individuals possessing the asserted qualifications, we provisionally accept Petitioner's proposed definitions, as they appear consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the '871 Patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("the prior art itself [may] reflect[] an appropriate level" as evidence of the ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)). Patent Owner is welcome to address the definition of one of ordinary skill in the art at trial.

C. Claim Construction

We construe claims "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.100 (2021). Therefore, we construe the challenged claims under the framework set forth in *Phillips v. AWH Corp*., 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). Under this framework, claim terms are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art, at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id*. Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs*. in the context of an AIA trial proceeding).

Petitioner contends that one of ordinary skill in art would understand "maintaining intravascular pressure," as used in claims 1 and 13, to mean

"maintaining pressure within blood vessels or a blood vessel;" "distal restrictor," as used in claims 10 and 22, to mean "the restrictor that is located furthest from the clinician;" "catheter extends across a vein wall," as used in claims 12 and 24, to mean, "catheter extends through a vein wall;" and "resistors" as used in claims 5–7 and 17–19, to mean "restrictors." Pet. 25–29 (emphasis and citations omitted). In response, Patent Owner address only the meaning of "maintaining intravascular pressure." Prelim. Resp. 13–20.

1. "maintaining intravascular pressure"

Independent claims 1 and 13 recite, "activating the one or more restrictors within the superior vena cava to at least partially occlude flow through the superior vena cava while maintaining intravascular pressure." Within the challenged claims, the parties refer to "[while] maintaining intravascular pressure" as elements [1f] and [13g] of claims 1 and 13, respectively. *See e.g.*, Pet. 104, 106; Prelim. Resp. 1–2. The language of element [1f]/[13g] is not used in the Specification and the prosecution history is not helpful in its construction.

Patent Owner contends that we should construe "maintaining intravascular pressure" as meaning "maintaining systemic pressure" throughout the intravasculatory system as a whole. Prelim. Resp. 13–20. In support, Patent Owner asserts that the "goal" of the claimed invention was to overcome the side effects associated with prior art pharmacological treatments of pulmonary edema. *Id.* at 14 (citing Ex. 1001, 1:59–61). In this respect, the '460 Patent explains that prior art treatments for pulmonary edema employ loop diuretics or vasodilators, which are often supplemented with oxygen or, in extreme cases, mechanical ventilation. *Id.* at 1:49–52. The '460 Patent asserts, however, that "these treatments are less than ideal

because the edema is not always alleviated rapidly enough and for many patients[,] renal function is adversely affected." *Id.* at 1:53–55. The '460 Patent further states that a "significant problem" with the prior art pharmacological approach

> 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 hypotension and activates the Renin Angiotensin Aldesterone System, which leads to an increase in blood pressure. Eventually, this cycle leads to diuretic resistance and the worsening of renal function in almost 30% of admitted patients.

Id. at 1:59–67 (repeated words removed).

Although clearly focused on systemic intravascular pressure, Patent Owner's proposed construction is ambiguous as to its intended meaning of "maintained." Strictly construed, we might interpret "maintained" as requiring intravascular pressure after "activating the one or more restrictors within the superior vena cava to at least partially occlude flow through the superior vena cava," as required by claims 1 and 13, to be exactly the same as the intravascular pressure just prior to the procedure. The extrinsic art of record, however, suggests that one of ordinary skill in the art would expect occlusion of the superior vena cava to have at least some effect on intravascular pressure. *See* Ex. 1006 ¶ 19 (teaching feedback control systems to prevent "[e]xcessive obstruction of IVC [that] can lead to hypotension (dangerously low blood pressure)"). Considering one of the purported "goals" of the '460 Patent is to avoid the adverse effects of hypotension, it appears reasonable on the present record that "maintaining systemic pressure" contemplates a range of systemic pressure that does not "lead[] to

hypotension and activate[] the Renin Angiotenesin Aldesterone System." *See* Ex. 1001, 1:59–64; Prelim. Resp. 14–15.

Consistent with this portion of the Specification, the parties agree that maintaining systemic pressure excludes "reducing pressure like prior treatments." *See* Prelim. Resp. 13, 20 (quoting Pet. 26). But because the record does not make clear how broadly one of ordinary skill in the art would have defined hypotension—let alone the conditions under which hypotension activates the renin angiotensin aldosterone system—the parties are encouraged to address how one of ordinary skill in the art would understand the range of pressure (if any)—and any permissible temporal variance—encompassed by the term "maintaining."

In contrast to Patent Owner's focus on systemic pressure, Petitioner contends that "maintaining intravascular pressure" should be more broadly construed as "maintaining pressure within blood vessels or a blood vessel." Pet. 25–26. Supported by the testimony of Dr. Garcia, we understand Petitioner to argue that "maintaining intravascular pressure" encompasses three aspects: 1) maintaining systemic pressure, as argued by Patent Owner, but also 2) maintaining regions of reduced pressure between occlusion devices, and 3) maintaining regions of reduced pressure in the vicinity of those devices ("*i.e.*, upstream and downstream of a zone in a two-restrictor embodiment"). *See id.*; Ex. 1004 ¶¶ 42–47.

With respect to aspect 2), Patent Owner acknowledges that the '460 Patent "is replete with teaching of operating the devices of the invention to create localized low pressure zones" which, it asserts, do not inform the meaning of "maintaining intravascular pressure." Prelim. Resp. 14 (emphasis omitted). The Specification, however, describes a region bounded

by occlusion balloons and containing a catheter suction port to "maintain[] the pressure of the isolated area between about 2-5 mmHg and thus prevent collapse of the thoracic duct." *See* Ex. 1001, 13:2–7; Ex. 1004 ¶ 45. As such, the '460 Patent would appear to teach "maintaining intravascular pressure" above a set minimum within an isolated area.

Aspect 3) relates to maintaining pressure in the vicinity of a low-pressure zone, but outside of a region bounded by two restrictors as in aspect 2. Relevant to aspect 3), we understand the Specification to disclose feedback loops designed to maintain the jugular and innominate vein pressure above a baseline pressure minus a minimum significant pressure deviation or "safety delta." *See* Ex. 1001, 15:33–17:33; *see also id.* at 13:33–43 ("pump 50 can be operated to create a localized low pressure region at the junction of the jugular, subclavian and innominate veins to establish a pressure gradient in the vicinity of the thoracic and lymphatic duct outflow"). As quoted by Dr. Garcia, for example,

> The pump is activated to *maintain the jugular and innominate vein pressure* and thus the nominal blood flow . . . . As the *nominal pressure of the jugular vein is maintained* by the actuation of the pump, the pressure gradient across the proximal restriction is achieved by the pressure reduction within the area between the two restrictions.

Ex. 1004 ¶ 46 (quoting Ex. 1001, 17:48–56).

Considering the intrinsic record and the testimony of Dr. Garcia, Petitioner has the better argument on present record. For the purpose of institution, we provisionally construe "maintaining intravascular pressure," as used in independent claims 1 and 13 to mean, "maintaining pressure within blood vessels or a blood vessel" and encompassing: 1) maintaining a systemic pressure that does not lead to hypotension; 2) maintaining an

isolated region of reduced pressure between pairs of occlusion devices; and 3) maintaining a region of reduced pressure in the vicinity of an occlusion device. The parties are encouraged to submit additional argument and evidence as to the meaning of this term at trial.

2. "distal restrictor," the catheter extends across a vein wall," and "resistors"

Patent Owner "does not take a position on the constructions of the remainder of [the terms addressed by Petitioner] for the purposes of this Preliminary Response because no issue that must be decided by the Board depends on them." Prelim. Resp. 12. While we agree with Patent Owner that our Decision on Institution does not depend on a precise meaning of "distal restrictor," "the catheter extends across a vein wall," or "resistors." Petitioner presents reasoned argument and evidence as to their meaning, which we find useful in understanding the claims as a whole, and Petitioner's proposed definitions appear consistent with the intrinsic evidence of record. In the interest of clarity, we provisionally adopt Petitioner's proposed definitions for these terms, and invite Patent Owner to address the meaning of any relevant claim term at trial.

D. The Parties' Contentions

Petitioner contends that claims 1–10, 12–22, and 24 are anticipated by Kaiser (Ground 1). Pet. 27–55. Petitioner further argues obviousness based on Kaiser, specifically, that claims 11 and 23 are obviousness in view of Kaiser alone (Ground 5), claims 1–24 are obvious in view of Kaiser and Bannon (Ground 3/6), claims 11 and 23 are obvious in view of Kaiser and Gelfand (Ground 2/7), and claims 1–24 are obvious in view of Kaiser, Gelfand, and Bannon (Ground 4/8). Pet. 55–100. In each case, Petitioner presents reasoned arguments for unpatentability supported by the testimony of Drs. Garcia and Day. *See generally id.* at 27–100. We consider below the evidence and arguments contested in the Preliminary Response.

1. "advancing a catheter comprising one or more restrictors . . . into a superior vena cava," and activating and adjusting the restrictors "within the superior vena cava"

Patent Owner first argues that the cited references do not teach elements of independent claims 1 and 13 relating to the position of catheter elements in the SVC, specifically, "advancing a catheter comprising one or more restrictors . . . into a superior vena cava" (elements [1a][1c]/[13a][13c]), "activating the one or more restrictors within the superior vena cava" (element [1e]/[13f]), and that "one or more restrictors [within the superior vena cava] are adjusted based on feedback from one or more pressure sensors" (element [1g]). Prelim. Resp. 23–34. Petitioner relies on Kaiser and Gelfand for these elements, which we address in turn.

a) Kaiser

Petitioner relies on Kaiser as supporting all asserted Grounds. Pet. 10. Petitioner addresses where Kaiser discloses the above elements on pages 35–39 and 41–43 of the Petition. As we understand Petitioner's supporting

evidence, Drs. Day and Garcia explain why one of ordinary skill in the art would have recognized Kaiser to disclose the use of a catheter balloon or "adjustable component" to occlude blood flow in the SVC. *See, e.g.*, Ex. 1002 ¶¶ 227–233, 108 (citing Ex. 1007, 5:64–6:2, 6:60–64, claims 10, 17), 158 (citing same); Ex. 1004 ¶¶ 63–65, 68, 79–85. Petitioner's declarants further testify that although Kaiser and Gelfand focus on different medical objectives, both disclose "essentially the same components" to occlude the SVC. Ex. 1002 ¶¶ 228–237, 293; Ex. 1004 ¶¶ 93, 120.

Focusing on Kaiser's more preferred embodiments—those having a catheter balloon in the IVC—Patent Owner argues that "Kaiser does not include any teachings whatsoever that its flow impedance device 136 may be positioned within the SVC, as required by claim element 1[c]/13[c]." Prelim. Resp. 25.

Considering the arguments and evidence presently before us, Petitioner has the better position. Kaiser teaches that "at least one adjustable component may be configured to be placed percutaneously and selectively expanded in the vena cava with a mechanism to induce a pressure gradient along the inside of the adjustable component." Ex. 1007, 6:37–43. The adjustable component (e.g., an inflatable balloon), "may create a pressure gradient by . . . adjusting the blood flow impendence through the superior vena cava." *Id.* at 6:41–43, 60–64.

As reproduced below, Kaiser's claim 17 as it depends from claim 10, further emphasizes the positioning of the adjustable component in the superior vena cava.

> 10. A method for treating a patient with conduction disease and/or heart failure configured to monitor and/or treat the patient, comprising:

introducing a distal end of an elongate member into a venous side of a patient's heart, the distal end carrying at least one sensor configured to provide sensor data corresponding to pressures within or near the patient's heart and **an adjustable component configured to create a pressure gradient to blood flow within or near the patient's heart**;

manipulating the elongate member to position the adjustable component within a body lumen of the venous side of the patient's heart;

introducing at least one pacing component into or adjacent the patient's heart;

implanting **a housing containing a controller** within the patient's body adjacent the heart; and

coupling the controller to the at least one sensor and the adjustable component;

wherein the controller is programmed to adjust the adjustable component based at least in part on sensor data from the at least one sensor to create a desired pressure gradient to blood flow within the patient's heart to reduce intracardiac filling pressures within the patient's heart.

17. The method of claim 10, **wherein the body lumen within which the adjustable component is positioned in** one of an inferior vena cava, **a superior vena cava**, a right atrium, and a right ventricle of the patient's heart.

Ex. 1007, 17:37–61, 18:34–37 (bolding added).

As indicated above, Kaiser discloses and claims a method for "introducing a distal end of an elongate member [i.e., a catheter] into a venous side of a patient's heart . . . the distal end [of the catheter] carrying . . . an adjustable component configured to create a pressure gradient to blood flow within or near the patient's heart" (i.e., an expandable balloon or other adjustable restrictor), wherein the catheter is in communication with a

"controller . . . programmed to adjust the adjustable component based at least in part on sensor data . . . to create a desired pressure gradient to blood flow within the patient's heart," and wherein "the adjustable component [e.g., balloon] is positioned in . . . a superior vena cava." *See id.* As such, the plain language of Kaiser's claim 17, as it depends from claim 10, teaches the positioning and use of a balloon catheter in the superior vena cava, as required in independent claims 1 and 13.

Patent Owner also appears to suggest that Kaiser does not enable the use of a balloon catheter in the superior vena cava. Referencing only a subset of the reference's disclosure, Patent Owner contends "Kaiser in fact only teaches positioning its 'flow impedance device 136' within the IVC, which is separate from and biologically different to the SVC, and which would require the use of different devices and techniques that are not disclosed by Kaiser." Prelim. Resp. 23–29 (citing, e.g., Ex. 1007, 7:17–19, 12:55–58, 13:37–43, 14:17–20). Patent Owner argues that there are "significant biologically [sic] differences between the IVC and the SVC including that the IVC is significantly larger, both in terms of its length and diameter." *Id.* at 30; *see id*. at 5–6, 26, 33 (asserting that the IVC has a diameter of 27–36 mm as compared to the "substantially smaller" 18–22 mm diameter of the SVC). Accordingly, Patent Owner argues, the IVC has "significantly more capacity to store excess blood (known as 'capacitance')

than the SCV." *Id.* at 6 (citing Ex. 2001,[8] Ex. 2002[9]). In light of these physiological differences, Patent Owner concludes that

> [n]one of the embodiments disclosed by Kaiser are suitable for deployment of its adjustable component within the SVC, and neither Petitioner nor its expert provide any explanation as to how Kaiser's adjustable component could alleged[ly] be positioned and used in such a location despite the significant biological differences between the SVC and IVC and the particular construction of the system of Kaiser to enable its use in the IVC.

Id. at 26.

Insofar as Patent Owner appears to raise lack of enablement, we encourage the parties to address whether Kaiser and/or Gelfand sufficiently enables the use of a catheter balloon in the SVC. *See*, *e.g.*, *Raytheon*, 993 F.3d at 1380 ("a reference that does not provide an enabling disclosure for a particular claim limitation may . . . be used to supply claim elements enabled by other prior art or evidence of record"). We further note the "presumption . . . that both the claimed and unclaimed disclosures in a prior art patent are enabled." *Amgen*, 314 F.3d at 1355*; see also In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012) (extending presumption to prior art printed publications). Moreover, at this stage of the proceedings, Patent Owner's conclusion is based entirely on attorney argument, which "is no substitute for evidence." *See Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989).

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[8] Lakna, "*Difference Between Superior and Inferior Vena Cava*," Pediaa (Aug. 28, 2018), https://pediaa.com/difference-between-superior-and inferior-vena-cava/.
[9] Tucker *et al.*, "*Anatomy, Abdomen and Pelvis, Inferior Vena Cava*," (July 27, 2021), *available at* https://www.ncbi.nlm.nih.gov/books/NBK482353/.

Considering Kaiser's express teaching that the catheter balloon may be positioned in the SVC, we find that Petitioner has the better position on the current record. As such, Petitioner has shown sufficiently for purposes of institution that a skilled artisan would understand Kaiser as disclosing the presently contested limitations of elements [1a], [1c], [1e], [1g], [13a], [13c] and [13f].

b) Gelfand

In addition to the teachings of Kaiser, Petitioner's Grounds 2/7 and 4/8 further rely on Gelfand as teaching the positioning and use of a balloon catheter in the SVC. *See*, *e.g.*, Pet. 10, 55–90, 95–96, 99–100. Petitioner references Gelfand's disclosure "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).)" Pet. 68 (emphasis removed). Petitioner further notes Gelfand's disclosure that "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." *Id.* at 65–66 (citing Ex. 1006 ¶ 29; Ex. 1002 ¶¶ 252–253) (emphasis omitted). According to Petitioner, "Gelfand thus discloses advancing its catheter in the superior vena cava of a patient." *Id.* (referencing Ex. 1002 ¶¶ 249–254).

Focusing on Gelfand's Figure 1, Patent Owner contends that "Gelfand describes only the 'position[ing] of the balloon 106 . . . in the IVC 109 or RA 101.'" Prelim. Resp. 32 (quoting Ex. 1006 ¶ 33) (alteration in original).

Patent Owner then dismisses Gelfand's teaching that "occlusion balloon 106 . . . can be positioned in other places within the right heart and great veins such as in the . . . Superior Vena Cava (SVC) 110" as "a passing suggestion" that "nowhere describes how this would be done or that the balloon could be activated or adjusted in such locations." *Id.* (quoting Ex. 1006 ¶ 29). Referencing the same size and capacitance differences discussed with respect to Kaiser, Patent Owner concludes:

> It is thus clear that a device designed and configured for use in the IVC cannot simply be placed in the SVC and expect to function properly and Gelfand only describes a device configured for use in the IVC. Neither Gelfand nor Petitioner (or its expert) describe that the same catheter and balloon could be placed and operated within the differently located and sized SVC, or what changes would need to be made to accommodate for such different placement.

Id. at 33–34.

As with its similar argument regarding Kaiser, we accord Patent Owner's conclusion little weight at present because it is based entirely on attorney argument, whereas the level of ordinary skill is high. *See Johnston*, 885 F.2d at 1581; section, II.B, above. In contrast, Petitioner's position that one of ordinary skill in the art would understand Gelfand to disclose the positioning requirements within the superior vena cava, is supported by the testimony of Drs. Day and Garcia. In accord with our present understanding of the level of ordinary skill in the art, Dr. Day is a biomedical engineer, focusing on "medical devices that interact with the circulatory system," and having experience with "blood flow and fluid dynamics, as well as medical devices inserted through or attached to blood vessels for cardiovascular treatment and blood flow modulation." Ex. 1002 ¶ 3; *see* Ex. 1003. And Dr. Garcia is a heart surgeon with a "primary focus as an interventionalist on

catheter based therapies for acute myocardial infarction, unstable coronary syndromes, classic stable angina." Ex. 1004 ¶ 6; *see* Ex. 1005.

Addressing Gelfand's express teaching that the catheter balloon may be positioned in the SVC, Dr. Day testifies that, "[h]aving reviewed Gelfand's methods, systems and devices, I find that they could be used in the SVC without any substantial modification other than the catheter potentially being inserted into a vein upstream of the SVC." Ex. 1002 ¶¶ 253–254. Dr. Garcia similarly opines that

> Gelfand discloses occluding the SVC or IVC with a balloon catheter device to reduce blood flow to the heart. Gelfand's catheter is a type of Swan-Ganz catheter, a commonly used catheter with which I and other clinicians are very familiar, and Gelfand discloses that its catheter can be inserted and placed using conventional techniques.

Ex. 1004 ¶ 95 (citing Ex. 1006 ¶¶ 26–28 (Dr. Day's overview of therapeutic balloon catheters)). Referencing Dr. Day's testimony, Dr. Garcia further states that

> from an engineering perspective . . . [using Gelfand's catheter to occlude the SVC] simply requires using a sufficiently large balloon, which would only be slightly larger than the balloon disclosed by Gelfand. From a clinician's perspective, there would have been no difference in using Gelfand's device to partially occlude the SVC and in using it to fully occlude the SVC. The device would simply have been inserted percutaneously, advanced so that the balloon is in the SVC, and then operated to inflate the balloon to the inner diameter of the SVC.

Id. ¶ 124; *see also id.* ¶¶ 108–111 (further explaining why one of ordinary skill in the art would know how "to place the occlusion balloon in the SVC as taught by Gelfand").

In section II.D.1.a, we determined that Petitioner has shown sufficiently for purposes of institution that Kaiser teaches and/or suggests the presently contested limitations of elements [1a], [1c], [1e], [1g], [13a], [13c], and [13f]. In light of the above, we find that Petitioner has shown sufficiently for purposes of institution that Gelfand also teaches and/or suggests these elements.

2. "maintaining intravascular pressure"

Elements [1f] and [13g] of independent claims 1 and 13, respectively, generally relate to the operation of a balloon catheter in a patient's superior vena cava "while maintaining intravascular pressure." As discussed in greater detail above, we provisionally construe "maintaining intravascular pressure" to mean, "maintaining pressure within blood vessels or a blood vessel," which variously encompasses aspect 1) maintaining a systemic pressure that does not lead to hypotension; aspect 2) maintaining an isolated region of reduced pressure between pairs of occlusion devices; and aspect 3) maintaining a region of reduced pressure in the vicinity of an occlusion device. *See* section II.C.1, above.

Petitioner relies on Gelfand and Kaiser as disclosing element [1f]/[13g]. *See* Pet. 40–42, 71–72, 74. Applying its proposed construction of "while maintaining intravascular pressure" "to mean 'maintaining systemic pressure,' in contrast to 'reducing pressure like prior treatments,'" Patent Owner contends that neither Kaiser nor Gelfand discloses this limitation. Prelim. Resp. 34–39.

a) Kaiser

According to Petitioner, "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 . . . 'maintaining intravascular pressure." Pet. 40 (citing Ex. 1007, 11:31–33); *see also* Ex. 1004 ¶¶ 75–77 (further citing Ex, 1007, 2:67–3:4). We understand this argument as directed to aspect 1) of our provisional construction.

In response, Patent Owner argues that Kaiser is directed to optimizing intra-cardiac filling pressures, rather than intravascular pressure. Prelim. Resp. 35–39 (citing Ex. 1007, Abstr., 1:15–17, claims 1, 10, 20). More to the point, the particular passage Petitioner relies on discloses adjusting the size of an expandable member within the heart, at least in part, "based upon cardiac output trends and/or pressure measurements within the left atrium 92 or left ventricle 94." *See* Ex. 1007, 11:20–25. Standing alone, this passage does not support Petitioner's position. *See* Prelim. Resp. 40.

But Kaiser more broadly discloses control of an expandable member based on "pressures within or near the heart." Ex. 1007, 6:6–10, 7:66–8:2, claim 1. With respect to aspect 1) of element [1f]/[13g], Petitioner points to Kaiser's explanation that its invention "moves extraneous and congesting fluid to the high capacitance vessels below a pressure gradient device placed within or downstream of the inferior vena cava." Pet. 40; Ex. 1007, 2:64–67.[10] Kaiser explains that, due to "the high capacitance of the venous system, a large volume of blood can be relocated, with a significant decrease in intra-cardiac pressures and with only a minimal (if any) increase in pressure

[10] As discussed in section II.D.1.a, above, Petitioner has adequately shown that Kaiser similarly discloses positioning its device in the superior vena cava.

below our device." Ex. 1007, 2:67–3:4; *see* Pet. 40; Ex. 1004 ¶ 76–77.[11] Thus, and relying on the testimony of Dr. Garcia, Petitioner reasonably contends that occlusion of the IVC or SVC as taught by Kaiser results in significant decreases in cardiac pressure and pressure downstream of the balloon, "while pressure upstream of the balloon remains steady because of the capacitance of blood vessels in the entire upper part of the body." Pet. 40; *see* Ex. 1004 ¶¶ 75–77.

> We also note Patent Owner's assertion that Kaiser
>
> merely teaches that the size of the balloon can be changed based on changes in the pressure, without any reference to whether the changes in size of the balloon are intended to keep the pressure at any particular level, or whether the changes are successful in accomplishing any such goal.

Prelim. Resp. 37. For the purpose of institution, however, we find sufficient Dr. Garcia's testimony that Gelfand's and Kaiser's "devices perform the same function (SVC occlusion) in essentially the same manner," such that using either device to occlude the SVC would "maintain[] intravascular pressure," as required by element [1f]/[13g]. *See* Ex. 1004 ¶¶ 117, 293.

Considering the above, and the entirety of the record before us, Petitioner has shown sufficiently that one of ordinary skill would understand Kaiser to disclose at least aspect 1) of "while maintain[ing] intravascular pressure."

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[11] Although both Petitioner and Dr. Garcia emphasize Kaiser's teaching that the balloon catheter results in "*only a minimal (if any) increase in pressure below* [the] *device*," it is not clear whether they intend to rely on aspect 3) of our proposed construction in this IPR. *See* Pet. 40 (citing Ex. 1007, 3:1–4); Ex. 1004 ¶ 76 (same).

b) Gelfand

As we understand the Petition, Petitioner contends that Gelfand discloses element [1f]/[13g] because its device "would occlude the SVC in exactly the same manner as taught by Kaiser", thus, "maintaining intravascular pressure in the ways taught by Kaiser." Pet. 72 (referencing Ex. 1002 ¶¶ 267–268; Ex. 1004 ¶¶ 113–118. Dr. Garcia further states that

> Gelfand discloses that its methods can maintain a target blood pressure in the SVC or IVC by adjusting the size of the balloon and hence the degree of occlusion. Gelfand states that "algorithms . . . can be used to *maintain a physiologic parameter* or calculated index *at the target level* or within the desired band. Control signals can be applied continuously or periodically to adjust the size of the balloon." (Ex. 1006, ¶ [0054].)

Ex. 1004 ¶ 115. According to Dr. Garcia, one of the "physiologic parameters" highlighted by Gelfand for maintenance at a target level is central venous pressure. *Id.* (citing Ex. 1006 ¶¶ 51–54). Dr. Garcia explains that "'[c]entral venous pressure (CVP),' is 'the pressure of blood within the venous system in the superior and inferior vena cava.'" *Id.* ¶ 116 (citing Ex. 1019). And "[b]ecause the SVC and IVC are blood vessels, when Gelfand discloses maintaining CVP at a target level, it discloses that using its device can 'maintain[] intravascular pressure.'" *Id.* (second alteration in original). As such, we understand Petitioner to argue that Gelfand discloses "maintaining intravascular pressure" under aspects 1) and 3) of our proposed construction.

Noting that Gelfand discloses safeguards during the operation of its device to avoid hypotension and assure that the device does not limit blood flow "below the level required to maintain adequate vital organ function," Patent Owner asserts that "far from maintaining systemic blood pressure . . .

Gelfand in fact teaches that the opposite is true and that safeguards must therefore be implemented for patient safety." Prelim. Resp. 38–39 (citing Ex. 1006 ¶¶ 19, 50–51, 56) (emphasis removed).

But as with the '460 Patent, Gelfand discloses the use of balloon catheters as a means to avoid the hypotensive side effects of prior art pharmacologic treatments. *See e.g.*, Ex. 1001, 1:59–67; Ex. 1006 ¶¶ 10, 19. To the extent the '460 Patent discloses use of a balloon catheter while maintaining systemic pressure, we discern on the present record no reason why a person of ordinary skill in the art would not understand that deployment of Gelfand's balloon catheter also maintains systemic pressure as we presently understand the term. On this record, that Gelfand discloses safeguards to ensure that undesirable deviation from the target pressure does not harm the patient does not counsel otherwise.

Considering the arguments and evidence presently before us, Petitioner has shown sufficiently for purposes of institution that a skilled artisan would understand Gelfand as disclosing the use of a balloon catheter "while maintaining intravascular pressure," as required by the independent claims.

III. CONCLUSION

Each of Petitioner's Grounds rely on Kaiser or Kaiser in combination with Gelfand with respect to the presently contested limitations of elements [1a], [1c], [1e], [1f], [1g], [13a], [13c], [13fg] and [13g]. As discussed above, Petitioner has shown sufficiently for the purpose of institution that both Kaiser and Gelfand disclose or suggest these elements. With respect to the remaining elements of claims 1–24 challenged under Grounds 1, 2/7, 3/6, 4/8 and 5, Petitioner presents reasoned arguments for unpatentability

supported by the testimony of Drs. Garcia and Day, which Patent Owner does not presently contest. *See generally* Pet. 27–100; Prelim. Resp.

Having considered the record before us, we conclude that the information presented in the Petition establishes that Petitioner has shown a reasonable likelihood of prevailing in showing that claims 1–24 of the '460 Patent are unpatentable. Accordingly, we institute *inter partes* review of the challenged claims on all grounds presented in the Petition.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is granted; and

FURTHER ORDERED that the requested *inter partes* review is instituted with respect to claims 1–24 of the '460 Patent.

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