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Paper 39
Date: April 4, 2023

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*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Procedural Background

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.").

In view of the then-available, preliminary record, we concluded that Petitioner satisfied the burden, under 35 U.S.C. § 314(a), to show that there was a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. Accordingly, on behalf of the Director (37 C.F.R. § 42.4(a) (2018)), and in accordance with *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018) and the Office's Guidance on the Impact of *SAS* on AIA Trial Proceedings (Apr. 26, 2018),[1] we instituted an *inter partes* review of claims 1–24 on all the asserted grounds. Paper 11 ("Inst. Dec."), 37.

After institution, Patent Owner filed a Patent Owner Response to the Petition. Paper 19 ("POR"). Petitioner filed a Reply to Patent Owner's Response (Paper 23, "Reply") and Patent Owner filed a respective Sur-reply (Paper 28, "Sur-reply").

On January 10, 2023, the parties presented arguments at oral hearing, the transcript of which is of record. Paper 38 ("Tr."). In light of argument raised at oral hearing, we authorized the parties to submit simultaneous supplemental briefing on the construction of "maintaining intravascular pressure." Paper 33. Accordingly, the parties submitted supplemental briefs

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

(Paper 34, "PO Sup."; Paper 35, "Pet. Sup.") and corresponding responsive briefs (Paper 36, "PO Sup. Reply"; Paper 37, "Pet. Sup. Reply").

B. Real Parties-in-Interest

Petitioner identifies itself as the real party-in-interest. Pet. 7. Patent Owner identifies itself as the real party-in-interest. Paper 24, 1.

C. Related Matters

In addition to the current matter, Petitioner 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").

The '871, '069, and '460 Patents issued from a series of continuations the first of which was 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. Ex. 1001, codes (60), (63).

D. 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]

[2] Kaiser et al., US 9,878,080 B2, issued Jan. 30, 2018. Ex. 1007.
[3] Gelfand et al., US 2006/0064059 A1, publ. Mar. 23, 2006. Ex. 1006.

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

[4] Bannon et al., *Anatomic considerations for central venous cannulation*, 4 RISK MANAGEMENT AND HEALTHCARE POLICY 27–39 (2011). Ex. 1012.

of Kaiser, the combination of Kaiser and Gelfand, and the combination of Kaiser, Gelfand, and Bannon, respectively. Ground 6 is, therefore, duplicative of Ground 3, Ground 7 is duplicative of Ground 2, and Ground 8 is duplicative of Ground 4.

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). Patent Owner relies, *inter alia*, on the Declaration of Dr. Stephen J.D. Brecker, M.D. Ex. 2005.

E. 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." *Id.* at 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. Dr. Garcia explains that, "[p]ulmonary edema results from left-side heart failure: when the left ventricle cannot pump sufficient blood, blood from the lungs has difficulty returning to the left atrium of the heart, which causes

fluid build-up in the lungs." Ex. 1004 ¶ 34; *see also* Ex. 2005 ¶¶ 33–36 (further details regarding the pathology of pulmonary edema and heart failure).Accumulation of this excess fluid in the air spaces of the lungs may lead to respiratory failure and compromised renal function. Ex. 1001, 1:46–48. 7:58–65.

According to the '460 Patent, the "risk of developing acute heart failure or compromised renal function may be avoided by rapid lymphatic fluid removal from the lymphatic system." *Id.* at 7:63–65. The '460 Patent states that current treatments for pulmonary edema employ loop diuretics or vasodilators, which are not ideal because they are "based on the need to reduce intravascular blood pressure," which can activate the Renin Angiotensin Aldosterone System ("RAA system") and lead to diuretic resistance. *Id.* at 1:34–67, Moreover, with prior art pharmacological-based treatments, "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 disclosing methods and systems for reducing edema "by lowering the outflow pressure in a region around the thoracic/lymphatic duct outflow." *Id.* at 6:50–53. By "lowering the outflow pressure at the thoracic and/or lymphatic ducts, higher lymphatic return will be achieved, enabling the lymphatic vessel flow to be at or near normal levels." *Id.* at 6:53–56. According to the '460 Patent, this approach provides

> a number of advantages over existing techniques for treating pulmonary edema. In particular, a higher rate of fluid return from the thoracic and lymphatic outflow ducts enables faster lymphatic fluid removal and resolution of the edema episode. A risk of developing acute heart failure or compromised renal function may be avoided by rapid lymphatic fluid removal from the lymphatic system. As a result of this treatment method pressure in a relatively large area surrounding the thoracic and

> lymphatic ducts outflow ducts can be reduced thereby allow[ing] the procedure to be performed without complicated navigational guidance.

Id. at 7:58–8:2.

The disclosed methods and systems employ an implanted "indwelling catheter within a vein of a patient" with a "first restriction." *Id.* at 2:7–13. 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 2:13–22.

Figure 1 of the '460 Patent, reproduced below, shows a representative system for removing excess lymphatic fluid.

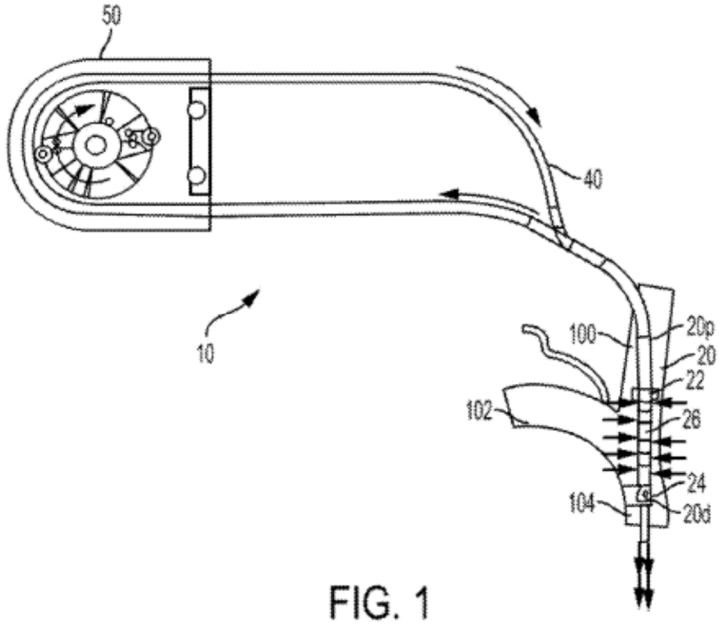


FIG. 1

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.

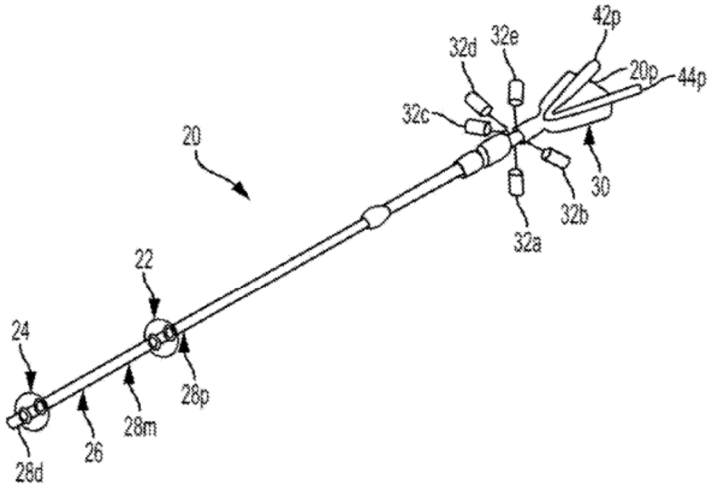


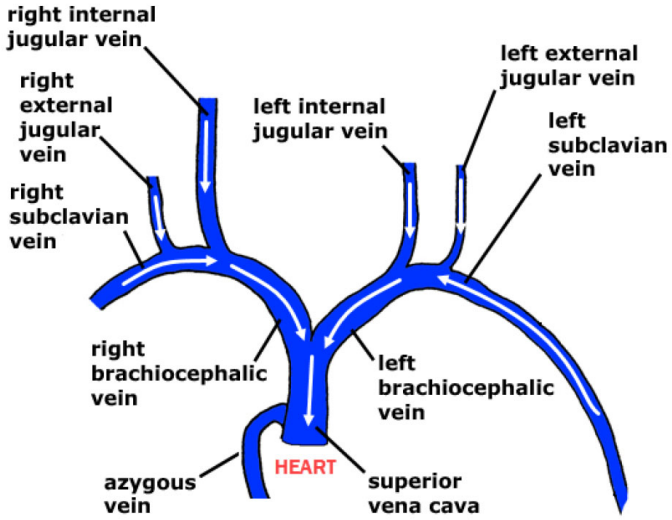
FIG. 2

Figure 2 is a perspective view of the indwelling catheter of Figure 1, showing a first (proximal) restriction 22 and a second (distal) restriction 24. *Id.* at 4:39–40, 7:36–40.

> The proximal restriction 22 should be configured so as to partially restrict flow when it is activated, but to allow some fluid to flow past the restriction. The distal restriction 24, on the other hand, can be configured to fully restrict fluid flow when it is activated. The purpose of the restrictors is to allow the normal flow of blood to continue. However, the activation of the restrictions creates a localized pressure differential between the region proximal to the proximal restriction and the region between the two restrictions.

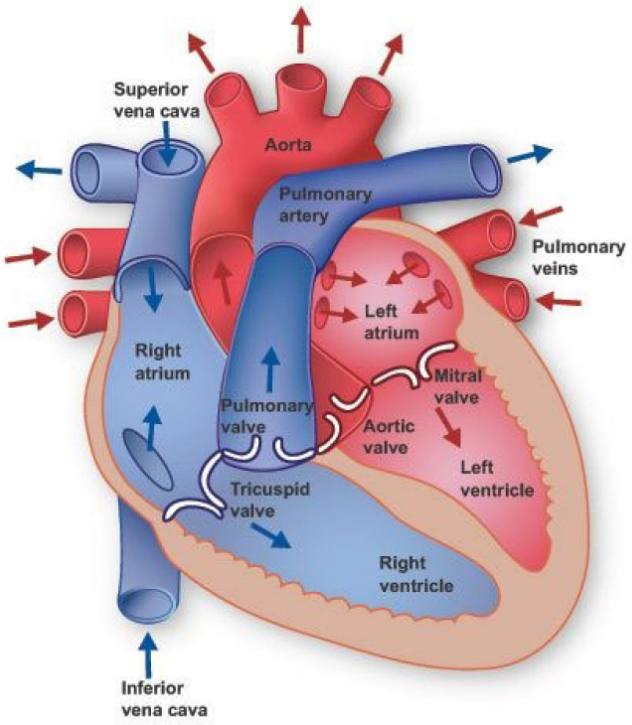
Id. at 10:18–27. Port 32*d* is used to deliver fluid to restriction 22 and port 32*a* is used to deliver fluid to restriction 24. *Id.* at 9:7–15. Within lumens inside catheter 20, pressure sensors can be positioned "to be used for sensing pressure at various locations along the vein in which the catheter 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. "[C]ontrol module 200 can include multiple feedback loops to adjust performance of the system 10 to create and maintain a low pressure zone while the lymphatic fluid is cleared." *Id.* at 15:33–36 (*see generally id.* at 15:36–17:33 (describing exemplary feedback loops)). 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. *See 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. *See* 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.

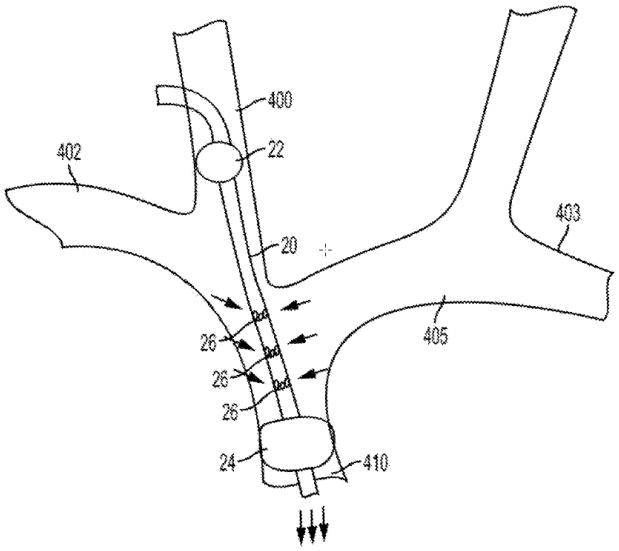


FIG. 27

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.

Ex. 1001, 22:13–31.

F. 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 Callaghan's system to adjust the degree of balloon inflation in response to a sensed pressure." *Id.* at 91. 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.* 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.

G. Priority Date of the '460 Patent Claims

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 the first of which was filed on February 19, 2015, as the '930 Application. Ex. 1001, codes (21), (60), (63). 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 "does not contest that each of the references relied on by the Petition are prior art of the '460 patent." POR 19.

It is undisputed that, for the purposes of this Decision, the knowledge and understanding of a person of ordinary skill in the art (POSA) is materially unchanged whether the June 1, 2014, filing date of the provisional application, or the February 19, 2015, filing date of the first non-provisional application is the applicable priority date. *See* Inst. Dec. 9–10; POR 19–20; Ex. 2005 ¶ 62; Ex. 1002 ¶ 97 (referencing "a POSA at the time of the 2014–2015 priority date"). Finding no evidence to the contrary, we agree with Patent Owner that "the Board need not decide . . . whether the '460 patent is

entitled to the benefit of the filing date of the provisional application to which it claims priority." POR 19.

H. 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). As illustrated on pages 8–10 of Patent Owner's Response, claim 13 recites similar terms as claim 1. *See* POR 8–10 (highlighting contested elements of claims 1 and 13).

I. 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. *Id.* at 8:57–58.

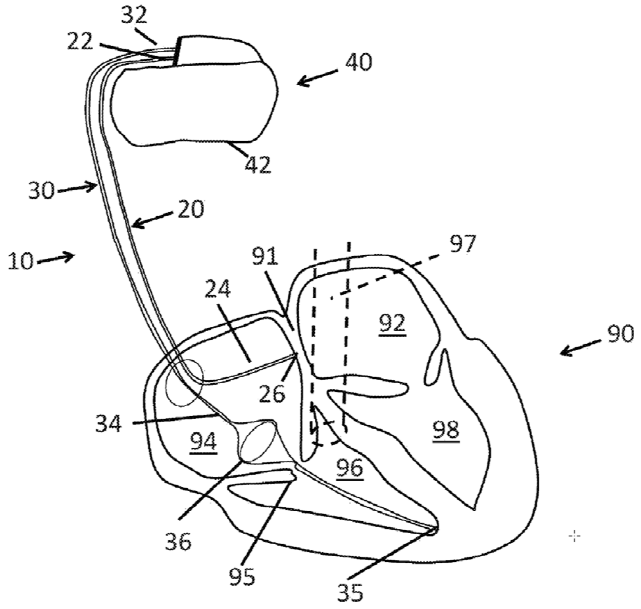


FIG. 1

[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* e.g., Pet. 33, n.9; Ex. 1002 ¶¶ 115, 117, 229, 148–150.

[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*, *e.g.*, Ex. 1002 ¶¶ 107, 114, 231.

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, 5:64–6:2, 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.

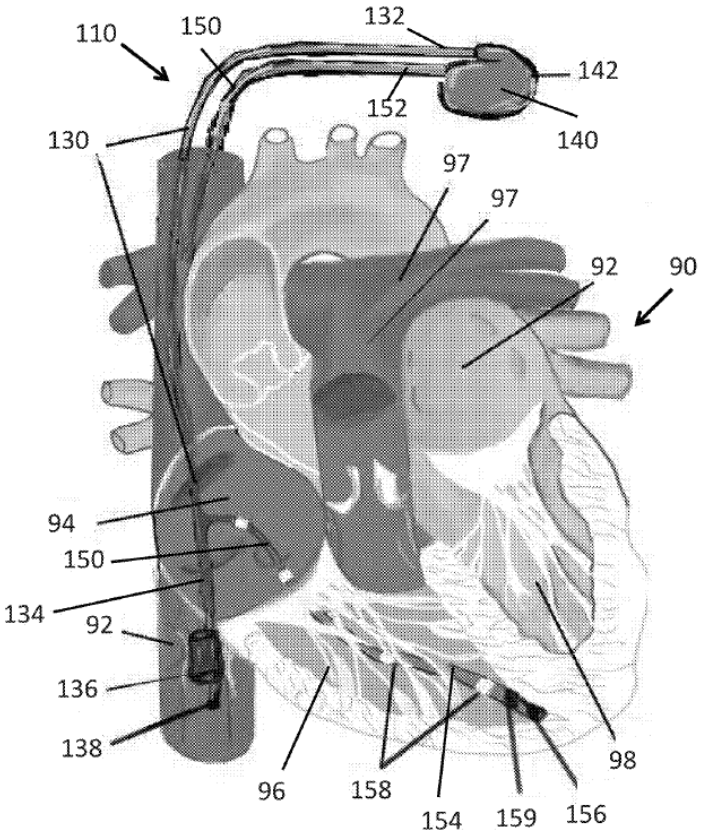


FIG. 2

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; *see also id.* at 6:31–36 (in "another embodiment, the at least one pressure sensor may be configured to be located in the . . . superior vena cava"). 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; *see also id.* at 6:49–59 ("[T]he controller may utilize changes in blood pressure to induce a mechanical change in the adjustable component. . . . [T]he pressure below or upstream of the adjustable device may maintain a pressure of about 10 mm[H]g."), 8:65–67, 11:3–5, 11:20–25, 14:17–27 ("The pressure differential imposed across the device [placed in the inferior vena cava] was approximately 3 mmHg."), Fig. 4.

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.* at 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 discloses to "reduc[e] 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. *Id.* ¶ 23, Fig. 3.

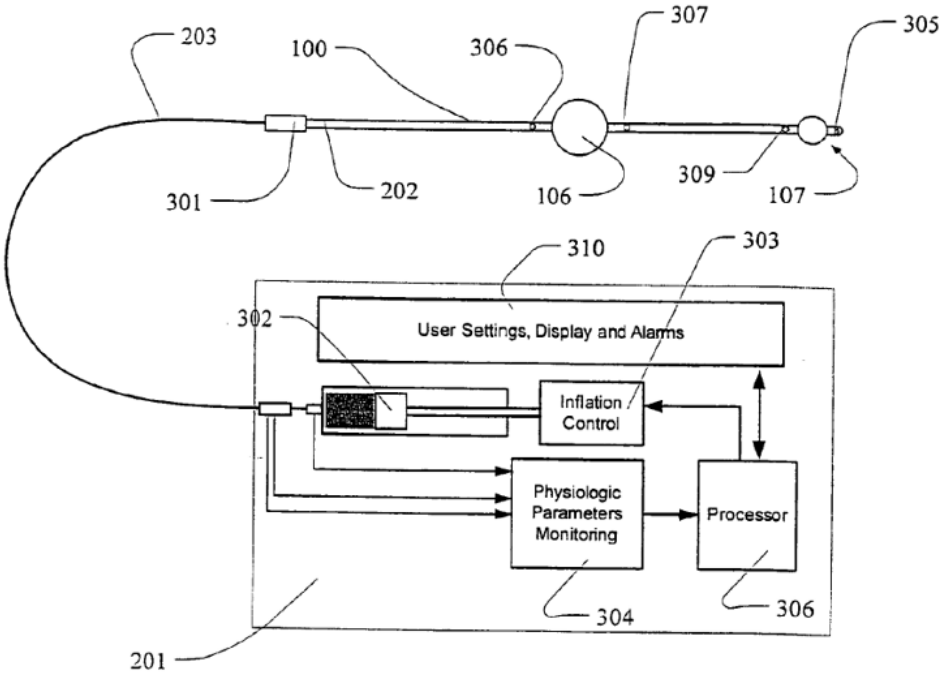


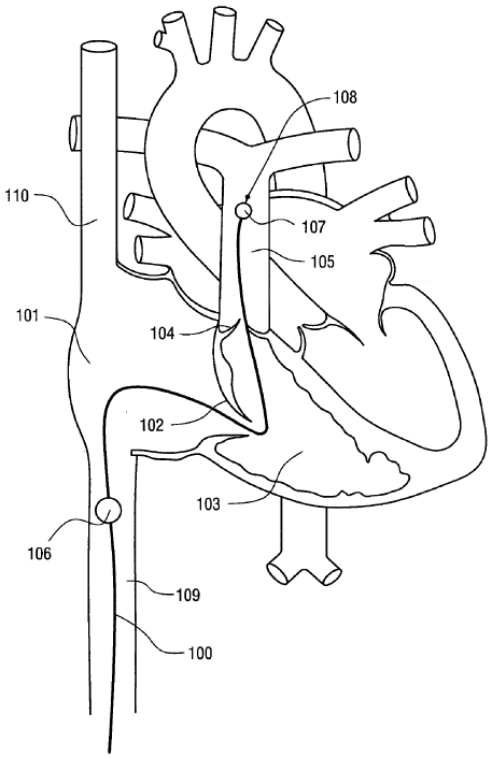
Figure 3 shows catheter 100 including oxygen sensor 305 and blood pressure sensors 306 and 309, in communication with electronic subsystem 304 of controller 201. *Id.* ¶ 51; *see generally id.* ¶¶ 23, 43–51.

[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,

> [t]he 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 to these preferred catheterization methods, 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 (footnote 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 and alteration marks 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). Prior art patents and printed publications, however, are presumed enabled. *See, e.g.*, *id.* at 1354–55 ("presumption . . . that both the claimed and unclaimed disclosures in a prior art patent are enabled"); *Impax Labs., Inc. v. Aventis Pharm., Inc.*, 545 F.3d 1312, 1316 (Fed. Cir. 2008) ("presumption that the anticipating disclosure also enables the claimed

invention"); *In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012) (presumption extends to prior art printed publications).

"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) (citations 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).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 *Jacobson Bros*.).

Petitioner proposes a two-part definition of a person of ordinary skill in the art. The first part 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. For the second part, Petitioner recasts the above team as a single person having all of the above qualifications, or "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." Pet. 25; Ex. 1002 ¶ 99; Ex. 1004 ¶ 56.

In our Institution Decision, we provisionally adopted Petitioner's two-part definition as it appeared consistent with the high level of skill in the art reflected in the prior art of record and the disclosure of the '460 Patent. Inst. Dec. 25–27.

Prior to institution, Patent Owner argued that we need not address Petitioner's proposed definition "[b]ecause no issue that must be decided by the Board depends on the level of ordinary skill." Prelim. Resp. 12. Post-institution, Patent Owner "generally agree[d] that Petitioner's proposed definitions of an 'Engineer POSA' and a 'Clinician POSA' accurately describe the level of ordinary skill in the field of methods of treating heart

failure that require use of a medical device in 2014/2015, which is the field of the '460 Patent." POR 20–21 (citing Ex. 2005 ¶¶ 58–63, 141(a)–(c)).

Patent Owner asserts, however, that it is improper to define a POSA as a multidisciplinary team, because in referring to "***a*** person having ordinary skill in the art," 35 U.S.C. § 103 and relevant case law require that we identify *a single hypothetical person* as having all the necessary skills and understanding. *Id.* at 21–22 (citations omitted).[8] Patent Owner does not, however, object to the concept of multidisciplinary teams, *per se*, in defining the person of ordinary skill in the art. To the contrary, Patent Owner argues that in *Indivior*, "the Federal Circuit approved the finding 'that **a person** of ordinary skill would be **on a team** with an engineer or scientist with experience in manufacturing films.'" Sur-reply 3–4 (citing *Indivior Inc. v. Dr. Reddy's Labs.,* S.A., 930 F.3d 1325, 1344 (Fed. Cir. 2019)).

Patent Owner's contention that the hypothetical person of ordinary skill in the art may not comprise a multidisciplinary team, but may be "a member" of that same multidisciplinary team, strikes us as a distinction without a difference. *See id.* at 4. Thus, although we disagree with Patent Owner's analysis, we rephrase part one of our provisionally adopted definition to reference "*a member* of a multidisciplinary team."

[8] Neither party persuades us that the district court cases cited as allegedly rejecting (*see* POR 21) or approving of (*see* Reply 3 n.2) interdisciplinary team-based POSA definitions are determinative here. We are aware, however, of Board decisions defining the person of ordinary skill in terms of multi-disciplinary teams. *See, e.g.*, IPR2021-009761, Paper 42 at 26–29 (PTAB Dec. 6, 2022); IPR2017-00854, Paper 109 at 10–11 (PTAB July 11, 2018); IPR2016-01182, Paper 11 at 9 (PTAB Nov. 7, 2016).

Patent Owner also argues for an alternative definition encompassing "a Clinician POSA whose experience is in interventional cardiology," "without the need for assistance from an Engineer POSA." POR 21–25; Sur-reply 1–4. In particular, Patent Owner proposes that we define one of ordinary skill in the art as:

> (1) an Engineer POSA receiving assistance from a Clinician POSA;
>
> (2) ***a Clinician POSA***
>
> (a) receiving assistance from an Engineering POSA or
>
> (b) ***whose experience is in interventional cardiology***; or
>
> (3) a single person with the qualifications of both an Engineer POSA and a Clinician POSA.

POR 25 (paragraphing and emphasis added).

In support, Patent Owner relies on the testimony of Dr. Brecker. POR 22–24 (citing Ex. 2005 ¶¶ 4–15, 64, 65, 141(b),(c)). Dr. Brecker testifies, for example, that he "developed inventions relating to new medical devices for the treatment of heart disease on which I am the only named inventor (*i.e.*, no person separately qualifying as an Engineer POSA is named as a co-inventor with me)," and he is "able to fully understand every aspect of the methods disclosed and claimed in the Challenged Patents without the assistance of an engineer." Ex. 2005 ¶ 64.[9] As noted by Patent Owner, however, Dr. Brecker "is an interventional cardiologist with over 25 years of experience, including as a clinician, researcher, teacher, and innovator," whose background and experience far exceeds that of the Clinician POSA at

[9] In this respect we note Petitioner's evidence that Dr. Brecker's claims to engineering expertise are grounded on "inventing devices . . . much simpler than the balloon catheter devices at issue." Reply 4 n.4 (citing Ex. 1032, 54:2–62:18, 59:7–24; Ex. 2015; Ex. 1030).

issue here. *See* POR 22; Ex. 2005 ¶¶ 4–15, Exhibit A (Dr. Brecker's *curriculum vitae*).

Patent Owner further points to the testimony of Dr. Day, Petitioner's engineering expert, suggesting that an Engineer POSA would defer to or "require assistance of a Clinician POSA 'to fully understand and opine on' some aspects of the technology of the '460 patent." POR 23–25 (citing Ex. 1002 ¶¶ 17, 85, 93, 95, 113, 146, 148, 152, 193, 251, 283, 286, 290–91, 297–300, 352–53; Ex. 2006, 20:9–13, 30:15–24, 45:8–46:3, 73:14–20, 75:15–25, 79:16–17, 79:22–80:12, 86:24–87:23, 95:12–22, 185:18–186:18). Patent Owner's cited testimony fails to persuade us that the Clinician POSA is one of ordinary skill in the art with respect to the full scope of the claimed invention. It does, however, amply underscore the interdisciplinary nature of the invention and related prior art.

In this respect, we agree with Petitioner that the full definition of a POSA must include input from both a Clinician POSA and an Engineer POSA as

> it is not sufficient that a clinician may *understand* the customized catheters at issue. Because clinicians like Brecker cannot develop and reduce such devices to practice (Ex. 1032, 65:23–71:18), they cannot determine the feasibility of modifications. Only an engineer is qualified to opine on engineering issues such as whether a POSA could modify Gelfand's or Kaiser's devices.

Reply 4 (footnote omitted). Supporting this view, we acknowledge Dr. Day's testimony that,

> there is the expert clinician who would employ these techniques and then the expert engineer who would design the methods or the devices. . . . [T]his is why . . . a POSA . . . would be an engineering POSA that had access and at times sought input from the clinician POSA or a clinician POSA that sought input

> from the engineering side or, in the really unique case of some person that had all of this training.

Ex. 2006, 19:22–20:15.

Considering argument and evidence of record, we define a person of ordinary skill in the art as

> a member of 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"); or
>
> an Engineer POSA receiving assistance from a Clinician POSA; or
>
> a Clinician POSA receiving assistance from an Engineering POSA; or
>
> a single person with the qualifications of both an Engineer POSA and a Clinician POSA.

With respect to the parties' proffered declarants, the record before us demonstrates that Dr. Day and Dr. Garcia are individually well-qualified to opine as to the perspective of an Engineer POSA and a Clinician POSA, respectively; and collectively qualified to opine from the perspective of one of ordinary skill in the art as to all aspects of the claimed invention and relevant prior art. *See, e.g.*, Ex. 1002 ¶¶ 3–15; Ex. 1003 (Dr. Day's *curriculum vitae*); Ex. 1004 ¶¶ 4–15; Ex. 1005 (Dr. Garcia's *curriculum vitae*). With respect to Patent Owner's declarant, Dr. Brecker's experience and credentials as an interventional cardiologist amply qualify him to speak to the perspective of one of ordinary skill in the art as a Clinician POSA. *See*

Ex. 2005 ¶¶ 4–15, Exhibit A. But because there is no evidence that he is an Engineering POSA, or receiving assistance from an Engineering POSA, we accord less weight to his opinions as they relate to the province of an Engineer POSA. *See Kyocera Senco Indus. Tools Inc. v. ITC*, 22 F.4th 1369, 1377–78 (Fed. Cir. 2022) (holding that "to be qualified to offer expert testimony on issues from the vantage point of an ordinarily skilled artisan in a patent case, an expert must at minimum possess ordinary skill in the art").

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).

In our Institution Decision, we provisionally adopted Petitioner's proposed construction of "resistors," as used in claims 5–7 and 17–19, to mean "restrictors"; "distal restrictor," as used in claims 10 and 22, to mean "the restrictor that is located furthest from the clinician"; and "catheter

extends across a vein wall," as used in claims 12 and 24, to mean, "catheter extends through a vein wall" because these definitions were "useful in understanding the claims as a whole." *See* Inst. Dec. 27, 31–32; Pet. 27–29. Patent Owner does not contest these constructions in this proceeding, and we adopt them here. *See* POR 43.

We also provisionally adopted Petitioner's proposed definition of "maintaining intravascular pressure," as used in independent claims 1 and 13, to mean "maintaining pressure within blood vessels or a blood vessel." *See* Inst. Dec. 27–32; Pet. 25–27; Prelim. Resp. 13–20. In our Institution Decision, we noted that this provisional construction encompassed: "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." Inst. Dec. 31. The parties have since provided extensive argument regarding the meaning of this term, which we summarize and address below. *See, e.g.*, POR 26–42; Reply 5–12; Sur-reply 5–9; PO Sup.; Pet. Sup.; PO Sup. Reply; Pet. Sup. Reply; Tr. 61:17–74:8, 40:20–50:16.

The words "maintain[ing] intravascular pressure" appear nowhere in the Specification of the '460 Patent, and it was not defined during prosecution of the '460 Patent or related family members. At best, a different, albeit related, term "reduce [or reduction of] intravascular blood pressure," appears in one paragraph of the Background section of the Specification ("Paragraph 6") in connection with a description of prior art treatments. Paragraph 6, quoted in part on page 1 of Patent Owner's Supplemental brief, recites:

> 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 [sic] hypotension and activates the Renin Angiotenesin Ald[o]sterone 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.

Ex. 1001, 1:59–67 ("Paragraph 6"). Petitioner correctly notes that, as used in Paragraph 6, "the term 'intravascular' *per se* refers only to the venous system because that is where blood pressure must be reduced to drain lymph." Pet. Sup. 2 (citing Ex. 1001, 1:29–35, 1:60–61; Ex. 1032, 23:5–24:13; Ex. 1033, 1, 3; Reply 7–11). We, nevertheless, agree with Patent Owner, that Paragraph 6 also relates to systemic pressure, including systemic arterial pressure. *See* PO Sup. 2 (noting that Paragraph 6's reference to "'hypotension' refers to arterial pressure"); Ex. 2005 ¶ 69.

Patent Owner contends that Paragraph 6 embodies "the problem being solved—creating a localized low-pressure zone to permit lymph to flow into the vasculature while maintaining systemic pressure to avoid problems of prior treatments," and reflects the "goal of the patented invention to overcome disadvantages with the prior art" pharmacological treatments of pulmonary edema. *See* PO Supp. 1 (citing, e.g., Ex. 1001, 1:34–67); POR 1, 28–30 (citing Ex. 2005 ¶¶ 69, 73). Further characterizing "the problem addressed by the invention [a]s how to avoid the activation of the RAA system, which problem results from reducing overall intravascular, and thus systemic arterial, blood pressure," Patent Owner proposes that we construe "maintaining intravascular pressure" as meaning "maintaining systemic

arterial pressure" or "maintaining systemic blood pressure, including arterial pressure." POR 26–27; Sur-Reply 7–8; PO Sup. 1.

In support of Patent Owner's construction, Dr. Brecker interprets Paragraph 6 as indicating that the "problem with conventional pharmacological therapies in the treatment of heart failure is that they can cause excessive fluid loss [and] dehydration," which "can lead to hypotension, which means that the systemic arterial blood pressure falls." Ex. 2005 ¶ 69. Dr. Brecker asserts that "[t]he design intent of the Challenged Patents is to provide a device-based solution that achieves the aim of treating heart failure without causing systemic hypotension—in other words, whilst maintaining systemic arterial pressure, *i.e.*, maintaining intravascular pressure." *Id.*

In this respect, Dr. Brecker asserts that the '460 Patent addresses the "need for improved methods and devices for the rapid and effective removal of excessive fluid that accumulates as a result of pulmonary edema" by "describ[ing] a method of treatment that includes a catheter with restrictions that can be used to reduce pressure in only the localized area near the lymph ducts in order to enable fluid to pass from the ducts into the veins without having the adverse effect of reducing pressure throughout the rest of the patient's circulatory system." *Id.* ¶¶ 42, 73. Dr. Brecker concludes, that "[i]n this clinical context" and "in the context of the ['460 Patent]," "maintaining pressure . . . means maintaining systemic arterial pressure during the treatment of heart failure." *Id.* ¶ 69.

Petitioner appears to interpret Patent Owner's position as implicitly assuming that each embodiment of the invention necessarily maintains systemic arterial pressure. *See* PO Sup. Reply 1; Pet. Sup. 2–3. To the extent

Petitioner's assessment is correct, such a position is undercut by Dr. Brecker's unambiguous testimony that simply lowering pressure in localized venous areas (as is taught in the Specification) is insufficient to maintain arterial pressure. *See* Pet. Sup. 2–3 (citing Ex. 2005 ¶ 82; Ex. 1032, 97:2–99:1; POR 35). According to Dr. Brecker, one of ordinary skill in the art would

> understand that just because a pressure is maintained during a procedure to treat heart failure in a localized area of a patient's circulatory system (or in the vicinity of a localized area) does not mean that the patient's systemic arterial pressure is maintained. Therefore, a POSA would understand that the limitation "maintaining intravascular pressure" refers to an additional requirement that the patient's systemic blood pressure be maintained while performing the claimed method and that it is the satisfaction of this requirement that demonstrates that the claimed invention accomplishes its stated goal.

Ex. 2005 ¶ 82.

We also note that Patent Owner's and Dr. Brecker's focus on maintaining systemic arterial pressure as the goal of the invention is not reflected in the plain text of the Specification, which appears to highlight instead the *speed* of the disclosed systems and methods in treating edema as compared to the prior art. In particular, we note that the Background section discloses that with prior art treatments, "edema is not always alleviated rapidly enough," and that "[e]ventually," a cycle of hypotension, activation of the RAA system, and increased blood pressure, "leads to diuretic resistance and the worsening of renal function in almost 30% of admitted patients." Ex. 1001, 1:49–67. Accordingly, the Specification states, "there remains a need for improved methods and devices for the rapid and effective

removal of excessive fluid that accumulates as a result of pulmonary edema." *Id.* at 2:1–3.

The '460 Patent then discloses systems and methods to reduce edema "by lowering the outflow pressure in a region around the thoracic/lymphatic duct outflow" such that "higher lymphatic return will be achieved, enabling the lymphatic vessel flow to be at or near normal levels." *Id.* at 6:50–56. According to the '460 Patent, this approach provides

> a number of advantages over existing techniques for treating pulmonary edema. In particular, a higher rate of fluid return from the thoracic and lymphatic outflow ducts enables *faster lymphatic fluid removal and resolution of the edema episode*. A risk of developing acute heart failure or compromised renal function may be avoided by *rapid lymphatic fluid removal* from the lymphatic system. As a result of this treatment method pressure in a relatively large area surrounding the thoracic and lymphatic [] outflow ducts can be reduced thereby allow[ing] the procedure to be performed without complicated navigational guidance.

Id. at 7:58–8:2 (emphases added); *see also id.* at 7:15–16 ("The components of the system can rapidly alleviate the edema and increase the patient response rate."). Accordingly, our reading of the Specification, including its goals and advantages, does not support Patent Owner's position that the Specification implicitly defines "maintaining intravascular pressure" to refer solely to systemic, and more specifically, arterial pressure.

In contrast to Patent Owner's focus on systemic (arterial) pressure, Petitioner contends that "maintaining intravascular pressure" should be more broadly construed as "maintaining pressure within blood vessels or a blood vessel" or, in the alternative, encompassing "maintaining pressure in areas of the venous system." Pet. Sup. 1 (emphasis omitted); Pet. 25 (citing Ex. 1018

(defining intravascular as, e.g., "within blood vessels or a blood vessel"));[10] Ex. 1004 ¶ 43.

Petitioner argues that "maintaining intravascular pressure" may be read to encompass three aspects: 1) maintaining systemic pressure, as argued by Patent Owner; 2) maintaining an artificially low pressure zone near the lymph ducts using a sensor-controlled suction pump (e.g., within a zone bounded by two occlusion devices), and 3) maintaining regions of reduced pressure outside of that zone but in the vicinity of the device ("*i.e.*, upstream and downstream of the zone in a two-restrictor embodiment"). *See* Pet. 25–26; Ex. 1004 ¶¶ 42–47.

With respect to aspect 1, Petitioner concedes that, in light of Paragraph 6 in the Background section of the '460 Patent, "'[m]aintaining intravascular pressure' could . . . be read to mean not reducing pressure like prior treatments, *i.e.*, maintaining systemic pressure." Pet. 25; Ex. 1004 ¶ 44 (Dr. Garcia's testimony that "this is one potential interpretation of 'maintain intravascular pressure'"). Petitioner argues, however, that "[a] patent claim should be construed to encompass at least one disclosed embodiment," and that Patent Owner's construction limited to this aspect does not meet that

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[10] We find unpersuasive Patent Owner's argument that Petitioner's construction improperly relies on a dictionary definition. *See, e.g.*, POR 28, 34 (citing *Phillips*, 415 F.3d at 1321). *Phillips* makes clear that it is permissible to "rely on dictionary definitions when construing claim terms" as long as they "are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence." *Id.* at 1324 (citation omitted). Patent Owner neither disputes any of the dictionary definitions collected in Exhibit 1018 nor persuades us that they "contradict any definition found in or ascertained by a reading of the ['460] patent." *Id.* at 1322–1323 (citing *Vitronics Corp. v. Conceptronic, Inc.,* 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996)).

standard. Pet. Sup. 2. (citing *Johns Hopkins Univ. v. CellPro, Inc*., 152 F.3d 1342, 1355 (Fed. Cir. 1998) ("[a] claim construction that does not encompass a disclosed embodiment is thus 'rarely, if ever, correct'")). In support, Petitioner argues that Patent Owner "can point to no teaching that any embodiment maintains systemic pressure, and the specification nowhere describes how systemic arterial pressure is maintained by the described methods." *Id.* at 2; *see also* Tr. 43:12–44:5 (Petitioner's argument that "if maintaining intravascular pressure were construed to mean maintaining systemic arterial pressure or any other systemic pressure, the specification would lack any written description or enablement support for this limitation; it's simply not described.").

Petitioner's argument is well taken. At best, the Specification makes a general reference to the placement of an arterial blood pressure sensor in a "position[] that may be prone to the accumulation of interstitial fluid." Ex. 1001, 13:18–22 ("For example, blood pressure sensors can be placed in the venous system, in the heart, in the arterial system, at the junction of the subclavian and jugular veins, and in the body at other target sites."). We agree with Petitioner that this generalized disclosure is insufficient to describe maintaining systemic (arterial) pressure, and, thus, does not support Patent Owner's proposed construction.

Patent Owner's belated reference (at oral argument) to the text, "[t]he purpose of the restrictors is to allow the normal flow of blood to continue," in column 10 of the '460 Patent is likewise unavailing for essentially the reasons set forth at page 3 of Petitioner's Supplemental Brief, which we adopt. *See* Ex. 1001, 10:22–23; Tr. 66:13–21, 95:9–96:5; PO Sup. 3; Pet. Sup. 3. A more complete version of the referenced passage states 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. The proximal restriction 22 should be configured so as to partially restrict flow when it is activated, but to allow some fluid to flow past the restriction. The distal restriction 24, on the other hand, can be configured to fully restrict fluid flow when it is activated. The purpose of the restrictors is to allow the normal flow of blood to continue. However, the activation of the restrictions creates a localized pressure differential between the region proximal to the proximal restriction and the region between the two restrictions.

Ex. 1001, 10:15–27. Taken in context, "[t]he purpose of the restrictors is to allow the normal flow of blood to continue," refers to intended ability of the restrictors to permit fluid flow when not activated. As such, the cited passage does not support Patent Owner's construction. Rather, and notwithstanding Patent Owner's interpretation of Background Paragraph 6, we agree with Petitioner that the '460 Patent's Specification "nowhere states that the claimed methods maintain systemic pressures, teaches a POSA how to maintain systemic pressures, or has any data showing that such pressures are maintained." *See* Pet. Sup. Reply 1.

In light of the above, we find that a construction of "maintaining intravascular pressure" *solely* limited to maintaining systemic pressure is not correct. Indeed, no example discusses maintaining any systemic pressure, let alone a systemic *arterial* pressure and Patent Owner does not persuade us that such limitations are implicit from the discussion of prior art in Paragraph 6. Rather, and in view of the support in the Specification for aspects 2 and 3 of Petitioner's proposed construction, discussed below, we agree with Petitioner that "[t]he specification describes maintaining blood pressure only in the venous system." Pet. Sup. 1.

With respect to aspect 2, maintaining regions of reduced pressure in an isolated area, the Specification describes a region of the venous system 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.

With respect to aspect 3, the Specification discloses maintaining venous pressure in the vicinity of a low-pressure zone. Ex. 1001, 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:

> 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) (alteration in original); *see also* Ex. 1001, 17:52–63 ("creat[ing] a low pressure zone in the vicinity of the junction of the jugular vein and the subclavian vein").

Relevant to both aspects 2 and 3, the Specification provides extensive disclosure of feedback loops to create and maintain regions of defined blood pressure in elements of the venous system based on pressure readings in and outside a defined low-pressure zone. *See* Ex. 1001, 15:33–17:33, Figs. 11A, 11B. The Specification teaches, for example, that "control module 200 can include multiple feedback loops to adjust performance of the system 10 to create and maintain a low pressure zone while the lymphatic fluid is

cleared." *Id.* at 15:33–36; Ex. 1004 ¶ 45. In an embodiment particularly relevant to aspect 3, the feedback loops maintain the jugular and innominate vein pressure above a baseline pressure minus a minimum significant pressure deviation or "safety delta." *See, e.g.*, Ex. 1001, 15:58–16:3.

Citing *Hockerson–Halberstadt*, Patent Owner asserts that a correct construction depends on an "interpretation of the entire claim in context, not a single element in isolation." PO Sup. 3 (emphasis omitted) (citing *Hockerson–Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999)). In particular, Patent Owner argues that "Petitioner's construction of 'intravascular' to mean the localized low-pressure zone is non-sensical and erroneously excludes preferred embodiments because activating restrictors to occlude flow **causes local pressure to drop and creates the low-pressure zone**; it does not maintain it." *Id.* (citing *EKO BRANDS v. Adrian Rivera Maynez Enters.*, 946 F. 3d 1367, 1373 (Fed. Cir. 2020)). But we do not read the '460 Patent to require the maintenance of normal intravascular pressure at or near the region of intervention. To the contrary, the Specification repeatedly discloses the creation and maintenance of low-pressure zones at or near the catheter apparatus restrictors during the course of treatment. *See, e.g.*, Ex. 1001, 15:33–36 ("control module 200 can include multiple feedback loops to adjust performance of the system 10 *to create and maintain a low pressure zone* while the lymphatic fluid is cleared") (emphasis added)), 13:2–8 ("A pressure sensing lumen, which is positioned proximately to the catheter suction port within the isolated area, can be used to control the rate of suction *by maintaining the pressure of the isolated area between about 2–5 mmHg* and thus prevent collapse of the thoracic duct due to excessive suction and ensure optimized lymph

drainage." (emphasis added)), 17:52–63 ("[T]he pressure gradient across the proximal restriction is achieved by the *pressure reduction within the area between the two restrictions*. Actuation of the pump helps to *create a low pressure zone in the vicinity of the junction of the jugular vein and the subclavian vein* by withdrawing fluid in this region, recirculating it through the pump, and discharging the fluid downstream of this region. Because the outflow of the thoracic and lymphatic ducts is located in this region, *the lower pressure will facilitate drainage of lymphatic fluid*.") (emphases added).

Accordingly, we agree with Petitioner that the '460 Patent "teaches activating and adjusting restrictors based on pressure readings to achieve and then maintain target venous blood pressures." Pet. Sup. Reply 2 (citing Ex. 1001, 15:33–36, 15:36–16:42, Fig. 11A). Implicit in the above analysis, and as expressly discussed at pages 11–12 of the Reply, which we adopt, we understand "maintaining" to refer to keeping intravascular pressure at a target level or range, which may be lower than a normal body pressure. *Cf*. POR 31–32 (Patent Owner's argument that "maintaining" is limited to non-hypotensive (i.e., substantially normal) systemic pressure).

In view of the above, we adopt and apply Petitioner's proposed construction of "maintaining intravascular pressure," to mean "maintaining pressure within blood vessels or a blood vessel." Our construction is not limited to maintaining a physiologically normal systemic pressure, and encompasses maintaining regions of low pressure in portions of the venous system between occlusion devices, or in the vicinity of one or more occlusion devices. We need not further define the meets and bounds of this

term to resolve any dispute between the parties or decide the merits of Petitioner's challenge.

D. Ground 1: Anticipation by Kaiser

As Ground 1, Petitioner challenges claims 1–10, 12–22, and 24 as anticipated by Kaiser. Pet. 29–55. Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* at 35–55. We have reviewed Petitioner's contentions and supporting evidence for those limitations not challenged by Patent Owner, and find Petitioner has demonstrated by a preponderance of evidence that Kaiser discloses these limitations. We address below Patent Owner's arguments for why Kaiser fails to disclose other elements of the challenged claims. Considering the record as a whole, we find that Petitioner has adequately shown that claims 1–10, 12–22, 24 are unpatentable as anticipated by Kaiser.

1. Positioning Catheter Elements in the Superior Vena Cava

Patent Owner argues that Kaiser fails to disclose elements of challenged claims 1 and 13 relating to the position of catheter elements in the SVC, specifically, "advancing a catheter apparatus comprising [. . .] one or more restrictors into the superior vena cava" (elements [1c]/[13c]); that the "operat[ion] [of] the catheter apparatus to regulate venous blood return through the superior vena cava . . . comprises activating the one or more restrictors within the superior vena cava" (elements [1e]/[13f]); "wherein the one or more restrictors are adjusted [within the superior vena cava] based on feedback from the one or more pressure sensors" (element [1g]); and "a control module that . . . controls the one or more restrictors [within the superior vena cava] based on the feedback from the one or more sensors"

element [13d–e]) (collectively, "the SVC positioning elements"). *See* POR 8–10, 44.

Relying on the testimony of Dr. Day, Petitioner addresses where elements [1c], [1e], 1[g], [13c], [13d–e], and [13g] are disclosed in Kaiser on pages 38–39 and 41–44 of the Petition. *See* Ex. 1002 ¶¶ 151–153, 156–163, 165, 167–176. Kaiser discloses for use in its method (1) a lead/catheter, which corresponds to the claimed 'catheter apparatus' with (2) an Adjustable Component, which corresponds to the claimed 'restrictor.'" *See id.* ¶¶ 107, 113–114, 148–150. According to Dr. Day, "Kaiser discloses that an 'adjustable component may be configured to be placed percutaneously and selectively expanded in the *vena cava*.'" *Id.* ¶ 152 (citing Ex. 1007, 5:64–6:1, 6:37–39);[11] *see also id.* ¶ 157 (citing Ex. 1007, 6:37–43, 10:9–15) (discussing Kaiser's teaching to activate the adjustable component (e.g., an inflatable balloon) to "occlude flow into or through a body lumen within or adjacent the heart").

According to Dr. Day, "in order to place and selectively expand the Adjustable Component in the vena cava, as taught by Kaiser, the lead/catheter must be advanced into the vena cava. The vena cava can be the SVC because . . . Kaiser discloses placing and activating the Adjustable Component in the SVC." *Id.* ¶ 153. In this respect, Dr. Day notes that "Kaiser repeatedly teaches that its method of occluding blood flow using the Adjustable Component can be used in the SVC." *Id.* ¶ 158 (citing Ex. 1007, 5:64–6:1, 6:60–64, Claims 10, 17). Dr. Day explains that "[b]ecause Kaiser discloses using the Adjustable Component to occlude blood flow through the

[11] For the sake of clarity, we omit Petitioner's and Dr. Day's parallel citations to Kaiser's priority application (Exhibit 1010).

SVC, it discloses regulating venous blood return through the SVC. All of the venous blood from the upper body (for example, the head and arms) returns to the heart through the SVC." *Id.* ¶ 159. With respect to element [1g], Dr. Day testifies that "Kaiser discloses that the Adjustable Component may be adjusted in size or configuration based pressure sensitive feedback." *Id.* ¶ 162 (citing Ex. 1007, 11:20–25, 11:31–33, Claims 10, 17).

Although Kaiser exemplifies in detail a method involving IVC occlusion, its disclosure makes clear that the method is also applicable to the SVC. *See, e.g.*, Ex. 1007, 6:60–64 ("the adjustable component may create a pressure gradient by . . . adjusting blood flow impedance through the superior vena cava"), 5:64–6:2 (disclosing "systems and methods may be provided to create a pressure differential" using "balloons . . . to increase a pressure drop through the . . . superior vena cava"), 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 . . . a superior vena cava."), 6:31–36 (positioning pressure sensor in the superior vena cava); *see also* Ex. 1010, 19–22 (claims of provisional application directed to reducing blood flow through the superior vena cava); *see also* Pet. 29–34, 36–39; Reply 14–16; Ex. 1002 ¶¶ 152–153, 156–159, 165, 167–176 (Dr. Day's testimony regarding the SVC positioning elements). Considering the arguments and evidence of record, including our own reading of Kaiser (*see supra* Section I.I.1), we find that Kaiser expressly discloses the contested element of Ground 1 relating to use of the restrictor in the SVC.

Patent Owner argues however, that "even if the Board does find that Kaiser discloses the use of a catheter balloon in the SVC . . . the disclosure

of Kaiser is insufficient to enable such use by a POSA." POR 46 (citing Ex. 2005 ¶¶ 110–116). According to Patent Owner, "Kaiser teaches numerous times that it works in the IVC because it is able to make use [of] the high capacitance of the venous system upstream of the IVC" but "does not provide any details showing how it could be used in the SVC, including anything from which a POSA could determine that Kaiser could be used successfully and safely in the SVC." *Id.* at 46–48 (citing Ex. 1007, 2:63–3:4, 12:52–64, 14:7–16; Ex. 2005 ¶¶ 109–114).

Patent Owner further argues that because "the vessels upstream of the SVC have significantly lower capacitance than the vessels upstream of the IVC," "the teachings of Kaiser regarding being able to make use of the high capacitance upstream of the IVC cannot be understood to also apply to or enable the use of Kaiser in the SVC" and, in fact, "could be potentially dangerous to the patient." *Id.* at 48–50 (citing Ex. 2005 ¶¶ 113–114); *see id.* at 13–16 (discussing differences between SVC and IVC and potential consequences of obstructing the SVC including SVC Syndrome and TCVO). As summarized by Dr. Brecker, because "Kaiser does not acknowledge that there is a significant and important difference between the SVC and the IVC in terms of the capacitance of the vessels upstream from them . . . . SVC occlusion would be very unlikely to enable the method of Kaiser to be used in that way." Ex. 2005 ¶ 111. Dismissing the opinions of Drs. Day and Garcia regarding the use of Kaiser's method in the SVC, Patent Owner concludes that "a Clinician POSA [would] require additional disclosure regarding how Kaiser could be used safely and successfully in the SVC." POR 50–51 (citing, e.g., Ex. 2005 ¶¶ 112–114). We do not find Patent Owner's argument persuasive.

It is Patent Owner's burden in this proceeding to overcome the presumption that Kaiser is enabled. *See, e.g.*, *Amgen*, 314 F.3d at 1354–55. This requirement is not excused in IPR proceedings. *See Apple Inc. v. Corephotonics, Ltd.*, 861 F. App'x 443, 450 (Fed. Cir. 2021) ("[R]egardless of the forum, prior art patents and publications enjoy a presumption of enablement, and the patentee/applicant has the burden to prove nonenablement for such prior art."). Considering all the argument and evidence of record, we find that Patent Owner has not overcome the presumption with respect to Kaiser for the reasons set forth on pages 13–21 of Petitioner's Reply, which we adopt in full and briefly address below.

With respect to enablement of Kaiser's device, we find persuasive Dr. Day's testimony that no substantial modification of Kaiser's IVC embodiment would be necessary to deploy it in the SVC. *See* Ex. 2006, 218:6–220:13; Ex. 1002 ¶ 112 (annotated version of Kaiser's Fig. 2 showing that the lead/catheter passes through the SVC to reach the IVC). With respect to enablement of Kaiser's method in the SVC, Dr. Brecker's analysis falls short of overcoming the presumption that Kaiser is enabling.

Dr. Brecker asserts, for example, that

> Kaiser also does not describe what pressure differential would need to be created through the use of a flow impedance device in the SVC in order to successfully perform its method using such a device in the SVC, and does not provide any exemplary pressure recordings demonstrating that its method can be successfully performed using a device in the SVC.

Ex. 2005 ¶ 110. We find persuasive, however, Petitioner's argument that Kaiser discloses representative pressure differentials, including an effective pressure differential for occluding the IVC (3 mmHg), which Dr. Brecker could not say would be ineffective for the SVC— but which a Clinician

POSA could test, along with other pressure differentials to see what results they produced if the SVC were occluded. Reply 17–18 (citing Ex. 1007, 14:22, Fig. 4 (table showing exemplary hemodynamic data obtained by creating a pressure differential in the inferior vena cava); Ex. 1032, 190:23–192:3 (Dr. Brecker's testimony that a Clinician POSA would know how to measure the pressures such as those disclosed in Figure 4), 193:14–194:17 (at least some information could be derived from animal testing)). At least because Patent Owner has not argued (let alone demonstrated) that such testing would be undue, Patent Owner has not satisfied its burden to show non-enablement.

2. "Maintaining Intravascular Pressure"

Patent Owner argues that Kaiser fails to disclose operation of the catheter apparatus, "wherein the method is performed while maintaining intravascular pressure," as recited in elements [1f] and [13g] of the independent claims. POR 52–56. Patent Owner's arguments, however, are predicated on a proposed construction of "maintaining intravascular pressure" as limited to maintaining systemic arterial pressure and, moreover, doing so at a level sufficient to avoid systemic hypotension. *See id.*

In responding to Petitioner's argument that "Kaiser teaches a 'minimal (if any) increase' in pressure in the localized area where its device causes excess fluid to be sequestered," Patent Owner argues that Kaiser's method "would inevitably be associated with a reduction in systemic arterial pressure." POR 53–54 (emphasis omitted) (citing Ex. 2005 ¶¶ 132–133; Ex. 1007, Abstr., 3:2–4). As discussed in Section II.C, above, however, "maintaining intravascular pressure" is not limited to maintaining systemic

arterial pressure. With respect to maintaining systemic *venous* pressure, however, we find persuasive Dr. Garcia's testimony that

> Kaiser's method uses occlusion by the Adjustable Component to create "mechanical diuresis," which entails "mov[ing] 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, 2:59–67). Kaiser explains its method either does not increase or only minimally increases blood pressure upstream of the Adjustable Component: "[g]iven 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 below our device*." (2:67–3:4.)

Ex. 1004 ¶ 76 (alterations in original) (footnote omitted). And, because "Kaiser repeatedly teaches that its method can involve occlusion not only of the IVC but also of the SVC[, o]ccluding the SVC would also have the same minimal or non-existent effect on upstream blood pressure." *Id.* ¶ 77. Dr. Garcia further testifies that,

> [a]lthough pressure downstream of the Adjustable Component would decrease, and there would be an increase in pressure immediately upstream of the Adjustable Component, the blood pressure throughout the upper part of the body, *i.e.*, in the veins that eventually drain into the SVC, would remain generally steady because of the capacitance of those veins, which carry approximately one-third of the venous blood in the body. In this way, Kaiser's method maintains intravascular pressure in those veins.

Id.; *see also* Pet. 40–41 (similar).

With respect to "maintaining intravascular pressure" as encompassing "maintaining a low-pressure zone" and/or "maintaining pressure in the vicinity of the low-pressure zone," we further find persuasive Dr. Garcia's testimony that Kaiser discloses this limitation. *See supra* Section II.C;

Ex. 1004 ¶ 78; Pet. 40–41. In particular, "Kaiser discloses maintaining blood pressure . . . by using pressure data obtained from its sensors to maintain blood pressure at a target level." Ex. 1004 ¶ 88 (citing Ex. 1007, 11:27–33, Claim 10).

In accord with the above, we agree with Petitioner that Kaiser discloses that the methods of the independent claims are performed "while maintaining intravascular pressure," as required by elements [1f] and [13g].

For the reasons set forth above, and considering the record as a whole, Petitioner has sufficiently shown that Kaiser anticipates claims 1–10, 12–22, and 24 of the '460 Patent.

E. Grounds 2–6: Obviousness in View of Kaiser, Gelfand, and Bannon

As Grounds 2 and 7, Petitioner challenges claims 1–24 as obvious in view of Kaiser and Gelfand. Pet. 55–90, 99. As Grounds 3 and 6, Petitioner challenges claims 1–24 as obvious in view of Kaiser and Bannon. *Id.* at 91–95. As Grounds 4 and 8, Petitioner challenges claims 1–24 as obvious in view of Kaiser, Gelfand, and Bannon. *Id.* at 95–96, 99–100. As Ground 5, Petitioner challenges claims 11 and 23 as obvious in view of Kaiser alone. *Id.* at 96–98. Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. Considering the argument and evidence of record as a whole, we find that Petitioner has adequately shown that claims 1–20 are unpatentable as obvious under Grounds 2–8.

According to Petitioner, Kaiser and Gelfand teach similar methods and devices:

> Kaiser and Gelfand teach methods of treating heart disease by using a device to occlude the SVC, and each teaches that doing so can counteract negative heart remodeling. Kaiser's method treats heart failure using a device whose components and

> features are analogous to those of Gelfand's device. Each device has a catheter with an adjustable blood-flow-occluding component such as a balloon. Each device is introduced percutaneously and advanced into the SVC. Each device occludes the SVC to control the amount of blood returning to the heart and creates a pressure differential across the balloon. In each device, a computerized controller adjusts the size of the balloon, and with it the degree of blood occlusion, based on feedback from catheter sensors.

Pet. 60–61. Petitioner admits however, that there are "differences [] in some of their intended effects—in Kaiser, optimized intracardiac pressures and 'mechanical diuresis'; in Gelfand, reducing heart wall stress." *Id.* at 61. Petitioner asserts, however, that "these effects are all obtained through the common mechanism of sensor-controlled SVC occlusion." *Id.*

Relying on the testimony of Drs. Day and Garcia, Petitioner asserts that one of ordinary skill in the art would have been motivated to use Gelfand's device to practice Kaiser's method "because it uses conventional and off-the-shelf components familiar to clinicians—Swan-Ganz 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 the device potentially easier to implement and use." Pet. 61 (citing Ex. 1002, ¶ 236; Ex. 1004, ¶¶ 92–93, 120, 122). According to Petitioner, one of ordinary skill in the art 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 according to Kaiser's algorithms." *Id.* at 61–62; *see* Ex. 1002 ¶ 227–237; Ex. 1004 ¶ 119–122.

Other than as argued under Grounds 1 and 2, Patent Owner does not argue the merits of Grounds 3–8, asserting instead that "Grounds 3–8 fail for the same reasons as Grounds 1–2"). POR 72 (capitalization normalized); *see also id.* (predicating the outcome of Grounds 3 and 4 on Petitioner's arguments with respect to Grounds 1 and 2, and the outcome of Grounds 5–8 on the arguments advanced "for the underlying independent claim"). Patent Owner asserts, for example, that Grounds 3, 5, and 7 fail "because Kaiser does not anticipate claims 1 and 13." *Id.* But as discussed in Section II.D, above, we find that Kaiser *does* anticipate the independent claims under Ground 1, which would seem to render at least Grounds 3, 5, and 7 moot.

Moreover, because we determined that Kaiser alone discloses each limitation of claims 1 and 13, and considering the absence of argument or evidence for secondary considerations of nonobviousness, we also find that claims 1–24 are rendered obvious by Kaiser alone (Ground 5, claims 11 and 23), Kaiser and Gelfand (Grounds 2 and 7, claims 1–24), Kaiser and Bannon (Grounds 3 and 6, claims 1–24) or Kaiser, Gelfand, and Bannon (Grounds 4 and 8, claims 1–24). *See Realtime Data, LLC. v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019) (affirming the Board's determination of obviousness because a single reference disclosed every element of the challenged claims). For completeness, however, we address below Patent Owner's arguments with respect to the merits of Ground 2 as applied to all obviousness grounds.

1. Positioning Catheter Elements in the Superior Vena Cava

Patent Owner first argues that one of ordinary skill in the art would understand that "to accomplish the intended purpose of . . . [Kaiser], one **must** use a device in the IVC," whereas Kaiser fails to enable one of

ordinary skill in the art to "position, activate, or adjust a restrictor within the SVC" as required by elements [1d] through [1f] of independent claim 1. POR 57; Sur-reply 16. As set forth in Section II.D.1, above, however, Petitioner has shown sufficiently that Kaiser satisfies these elements.

Patent Owner further argues that "Gelfand does not enable a POSA to use its method to position, activate, and adjust a restrictor within the SVC." POR 57 (citing Ex. 2005 ¶¶ 90–105). Although the Petition points to both Kaiser and Gelfand as disclosing the SVC positioning elements, we understand Petitioner's primary argument to be that one of ordinary skill in the art would employ *Gelfand's device* in Kaiser's method. *See* e.g., Pet. 55, 61–62, 67–68, 70–74, 80–81, 83–85, 89, 95, 99; Ex. 1002 ¶ 236–237, 266. As such, Ground 2 merely requires that Gelfand's device can be modified for use in the SVC, as per Kaiser's method. *See* Reply 22–23 (Petitioner's argument and evidence that Gelfand's device, or a routine modification thereof, could be used in the SVC). We find unavailing Patent Owner's assertions that Gelfand, standing alone, fails to enable the use of its device in the SVC, or its argument that "[a] POSA would not combine Kaiser with Gelfand . . . because doing so would negate reasonable expectation of success in the induction of mechanical diuresis," taught by Kaiser. *See* Sur-reply 17–19 (emphasis omitted).

In addition, as previously discussed with respect to Ground 1, it is Patent Owner's burden to overcome the presumption that an asserted reference is enabled. *See supra* Section II.D.1. Considering all the argument and evidence of record, we find that Patent Owner has not overcome the presumption with respect to Gelfand for at least the reasons set forth on

pages 21–29 of Petitioner's Reply, which we adopt in full.[12] Thus, assuming Kaiser alone does not enable placing a flow-restricting device in the SVC (contrary to our findings above), we find Gelfand enables doing so.

We first note our disagreement with Patent Owner's and Dr. Brecker's reading of a sentence taken from Gelfand's paragraph 29. *See* POR 58, 60–61; Ex. 2005 ¶¶ 95–97. Reproduced in full, with the relied-upon sentence highlighted, Gelfand states:

> FIG. 1 shows the method of obstructing the filling of the heart that the inventors perceived as the most efficient, safe and practical at the time of the invention. **An expert in cardiac catheterization can invasion [sic, envision] other ways of limiting blood flow to the heart.** Specifically 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 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.

Ex. 1006 ¶ 29 (emphasis added). Patent Owner reads the highlighted sentence as Gelfand's teaching that deployment of Gelfand's catheter to any location other than the IVC "would require 'modifications' that would need to be 'envisioned' by 'an expert in cardiac catheterization.'" POR 58 (alteration marks omitted). Considered in context, however, Gelfand states that "[a]n expert in cardiac catheterization can [envision] other ways of

[12] Although, for completeness, we address Patent Owner's arguments that Gelfand is not enabled, this property is not required with respect to the Kaiser/Gelfand Grounds because Petitioner has shown that Kaiser is enabled. *See Raytheon*, 993 F.3d at 1380 ("a reference that does not provide an enabling disclosure for a particular claim limitation may . . . be combined with[] another reference in which that limitation is enabled").

limiting blood flow to the heart," and then describes five specific modifications to Gelfand's method that "[a]n expert" (as represented by the Gelfand authors) would envision, including placing Gelfand's device in the SVC. Ex. 1006 ¶ 29; *see also* Tr. 91:4–23 ("Gelfand then proceeds to tell you exactly what that expert would envision, using the device in the SVC"). Having identified these modifications, Gelfand discloses that they would have a "similar effect of reducing the filling of the heart" without "substantially chang[ing] the invented method, system or device." Ex. 1006 ¶ 29. Gelfand's express teaching that its method can be modified for use in the SVC without "substantially chang[ing] the . . . system or device," undercuts Patent Owner's assertion that one of ordinary skill in the art could not "come up with the necessary modifications to use Gelfand in the SVC." POR 59.

Consistent with our reading of Gelfand's paragraph 29, we find persuasive Dr. Day's testimony that, "there is no functional difference between the SVC and the IVC that would preclude a catheter from functioning once in the SVC." Ex. 2006, 73:21–74:5; *see also* Ex. 1002 ¶ 265 (the "methods of balloon activation and operation are the same regardless of whether the occlusion balloon is placed in the SVC or the IVC"). We likewise find persuasive Dr. Day's testimony that, "Gelfand's methods, systems and devices . . . 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; *see also id.* ¶¶ 265–266 (similar testimony specific to element [1e]); Ex. 2006, 93:11–99:16, 71:7–78:15, 86:13–87:19, 88:14–90:9, 97:10–13.

And to the extent Gelfand's device needed to be modified for use in Kaiser's method, we find persuasive Dr. Day's testimony that, "balloon activation and operation are the same regardless of whether the occlusion balloon is placed in the SVC or the IVC," and that an Engineer POSA would have found any such modifications "routine." Ex. 1002 ¶ 265; Ex. 2006, 205:8–212:21 ("they're just different variants or dimensions of the invention"); *see also id.* at 178:18–181:7 (Dr. Day's testimony that the use of Gelfand's device in Kaiser's method may involve non-substantive "variations of the design" such as "moving the position of a sensor, or size of a balloon" but that "the heart of the Kaiser method, mechanical diuresis, could absolutely be performed with the Gelfand device, no modifications.").

We, likewise, find persuasive Dr. Garcia's testimony 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 ¶¶ 27–32 (Dr. Day's overview of therapeutic balloon catheters)). Dr. Garcia further states that

> [f]rom 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. ¶ 110; *see also id.* ¶¶ 108–111 (detailed explanation of why one of ordinary skill in the art would know how "to place the occlusion balloon in the SVC as taught by Gelfand"), 124.

As further noted by Petitioner, "[Dr.] Garcia explained that Gelfand discloses, and a POSA would know, that a modified Swan-Ganz catheter like Gelfand's could be inserted via the right internal jugular vein so as to place the occlusion balloon in the SVC." Reply 23 (citing Ex. 1004 ¶¶ 100–112, 136, 141-153 (showing modified version of Gelfand's Figure 1); Ex. 2006, 101:8–103:10); *see also id.* at 24–25 (citing Ex. 1032, 51:19–53:23, 204:4–205:22, 206:10–208:24) (Dr. Brecker's admissions that diameters of Gelfand's catheter would allow SVC placement via jugular vein and that placement of Swan-Ganz catheters through the SVC via the right internal jugular vein was known).

We also agree with Petitioner that Patent Owner has failed to show that Gelfand does not enable positioning or inflating a catheter balloon in the SVC as required to practice the claimed method. Reply 23–28 (citations omitted). In this respect, we agree with Petitioner that allegedly "'missing' details are either not actually missing or are well known to POSAs," and that the level of detail supplied by Gelfand is on par with the level of detail provided by the '460 Patent. *Id.* at 21–22, 25 (citing, e.g., Ex. 1032, 75:18–78:11, 224:21–225:4; Ex. 1001, 22:12–14).

We also agree with Petitioner that Patent Owner has failed to establish that Gelfand lacks enablement of the overall method when the catheter is placed in the SVC. *See* Reply 28–29. In this respect, we note Dr. Brecker's agreement that "partially occluding the SVC could produce the 10 percent reduction in the amount of venous blood returned to the heart mentioned by Gelfand" (Ex. 1032, 140:22–141:15; *see* Ex. 1006 ¶ 17); Dr. Garcia's testimony regarding how a Clinician POSA would implement Gelfand's method in the SVC (Ex. 2007, 110:13–114:4, 120:8–124:16); and Dr. Day's

testimony that an Engineer POSA could implement the desired flow reduction (Ex. 1002 ¶ 265; Ex. 2006, 73:21–74:6, 77:21–79:15, 94:24–95:6 (Dr. Day's testimony that from an engineering perspective "[i]f you can get the occlusion balloon into the SVC, it will absolutely work in the SVC"), 185:18–186:18).

And as to Patent Owner's argument that Gelfand's method is not enabled to be used "successfully and safely in the SVC," (*see, e.g.*, POR 58–59), we agree with Petitioner that these are aspects of utility, that do not undermine Petitioner's showing that the art discloses the method as claimed. Reply 13–14, 18–19 (citing authority for the proposition that "a prior art reference need not demonstrate utility in order to serve as an anticipating reference under section 102"); *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1326 (Fed. Cir. 2005).

We further agree with Petitioner that Patent Owner has not met its burden of proving that Gelfand fails to enable one of ordinary skill in the art to practice its methods safely and effectively, particularly in view of Dr. Brecker's assertions of problems that *might*, but would not necessarily arise. *See* Reply 17–18 (citing, *e.g.*, Ex. 1032, 141:16–143:22, 172:17–173:18, 187:17–188:7); Ex. 2005 ¶¶ 99 (Dr. Brecker discussing experience a Clinician POSA would "not necessarily have"), 102 (Dr. Brecker's testimony that "a procedure for occluding blood flow *may* have different consequences when performed in the SVC as compared to the IVC") (emphasis added).

Relying on the testimony of Dr. Brecker, Patent Owner also argues that "obstructing the IVC is much less risky" to the patient than obstructing the SVC, which can result in "'SVC syndrome' . . . a type of thoracic central

venous obstruction ('TVCO' [sic, TCVO])." POR 15–16 (citing Ex. 2005 ¶ 114; Ex. 2012; [13] Ex. 2013,[14] 6–8; Ex. 2014[15]). But even if Patent Owner and Dr. Brecker are correct, knowledge of the relative risk does not overcome the express teachings of Gelfand and Kaiser to occlude the SVC.[16, 17]

Moreover, on page 23 of its Reply, Petitioner casts substantial doubt on the factual underpinnings of Dr. Brecker's opinion. Reply 19–20 (citing Ex. 2005 ¶ 114; Ex. 2012; Ex. 2013; Ex. 2014, 2, 5; Ex. 1032, 148:3–150:5, 152:4–156:9, 157:17–23, 162:8–164:20). For example, on cross-examination, Dr. Brecker admitted that the source for his opinion that IVC Syndrome is less common "provides no data concerning the actual incidence of IVC syndrome vis-à-vis SVC syndrome," but rather, "says that IVC

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[13] Younes *et al.*, *Clinical features, diagnosis, and classification of thoracic central venous obstruction*, UpToDate (May 6, 2022), *available at* https://www.uptodate.com/contents/clinical-features-diagnosis-and-classification-of-thoracic-centralvenous-obstruction.
[14] Mousa *et al.*, *Overview of thoracic central venous obstruction*, UpToDate (Feb. 23, 2022), *available at* https://www.uptodate.com/contents/overview-of-thoracic-centralvenous-obstruction.
[15] Lawrensia *et al.*, *Inferior Vena Cava Syndrome*, StatPearls (May 3, 2022), *available at* https://www.ncbi.nlm.nih.gov/books/NBK560885.
[16] Although not necessary to our determination, we note that the record does not adequately explain how one of ordinary skill in the art would relate chronic SVC obstruction leading to SVC syndrome or TCVO to controlled, and presumably short-term, balloon catheter interventions taught by Kaiser and Gelfand.
[17] With respect to Ground 2 (discussed below) we further note that a showing of obviousness does not require "the *best* option, only that it be a *suitable* option." *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1197–98 (Fed. Cir. 2014).

syndrome is more frequently missed because SVC syndrome has specific symptoms that are easier to identify." Ex. 1032, 162:8–164:20. And contrary to the assertion at paragraph 114 of his Declaration that "'[i]ntravascular devices,' such as the ones used by Gelfand and Kaiser, 'placed into the thoracic central venous system are the most common cause of TCVO'" (Ex. 2005 ¶ 114 (alteration in original)), Dr. Brecker conceded at deposition that one of his sources taught that "[m]alignancy is the most common cause of superior vena cava (SVC) obstruction (i.e., SVC syndrome), accounting for roughly 60 to 80 percent of cases" (Ex. 1032, 152:2–153:13), whereas his other source taught that TCVO-causing devices primarily go through the *subclavian vein* (*id.* at 153:24–156:9)—which, Petitioner notes, is neither mentioned in, nor required by Gelfand or Kaiser (Reply 20 (citing Ex. 1032, 157:17–23)).

The deficiencies in Patent Owner's position on enablement are underscored by post-priority evidence of Rosenblum[18] and Kapur.[19] Reply 20–21 (citing Ex. 1035; Ex. 2008); *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001) ("Enablement of an anticipatory reference may be demonstrated by a later reference."). Rosenblum discloses that "[i]n a preclinical model of heart failure, 12 to 18 hours of intermittent SVC occlusion failed to induce any neurological or vascular injury," and "[i]n a recent proof of concept clinical study, temporary occlusion of the SVC during right heart catheterization . . . . was

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[18] Rosenblum et al., *Conceptual Considerations for Device-Based Therapy in Acute Decompensated Heart Failure*, Circulation: Heart Failure (Apr. 2020), available at https://www.ahajournals.org/doi/epub/10.1161/CIRCHEARTFAILURE.119.006731.
[19] Kapur et al., U.S. Patent No. 10,842,974 B2, issued Nov. 24, 2020.

well tolerated without neurological safety concerns." Ex. 2008, 9 (footnote omitted). Kapur discloses "treating conditions such as heart failure and/or pulmonary hypertension by at least partially occluding flow through the superior vena cava for an interval spanning multiple cardiac cycles." Ex. 1035, Abstr. According to Kapur, "[u]nlike IVC occlusion, prolonged SVC occlusion maintains systemic blood pressure," moreover, "selective intermittent occlusion of the superior vena cava ('SVC') poses fewer potential adverse risks than occlusion of the inferior vena cava ('IVC')." *Id.* at 5:14–33, 11:48–12:29.

In view of the above, we agree with Petitioner, that Kaiser, Gelfand, and the combination of Kaiser and Gelfand, disclose and enable elements the SVC positioning elements of independent claims 1 and 13.

2. "Maintaining Intravascular Pressure"

Applying its preferred construction, Patent Owner argues that "[t]he combination of Kaiser with Gelfand does not render obvious performing the method[s] of claim 1 and 13 'while maintaining intravascular pressure.'" POR 65–72. In Section II.D.2, above, we determined that, properly construed, Kaiser alone discloses this limitation. In its Response, Patent Owner argues that one of ordinary skill in the art "would understand that Kaiser's method could not be performed using Gelfand's device 'while maintaining intravascular pressure,'" because "Gelfand does not describe that its device can be used in a procedure 'while maintaining intravascular pressure.'" POR 65–66 (citing Ex. 2005 ¶¶ 104, 114–116, 124–130, 140, 141(f)).

We do not entirely grasp Patent Owner's logic of requiring *Gelfand* to describe its device as "maintaining intervascular pressure," when the basis of

Petitioner's argument is that Gelfand's device may be used to perform *Kaiser's method,* and in light of Patent Owner's assertion that "the Petition does not rely on any teachings of Gelfand with respect to this limitation." *Id.* at 66 n.11. We, nevertheless, address Patent Owner's argument that Gelfand fails to disclose use of its device "while maintaining intravascular pressure," in light of Petitioner's assertion that "[b]ecause a POSA motivated to use Gelfand's device to practice Kaiser's method would occlude the SVC in exactly the same manner taught by Kaiser, Gelfand's device would also successfully maintain intravascular pressure in the ways taught by Kaiser." *See* Pet. 72.

As with its arguments directed to Kaiser under Ground 1, Patent Owner's arguments with respect to Gelfand are predicated on its proposed construction of "maintaining intravascular pressure," as limited to maintaining systemic (arterial) pressure, and moreover, doing so at a level sufficient to avoid systemic hypotension. *See, e.g.*, POR 70–71 (arguing that Gelfand's disclosure of a safety feature to ensure that "blood pressure does not drop 'below the level required to maintain adequate vital organ function' is not the same as maintaining the patient's systemic arterial pressure" sufficient to avoid hypotension).

As discussed in Section II.C, "maintaining intravascular pressure" is not limited to maintaining arterial pressure. Because this term is broader, as already discussed above, Gelfand satisfies this element by disclosing means for maintaining central venous pressure at a target level, and further by maintaining overall systemic intravascular pressure within safe limits, including by avoiding or reversing hypotension. *See* Ex. 1006 ¶¶ 10, 19, 51–54, 88, 89; Ex. 1004 ¶¶ 113–117 (citing, e.g., Ex. 1006 ¶¶ 51–54). And as

Dr. Day explains, "[b]ecause the SVC and IVC are blood vessels, when Gelfand discloses maintaining CVP [(central venous pressure)] at a target level, it discloses that using its device can 'maintain[] intravascular pressure.'" Ex. 1004 ¶ 116 (third alteration in original).

Our construction of "maintaining intravascular pressure" also encompasses maintaining a localized pressure. *See supra* Section II.C. In this respect, Patent Owner admits that "Gelfand's disclosure of an algorithm that 'can be used to maintain a physiologic parameter' such as central venous pressure ('CVP') 'at a target level,' . . . relates to maintaining a localized pressure." POR 71–72 (citing Ex. 1006 ¶¶ 54, 52; Ex. 2005 ¶ 125).

In accord with the above, we agree with Petitioner that the cited prior art discloses the practice of the method of claim 1, "while maintaining intravascular pressure," as required by independent claims 1 and 13.

Considering the record as a whole, we find that Petitioner has adequately shown that claims 1–24 are unpatentable as obvious under Grounds 2–6.

III. CONCLUSION[20]

For the foregoing reasons, we determine that Petitioner has established by a preponderance of the evidence that claims 1–24 of the '460 Patent are unpatentable.

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[20] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent

In summary:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–10, 12–22, 24	102	Kaiser	1–10, 12–22, 24	
1–24	103	Kaiser, Gelfand,	1–24	
1–10, 12–22, 24	103	Kaiser, Bannon	11, 23	
1–24	103	Kaiser, Gelfand, Bannon	11, 23	
11, 23	103	Kaiser	11, 23	
11, 23	103	Kaiser, Bannon,	11, 23	
11, 23	103	Kaiser, Gelfand	1–10, 12–22, 24	
11, 23	103	Kaiser, Gelfand, Bannon,	1–24	
Overall Outcome			1–24	

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–24 of U.S. Patent No. 10,639,460 B2 are held unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirement of 37 C.F.R. § 90.2.

Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

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