

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABIOMED, INC.,
Petitioner,

v.

WHITE SWELL MEDICAL LTD.,
Patent Owner.

IPR2021-01477
Patent 10,653,871 B2

Before ROBERT A. POLLOCK, TIMOTHY G. MAJORS, and
CYNTHIA M. HARDMAN, *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 1–16 of U.S. Patent No. 10,653,871 B2 (Ex. 1001, “the ’871 Patent”). Paper 1 (“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) (“Guidance”),¹ we instituted an *inter partes* review of claims 1–16 on all the asserted grounds. Paper 13 (“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 37 (“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 32. 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 33, “PO Sup.”; Paper 34, “Pet. Sup.”) and corresponding responsive briefs (Paper 36, “PO Sup. Reply”; Paper 35, “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 IPR2021-01478, challenging claims 1–16 of the ’871 Patent on different grounds; PGR2021-00107, challenging claims of U.S. Patent No. 10,926,069 (“the ’069 Patent”); and IPR2021-01564 and IPR2021-01565, both challenging claims of U.S. Patent No. 10,639,460 (“the ’460 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 1–16 of the ’871 Patent on the following grounds (Pet. 9):

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1, 3–16	102	Gelfand ²
2	1–16	103	Gelfand, Kaiser ³

² Gelfand et al., US 2006/0064059 A1, publ. Mar. 23, 2006. Ex. 1006.

³ Kaiser et al., US 9,878,080 B2, issued Jan. 30, 2018. Ex. 1007.

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
3	3, 16	103	Gelfand, Bannon ⁴
4	3, 16	103	Gelfand, Kaiser, Bannon
5	15	103	Gelfand, knowledge of person of ordinary skill in the art
6	15	103	Gelfand, Kaiser, 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 and 6, 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 and 6, collapse into obviousness in view of Gelfand, and the combination of Gelfand and Kaiser, respectively. Ground 6 is, therefore, duplicative of Ground 2 with respect to claim 15.

In addition to Petitioner’s reliance on Gelfand, Kaiser, 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.

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

(Ex. 1004). Patent Owner relies, *inter alia*, on the Declaration of Dr. Stephen J.D. Brecker, M.D. Ex. 2005.

E. The '871 Patent and Relevant Background

The '871 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,” which can create a restriction within the vein to define a localized low-pressure zone adjacent to an outflow port. Ex. 1001, code (54), Abstr.

According to the '871 Patent, under normal circulatory conditions of the arterial and venous systems, “the lymph fluid is cleared back through the lymphatic system.” Ex. 1001, 1:28–33. However, in pathological conditions, a pressure gradient is reduced such that the lymphatic system cannot clear additional fluid. *Id.* at 1:37–42. 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 (providing 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. *See* Ex. 1001, 1:46–48, 7:58–65.

According to the '871 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. Further, according to the Patent, current treatments for pulmonary edema employ loop diuretics or vasodilators 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 1:49–67. 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 ’871 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 6:52–53. 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 ’871 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.

The disclosed methods and systems employ an implanted “indwelling catheter within a vein of a patient” with a “first restriction.” *Id.* at 2:6–12. The first restriction is used to localize a low pressure zone within a portion of the vein to enable fluid to pass from a lymph duct outflow port into the

vein, in which the first restriction can be an “expandable balloon formed on an outer wall of the catheter.” *Id.* at 2:12–22.

Figure 1 of the '871 Patent, reproduced below, shows a representative system for removing excess lymphatic fluid.

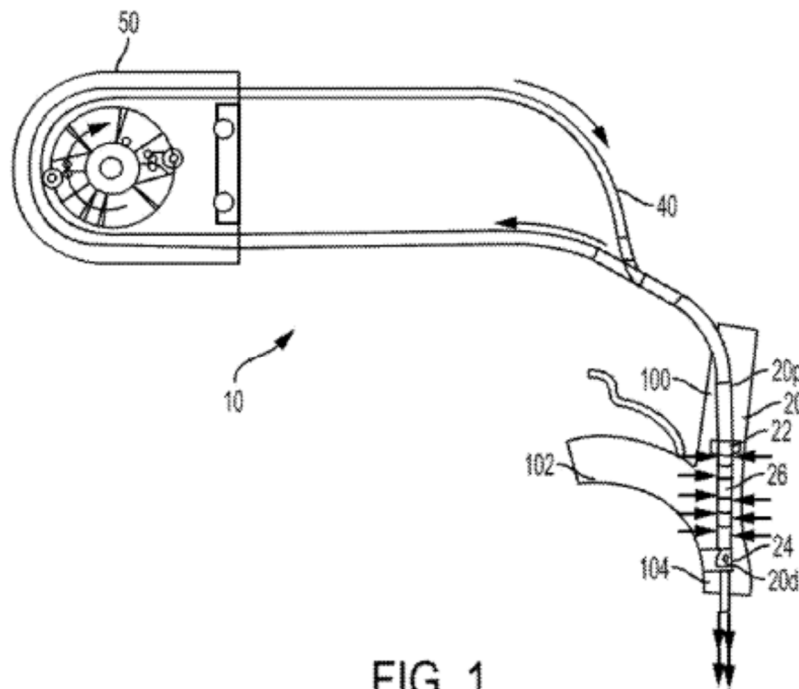


FIG. 1

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, 7:58–65. 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 '871 Patent is reproduced below.

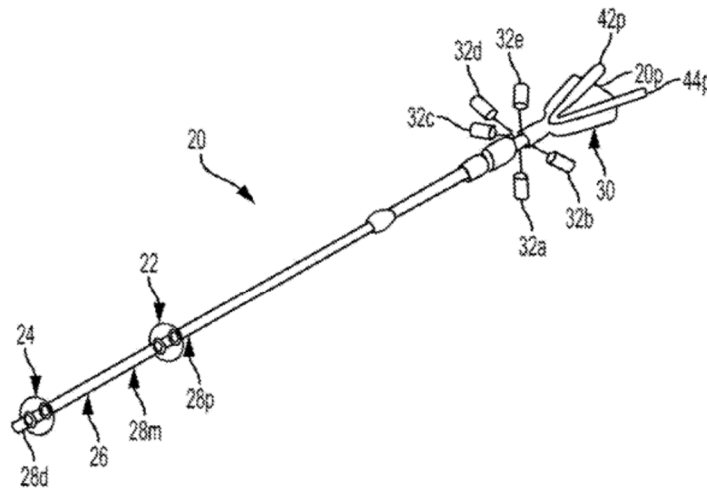


FIG. 2

Figure 2 is a perspective view of the indwelling catheter 20 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.

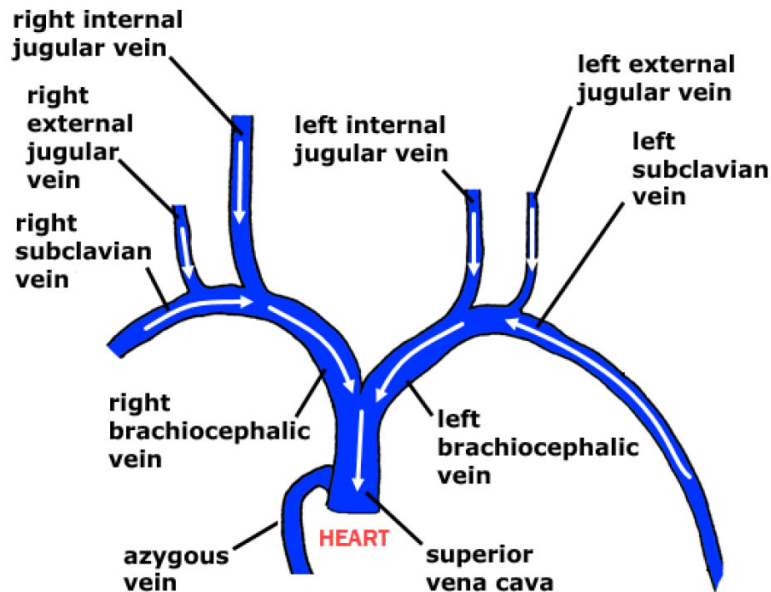
Id. at 10:18–27. Port 32*d* is used to deliver fluid to restriction 22 and port 32*a* is used to deliver fluid to restriction 24. *Id.* at 9:7–15. Within lumens inside catheter 20, pressure sensors can be positioned “to be used for sensing

pressure at various locations along the vein in which the catheter is implanted.” *Id.* at 9:15–19.

According to the ’871 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, Fig. 10. 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)).

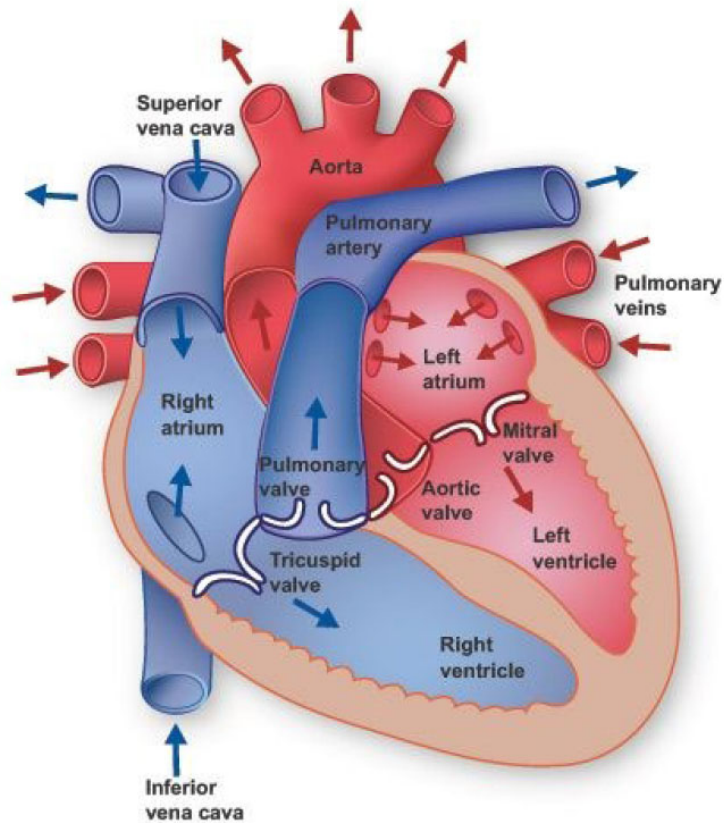
A catheter such as illustrated in Figure 1 may be placed, for example, in a jugular, subclavian, or innominate vein using a “placement technique . . . well known to those skilled in the art.” *See, e.g., id.* at 8:3–15, 10:1–11, 12:50–54, 13:39–43, 17:36–44. As explained by Petitioner’s declarant, Dr. 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 '871 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 '871 Patent is reproduced below.

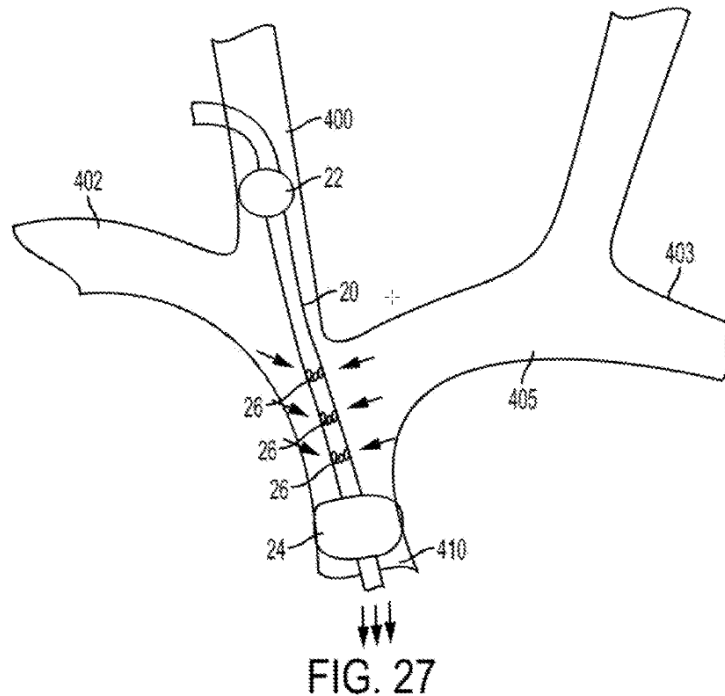


Figure 27 shows a catheter positioned, in part, at the superior vena cava.

With reference to Figure 27, the '871 Patent states that

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

Id. at 22:13–31.

F. Relevant Prosecution History of the '871 Patent

The '871 Patent issued from Application No. 16/592,988 (“the '988 Application”). Ex. 1001, code (21). The '988 Application was filed with a preliminary amendment canceling all claims in lieu of claims similar to the claims at issue here. *See* Ex. 1008, 681–686. The Examiner provisionally

rejected the newly-added claims for obviousness-type double patenting and two dependent claims for indefiniteness because they recited “the one or more resistors,” which had no antecedent, but appeared to reference the term “restrictors.” *Id.* at 97. In that same Office Action, despite provisionally rejecting the claims, the Examiner found the claims would be allowable upon the filing of a terminal disclaimer, and indicated the “reasons for the indication of allowable subject matter,” included that:

The prior art does not teach or suggest 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 and adjusting the one or more restrictors based on feedback from one or more sensors.

Id. at 100–102. According to the Examiner,

[t]he closest prior art is Lee (US 2009/0131785), which teaches a balloon catheter for selectively restricting flow through the vena cava, However, Lee’s device is configured to be placed in the inferior vena cava (Figure 1), and therefore does not perform the claimed function of regulating venous blood return through the superior vena cava.

Id. at 101 (emphases omitted).⁵

The Examiner further stated that,

Callaghan (US 2012/0029466) also teaches a method for treating heart failure [0003] wherein a catheter system is implanted in the superior vena cava [0057] and comprises one

⁵ Petitioner infers that the Examiner overlooked Lee’s teaching that “catheter assembly 10 [of Figure 1] is capable of occluding a variety of vascular and non-vascular lumens, *such as* the IVC.” Pet. 19 n.9 (citing Ex. 1017 ¶ 18). But as noted by Petitioner, Lee discloses occlusion of the right atrium or IVC and does not mention the SVC. *See* Reply 13–14, n.8 (citing Ex. 1017 ¶ 4).

or more restrictors for regulating blood flow. However, Callaghan does not teach or suggest one or more sensors, wherein the catheter . . . activat[es] the one or more restrictors within the superior vena cava to at least partially occlude flow through the superior vena cava and adjust[s] the one or more restrictors based on feedback from one or more sensors.

Ex. 1008, 102 (emphases omitted).

In response, the applicants filed terminal disclaimers and amended the two dependent claims. *See id.* at 60–65. The Examiner then allowed the application “for the reasons set forth in the previous office action.” *Id.* at 32.

G. Priority Date of the '871 Patent Claims

The '871 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); *see supra* Section I.C. Petitioner argues that multiple elements of independent claim 1 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. 20–22. Patent Owner, however, “does not contest that each of the references relied on by the Petition are prior art of the '871 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. 10–11; POR 19; Ex. 2005 ¶ 62; Ex. 1002 ¶ 94 (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 ’871 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 1–16 of the ’871 Patent. Pet. 9. Claims 1 and 5 are illustrative of the issues before us. Claim 1, the sole independent claim, recites:

- [1p] A method for treating heart failure in a patient, the method comprising:
 - [1a] providing a system comprising:
 - a catheter apparatus comprising one or more restrictors and one or more sensors;
 - [1b] and a control module operable coupled to the catheter apparatus,
 - [1c] wherein the control module receives feedback from the one or more sensors and controls the one or more restrictors based on the feedback from the one or more sensors;
- [1d] advancing the catheter apparatus into a superior vena cava of a patient; and
- [1e] operating the catheter apparatus to regulate venous blood return through the superior vena cava, wherein operating at least comprises activating the one or more restrictors within the superior vena cava to at least partially occlude flow through the superior vena cava
- [1f] and adjusting the one or more restrictors based on feedback from the one or more sensors,
- [1g] thereby treating heart failure in the patient.

Ex. 1001, 23:36–24:6; Pet. 105 (paragraphing and labeling as added in Petitioner’s claim listing). Depending from claim 1, claim 5 states: “wherein

the method is performed while maintaining intravascular pressure.”

Ex. 1001, 24:13–14; Pet. 106.

I. Overview of Asserted References

1. 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.* Gelfand explains that “approximately 85% of . . . new cases of heart failure are a direct consequence of a large MI,” and that adverse post MI remodeling can result in ventricular aneurysm and “symptoms and signs of congestive heart failure.” *Id.* ¶¶ 7, 13.

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 thus discloses to “reduce[] the severity and complications of MI by reducing infarct size and/or expansion by reducing stress (tension) in the wall of the ventricles of the heart by controllably reducing the amount of blood that fill the ventricles.” *Id.* ¶ 14. In particular, “[t]he invention limits infarct size and/or expansion by reducing tension in the walls of the heart by temporarily partially occluding parts of the circulatory system such as the great veins that re-fill the heart with blood after each ejection cycle.” *Id.* ¶ 16; *see also id.* at Title (“Treatment of Infarct Expansion by Partially Occluding Vena Cava”); *id.* ¶ 25 (describing the invention as designed to “reduce tension in the walls of the heart by temporarily, controllably and reversibly partially occluding great veins that determine the filling of the heart”).

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.* ¶¶ 26–28.⁶ Gelfand states that this 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.

⁶ 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.

Figure 3, reproduced below, shows Gelfand's catheter and associated hardware. *Id.* ¶ 23, Fig. 3.

Figure 3

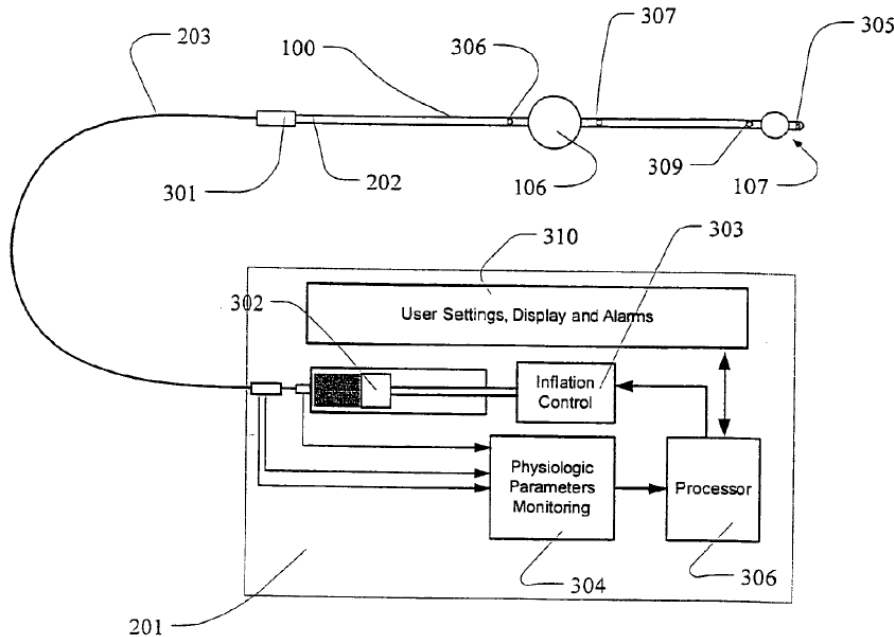


Figure 3 shows catheter 100 including oxygen sensor 305 and blood pressure sensors 306 and 309, in communication with electronic subsystem 304 of controller 201. *Id.* ¶ 51; *see generally id.* ¶¶ 23, 43–51. “Physiologic signals from the monitoring sub-system 304 are transmitted to the processor 306 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.” *Id.* ¶ 21.

Figure 1

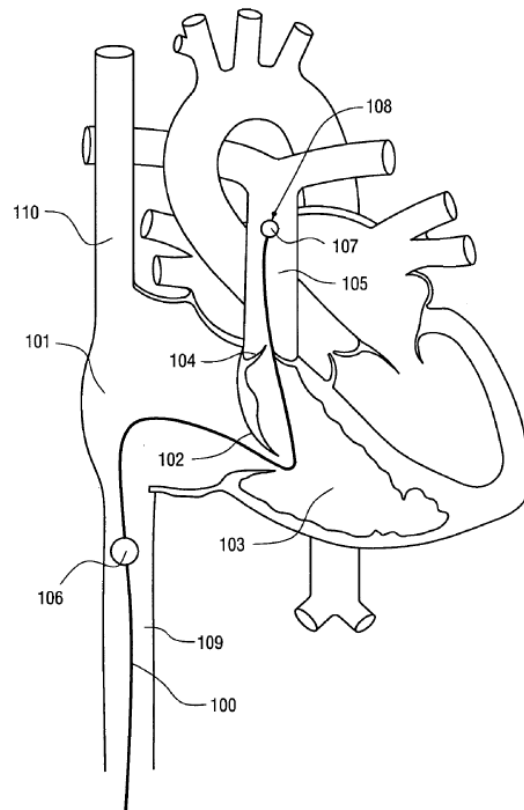


Figure 1 shows catheter 100 threaded through the right atrium 101 with a distal PA balloon 107 positioned in the pulmonary artery and occlusion balloon 106 positioned in the inferior vena cava 109. *See id.* ¶¶ 28–29.

Gelfand indicates that the orientation shown in Figure 1 is a preferred embodiment, but 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 (emphases added). Consistent with the above, Gelfand concludes that, “[t]he invention is not to be limited to the disclosed embodiment” but

covers all of various modifications and equivalent arrangements included within the spirit and scope of the appended claims. Common to all the embodiments is that the flow of blood to the heart is partially impeded by obstruction of great vessels to reduce the wall tension of the heart and allow it to heal after the acute MI. The obstruction is controlled based on physiologic parameters to avoid excessive reduction of blood flow.

Id. ¶ 58.

2. 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. Kaiser teaches that this “pressure differential may sequester extraneous blood volume 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”⁷ and at least one adjustable component⁸ (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.

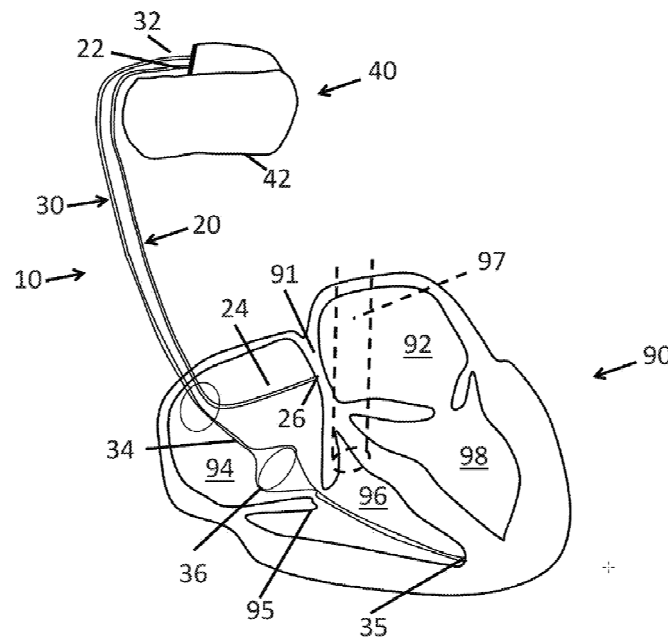


FIG. 1

⁷ 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 lumens,” or where a lead “may be a catheter including an inflation lumen.” *Id.* at 8:26–36, 10:26–29. In light of Kaiser’s nomenclature, we adopt Petitioner’s “lead/catheter” notation as appropriate. *See* Pet. 59 n.11; Ex. 1002 ¶¶ 206, 241.

⁸ Kaiser variously uses “adjustable component,” “expandable member,” “balloon” and “flow impedance device” in reference to catheter flow restriction elements. As the precise meaning of these terms is uncontested, we adopt Dr. Day’s umbrella terms “expandable member” or “adjustable component” as referring to any or all of these terms. *See* Ex. 1002 ¶¶ 200, 243.

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 10:9–15. In other embodiments, an inflatable device may be positioned to cause a pressure drop in, for example, the pulmonary artery, IVC, or SVC. *Id.* at 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 tricuspid valve, superior vena cava, inferior vena cava, pulmonary artery, and/or right atrium”), 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.”).⁹

⁹ Patent Owner argues that Kaiser’s claim 17 (“or any equivalent”) was added by amendment after the priority date of the ’871 Patent and, thus, should not be considered prior art. POR 60–61. But as indicated in Petitioner’s Reply, in allowing these claims, “the PTO . . . necessarily found them described and enabled by Kaiser’s Specification.” Reply 25.

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

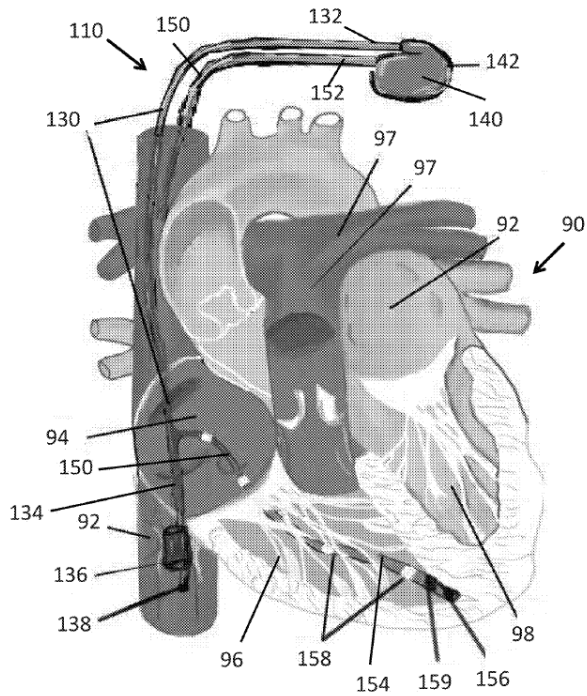


FIG. 2

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–

Supporting this finding, we note that dependent claim 5 of Kaiser’s provisional application discloses a system “wherein the at least one component is configured to selectively decrease blood flow through at least one of the . . . superior vena cava,” whereas claim 23 of that application recites a device that “adjust[s] blood flow into the left ventricle by . . . adjusting flow through the superior vena cava.” Ex. 1010, 19–22; *see also* Ex. 1002 ¶¶ 216–237 (Dr. Day’s detailed showing of support in Kaiser’s provisional application).

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.

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 (footnotes 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. 23; Ex. 1002 ¶¶ 94–95; 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. 23; Ex. 1002 ¶ 96; 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 ’871 Patent. Inst. Dec. 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. 10–11. Post-institution, Patent Owner “generally agrees 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 '871 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).¹⁰ 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.* 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.”

¹⁰ 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 19–25; 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 [he was] the only named inventor (*i.e.*, no person separately qualifying as an Engineer POSA is named as a co-inventor with [him]),” 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 ¶ 64.¹¹ 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

¹¹ 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 ’871 patent.” POR 24–25 (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 the 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 “distal restrictor,” as used in claim 14, to mean “the restrictor that is located furthest from the clinician,” and “catheter extends across a vein wall,” as used in claim 16, to mean, “catheter extends

through a vein wall,” because they were “useful in understanding the claims as a whole.” *See* Inst. Dec. 28–29; Pet. 23–27. Patent Owner does not contest these constructions in this proceeding, and we adopt them here. *See* POR 42–43.

We also provisionally adopted Petitioner’s proposed definition of “maintaining intravascular pressure,” as used in claim 5, to mean “maintaining pressure within blood vessels or a blood vessel.” Inst. Dec. 28–29; Pet. 23–25; Prelim. Resp. 11. In our Institution Decisions in IPR2021-01564 and IPR2021-01565, we further 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.” *See, e.g.*, IPR2021-01564, Paper 13 at 31 (PTAB April 12, 2022). The parties have since provided extensive argument regarding the meaning of this term, which we summarize and address below. *See, e.g.*, POR 25–36; Reply 5–11; Sur-reply 4–9; 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 ’871 Patent, and it was not defined during prosecution of the ’871 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 (“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, 27–30 (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 25–26; Sur-Reply 7; 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 ’871 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.* ¶ 73. Dr. Brecker concludes, that “[i]n this clinical context” and “in the context of the [’871 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 34–35). 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 ’871 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 6:52–56.

According to the ’871 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. 24–25 (citing

Ex. 1018 (defining intravascular as, e.g., “within blood vessels or a blood vessel”));¹² 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. 24–25; Ex. 1004 ¶¶ 42–47.

With respect to aspect 1, Petitioner concedes that, in light of Paragraph 6 in the Background section of the ’871 Patent, “[m]aintaining intravascular pressure’ could . . . be read to mean not reducing pressure like prior treatments, *i.e.*, maintaining systemic pressure.” Pet. 24; 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

¹² We find unpersuasive Patent Owner’s argument that Petitioner’s construction improperly relies on a dictionary definition. *See, e.g.*, POR 27–28 (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 [’871] patent.” *Id.* at 1322–1323 (citing *Vitronics Corp. v. Conceptoronic, 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, 13:11–32 (“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 ’871 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 ’871 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, 15:57–16:3.

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 ’871 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)), 13:2–7 (“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.*”) (emphasis added).

Accordingly, we agree with Petitioner that the ’871 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 30–31 (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 Gelfand

As Ground 1, Petitioner challenges claims 1 and 3–16 as anticipated by Gelfand. Pet. 27–54. Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* at 32–54. 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 Gelfand discloses these limitations. We address below Patent Owner's arguments for why Gelfand 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 and 3–16 are unpatentable as anticipated by Gelfand.

1. Positioning Catheter Elements in the Superior Vena Cava

Patent Owner argues that Gelfand fails to disclose elements [1d] through [1f] of independent claim 1 relating to the position of catheter elements in the SVC, specifically, “advancing the catheter apparatus into a superior vena cava” (element [1d]), “activating the one or more restrictors within the superior vena cava” (element [1e]), and “adjusting the one or more restrictors [within the superior vena cava] based on feedback from the one or more sensors” (element [1f]). *See* POR 43.

Petitioner addresses where elements [1d] through [1f] are disclosed in Gelfand on pages 38–41 of the Petition. With respect to positioning within the SVC, Petitioner references Gelfand's disclosure “that the catheter is inserted through a puncture in a vein proximal to the IVC and then ‘advanced downstream (towards the heart) into the venous tree into the IVC

. . .’ (Ex. 1006, ¶ [0032]; *see also* ¶ [0028], Fig. 2) (showing catheter advanced so that balloon is positioned in the IVC).” Pet. 38 (emphasis omitted).

With respect to the SVC, in particular, Petitioner points to paragraph 29 of Gelfand disclosing that, “it is understood that the occlusion balloon 106, shown in the IVC 109, can be positioned in other places within the right heart and great veins such as . . . Superior Vena Cava (SVC) . . . [without] substantially chang[ing] the invented method, system or device.” Pet. 38–39 (citing Ex. 1006 ¶ 29; Ex. 1002 ¶ 135) (emphasis omitted; alterations in original). Although Patent Owner characterizes the express disclosure of Gelfand’s paragraph 29 as “a single, passing reference” to positioning its occlusion balloon in the SVC, Gelfand repeatedly teaches that all embodiments of its invention can be used to occlude the “great veins” or “great vessels”—which Dr. Brecker concedes include the SVC. POR 44; Ex. 1006 ¶¶ 16, 25, 29, 58; Ex. 1032, 108:5–14. According to Petitioner, “Gelfand thus discloses advancing its catheter in the superior vena cava of a patient.” Pet. 39 (referencing Ex. 1002 ¶¶ 131–135).

In its Preliminary Response, Patent Owner argued that in light of the “significant biological differences between the IVC and the SVC,” Gelfand was not enabling because:

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

See Inst. Dec. 30–31 (citing Prelim. Resp. 6, 15, 18; Exs. 2001,¹³ 2002¹⁴). Considering Patent Owner’s argument, we invited the parties “to address whether Gelfand . . . sufficiently enables the use of a catheter balloon in the SVC.” *Id.* at 31 n.11.

Revisiting this argument on pages 44–51 of the Patent Owner Response, Patent Owner relies on Dr. Brecker’s testimony that, despite its express teachings to use a catheter balloon in the SVC, “Gelfand does not disclose sufficient detail to enable [one of ordinary skill in the art] to carry out the claimed invention in the SVC.” Ex. 2005 ¶ 91 (*cited in* POR 44). In short, Patent Owner and Dr. Brecker argue that, in contrast to the details Gelfand provides for use of its catheter in the IVC, “Gelfand does not provide any details showing how it could be used . . . successfully and safely in the SVC.” POR 44–54, 49 (citing Ex. 2005 ¶¶ 28, 32, 34, 51, 94, 95, 100, 102).

Pointing to Gelfand’s statement that “[a]n expert in cardiac catheterization can invasion [sic, envision] other ways of limiting blood flow to the heart,” Patent Owner asserts 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.’” *Id.* at 44 (citing Ex. 1006 ¶ 29) (alteration marks omitted)). Patent Owner further contends neither an Engineer POSA nor a Clinician POSA is “necessarily such an expert.” *Id.* at 46–47 (citing Ex. 1006 ¶ 69; Ex. 2005 ¶¶ 95–97;

¹³ Lakna, “*Difference Between Superior and Inferior Vena Cava*,” Pediaa (Aug. 28, 2018), <https://pediaa.com/difference-between-superiorandinferior-vena-cava/>.

¹⁴ Tucker *et al.*, “*Anatomy, Abdomen and Pelvis, Inferior Vena Cava*,” (July 27, 2021), *available at* <https://www.ncbi.nlm.nih.gov/books/NBK482353/>.

Ex. 2006, 42:5–15, 42:24–43:21, 45:6–11; Ex. 2007, 59:6–60:11). Patent Owner further contends that, in light of the differences between the IVC and the SVC and their associated upstream vascular regions, even an expert in cardiac catheterization may not have the necessary experience and expertise to select and deploy a catheter in the SVC as taught by Gelfand. *Id.* at 47–48 (citing Ex. 2005 ¶¶ 97–99, 102; Ex. 1006 ¶ 30; Ex. 2007, 9:14–10:3, 12:2–25, 13:9–17:6); *see also id.* at 13–15 (background section discussing “significant differences between the IVC and the area that it drains and the SVC and the area that it drains”).

Moreover, Patent Owner argues, because approximately one-third of the blood flow returning to the heart is via the SVC, whereas two-thirds is via the IVC, one of ordinary skill in the art would recognize the IVC as “much better suited” to Gelfand’s occlusion techniques. POR 48–49 (citing Ex. 1006 ¶ 17; Ex. 2005 ¶¶ 99, 100). Patent Owner asserts, therefore, that significantly more obstruction would need to be provided in the SVC than in the IVC to achieve Gelfand’s suggested goal of reducing “venous blood returning to the heart . . . by 10%” “which ‘if possible at all, could have adverse consequences on the patient.’” *Id.* (citing Ex. 1006 ¶ 17; Ex. 2005 ¶ 99), *see id.* at 13–15 (discussing differences between SVC and IVC and potential consequences of obstructing the SVC). Dismissing the opinions of Drs. Day and Garcia to the contrary, Patent Owner concludes that “a POSA would not understand Gelfand as enabling a POSA to perform a procedure within the SVC for the purposes of occluding blood flow there.” *Id.* at 49–51 (citing, e.g., Ex. 2005 ¶ 102).

Considering the posture of this case, it is Patent Owner’s burden to overcome the presumption that Gelfand 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 Gelfand for at least the reasons set forth on pages 12–24 of Petitioner’s Reply, which we adopt in full and briefly summarize below.

First, however, we note our disagreement with Patent Owner’s reading of a sentence taken from Gelfand’s paragraph 29. *See* POR 44, 46–47; Sur-reply 11; Ex. 2005 ¶¶ 95–97. Reproduced in full, with the relied-upon sentence highlighted, the paragraph reads:

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 44 (alteration marks omitted). Considered in context, however, Gelfand states that “[a]n expert in cardiac catheterization can invasion [sic, envision] other

ways of 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. 91:4–24 (“Gelfand then proceeds to tell you exactly what that expert would envision, using the device in the SVC”). Having identified these modifications, Gelfand states 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 45.

On this record, 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 ¶ 140 (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 ¶¶ 131–135; *see also id.* ¶¶ 136–145 (similar testimony specific to elements [1e] and [1f]); Ex. 2006, 93:11–99:16, 71:7–78:15, 86:13–87:19, 88:14–90:9, 97:10–13. But to the extent Gelfand’s device needed to be modified, we find persuasive Dr. Day’s testimony that an Engineer POSA would have found such modifications

“routine.” Ex. 2006, 205:8–212:21 (“they’re just different variants or dimensions of the invention”).

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 ¶ 60 (citing Ex. 1006 ¶¶ 26–28 (Dr. Day’s overview of therapeutic balloon catheters)). Referencing Dr. Day’s testimony, 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. ¶ 119; *see also id.* ¶¶ 75–85, 119 (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”). As further noted by Petitioner, “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 15 (citing Ex. 1004 ¶¶ 75–82, 83 (showing modified version of Gelfand’s Figure 1), 84, 85, 137, 146–159; Ex. 2006, 101:8–103:10); *see also id.* at 15–16 (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 17–20 (citations omitted). In this respect, and more broadly, 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 ’871 Patent. *Id.* at 14, 17 (citing 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 20–21. 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); and Dr. Garcia’s testimony regarding how a Clinician POSA would implement Gelfand’s method in the SVC (Ex. 1002 ¶ 140; 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 45), 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, 21–22 (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 22–23 (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 (‘TCVO’).” POR 14–15 (citing Ex. 2005 ¶ 114; Ex. 2012;¹⁵ Ex. 2013,¹⁶ 6–8; Ex. 2014¹⁷). But even if Patent Owner and Dr. Brecker are correct, knowledge of the relative risk does not overcome

¹⁵ 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>.

¹⁶ 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>.

¹⁷ Lawrensia *et al.*, *Inferior Vena Cava Syndrome*, StatPearls (May 3, 2022), available at <https://www.ncbi.nlm.nih.gov/books/NBK560885>.

the express, and presumptively-enabled teachings of Gelfand (and Kaiser, discussed below) to occlude the SVC.^{18,19}

Moreover, on page 23 of its Reply, Petitioner casts substantial doubt on the factual underpinnings of Dr. Brecker's opinion. Reply 23 (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 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,’” 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

¹⁸ We also note that the evidence relied upon by Patent Owner does not adequately explain how one of ordinary skill in the art would relate chronic SVC obstruction leading to SVC syndrome or TCVO to the controlled, and presumably short-term, balloon catheter interventions taught by Gelfand and Kaiser.

¹⁹ And 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).

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 23 (citing Ex. 1032, 157:17–23)).

The deficiencies in Patent Owner’s position on enablement are underscored by post-priority evidence of Rosenblum²⁰ and Kapur.²¹ Reply 24 (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 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.

²⁰ 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>.

²¹ Kapur et al., U.S. Patent No. 10,842,974 B2, issued Nov. 24, 2020.

2. Treating a Patient with Heart Failure

The preamble and concluding phrase of claim 1 (elements [1p] and 1[g], respectively), recite: “A method for treating heart failure in a patient . . . thereby treating heart failure in the patient.” In its Sur-reply, Patent Owner *for the first time* contends that “Gelfand does not anticipate the claimed invention because Gelfand does not teach or suggest any method for treating a patient with heart failure.” Sur-reply 9–14 (capitalization normalized); *see also id.* at 17–18 (same argument in context of obviousness).

As this position had not previously been raised, the record contains no discussion of the salient, yet non-trivial issue of whether the preamble and/or the “wherein” clause of element 1[g] should be accorded patentable weight.²² *Compare, e.g., Bristol–Myers*, 246 F.3d at 1376 (claim language that “is only a statement of purpose and intended result” and that “does not result in a manipulative difference in the steps of [a] claim” is generally not limiting); *Minton v. Nat’l Ass’n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003) (“A whereby [or wherein] clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.”); *with Allergan Sales, LLC v. Sandoz, Inc.*, 935 F.3d 1370, 1377 (Fed. Cir. 2019) (“wherein” clause accorded patentable weight where “both Allergan and the Examiner explicitly relied on the ‘wherein’ clauses to distinguish the claimed methods over the prior art

²² Although the Sur-reply assumes that we should accord these limitations patentable weight, Patent Owner provides no claim construction analysis. And although the Petition addresses where elements 1[p] and 1[g] can be found in the prior art, it undertakes no analysis of the underlying construction. Pet. 32–33, 41.

during prosecution”). Although we might tend to find that the preamble and wherein clause are non-limiting, we decline to do so absent briefing by the parties.

We need not consider the construction of these terms, however, because we decline to consider Patent Owner’s untimely argument. Patent Owner has had ample warning of this possibility. In our Scheduling Order, we expressly cautioned Patent Owner that “any arguments not raised in the response may be deemed waived.” Paper 14, 9; *see also Cloudflare, Inc. v. Sable Networks*, IPR2021-00909, Paper 42 at 18 n.13, 32 n.21. (finding that Patent Owner forfeited arguments not raised in the response and in contravention to the scheduling order). Consistent with the Scheduling Order controlling this proceeding, our Trial Practice Guide makes clear that “Sur-replies should only respond to arguments made in reply briefs, comment on reply declaration testimony, or point to cross-examination testimony.” Patent Trial and Appeal Board Consolidated Trial Practice Guide (“Trial Practice Guide”) (Nov. 2019)²³ at 73–74. “While replies and sur-replies can help crystalize issues for decision, a reply or sur-reply that raises a new issue or belatedly presents evidence may not be considered.” *Id.* at 74 (further noting that “[r]espond,’ in the context of 37 C.F.R. § 42.23(b), does not mean proceed in a new direction with a new approach as compared to the positions taken in a prior filing”). While our Trial Practice Guide suggests that we may disregard Patent Owner’s Sur-reply in its entirety (*see id.* (“[t]he Board is not required to attempt to sort proper from improper portions of the reply or sur-reply”)), the compact nature of Patent Owner’s Sur-reply permits us

²³ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

to surgically disregard only the new argument presented in Sections IV, A–B of its brief.

At oral hearing, Petitioner explained in detail why Patent Owner’s focus on treating heart failure constituted new argument in contravention of our rules and practice. *See* Tr. 10:14–18, 17:8–19:13. Patent Owner did not respond to this contention. Nevertheless, and to the extent Patent Owner may later point to some suggestion that its heart failure argument is not “new,” we consider the merits of the parties’ arguments under the unexamined assumption that the term(s) are limiting.

In addition to revisiting the enablement arguments discussed above, Patent Owner contends that “the device and procedure of Gelfand is used to limit infarct expansion, prior to and to avoid heart failure.” Sur-reply 10. Because “Gelfand never contemplates treatment of a patient in heart failure, [it] does not enable any method for treating heart failure in a patient.” *Id.* at 14. We note that the portion of the Sur-reply directed to Patent Owner’s “treating heart failure” argument cites to three paragraphs of its expert’s testimony. Sur-reply 12–13 (citing Ex. 2005 ¶¶ 91, 94, 95). Although these paragraphs are directed to Patent Owner’s general argument that Gelfand’s method is not enabled for the SVC, none of them mention heart failure. Indeed, nowhere in his declaration (Exhibit 2005) does Dr. Brecker opine that Gelfand does not teach the treatment of heart failure. *See* Tr. 20:4–21:21 (Petitioner’s counsel noting that Dr. Brecker never addressed whether Gelfand treats heart failure).

In contrast, the assertions in the Petition that Gelfand discloses elements 1[p] and 1[g] are extensively supported by the testimony of Dr. Garcia. *See* Pet. 32–33, 41; Ex. 1004 ¶¶ 66–72; Ex. 2007, 105:14–106:6.

In short, Dr. Garcia points to Gelfand's teaching "that its 'invention reduces 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[s] the ventricles.'" Ex. 1004 ¶ 67 (citing Ex. 1006 ¶ 14). Dr. Garcia explains that "the 'complications of MI' treated by the device and method of Gelfand's invention include heart failure." *Id.* ¶¶ 67–71 (citing Ex. 1006 ¶¶ 5–7, 13). "Accordingly," Dr. Garcia states, "in disclosing treating the consequences of an MI, Gelfand discloses treating heart failure." *Id.* ¶ 72. Pointing to additional testimony of Dr. Day, Dr. Garcia further states that "Gelfand's method does so with a balloon catheter device having the components and features listed in the remaining elements of Claim 1." *Id.* Dr. Garcia concludes, that "[b]y using the balloon catheter to occlude the SVC in order to regulate the amount of venous blood returning to the heart, Gelfand's invention reduces heart wall stress, which in turn treats MI-induced heart failure by ameliorating left ventricular remodeling." *Id.*

Finding Dr. Garcia's un rebutted testimony consistent with our plain reading of Gelfand, we determine that Petitioner has sufficiently shown that, to the extent they are limiting, Gelfand discloses element 1[p] and 1[g].

3. "Maintaining Intravascular Pressure"

Specific to dependent claim 5, Patent Owner argues that Gelfand fails to disclose operation of the catheter apparatus, "wherein the method is performed while maintaining intravascular pressure." POR 67–71; Sur-reply 14–15. Patent Owner's arguments, however, 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 55–57 (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 set forth in Section II.C, “maintaining intravascular pressure” is not so limited. To the extent this term extends to a systemic pressure, we agree with Petitioner that, applying our construction of this term as “maintaining pressure within blood vessels or a blood vessel,” 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. Pet. 45–46 (citing Ex. 1006 ¶¶ 10, 19, 52, 54); Ex. 1004 ¶¶ 87–90. 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.’” 1004 ¶ 89.

As also noted in Section II.C, our construction encompasses regions of low pressure in portions of the venous system between occlusion devices, or in the vicinity of one or more occlusion devices. In this respect, Petitioner contends that the practice of Gelfand’s method creates and maintains a low-pressure zone downstream of an occlusion device. *See* Pet. 46 (citing Ex. 1006 ¶ 18; Ex. 1004 ¶ 91). Dr. Day explains that Gelfand

discloses that “the amount of venous blood returning to the heart (filling the heart) is reduced by creating a partial temporary obstruction (occlusion) in the IVC or RA. Obstruction can be achieved with an intravascular inflatable balloon placed inside the IVC or RA [right atrium].” (¶ [0018].)

As previously noted, these teachings apply to the SVC. The inherent result of temporarily obstructing (*i.e.*, occluding) the SVC in the manner disclosed by Gelfand is the creation and maintenance of a low pressure zone in the SVC downstream of the balloon.

Ex. 1004 ¶ 91 (alteration in original).

In accord with the above, we agree with Petitioner that Gelfand discloses the method of claim 1, “while maintaining intravascular pressure,” as required by dependent claim 5.

For the reasons set forth above, Petitioner has sufficiently shown that Gelfand anticipates claims 1 and 3–16 of the ’871 Patent.

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

As Grounds 2 and 6, Petitioner challenges claims 1–16 as obvious in view of Gelfand and Kaiser. Pet. 55–94, 100–101. As Ground 5, Petitioner challenges claim 15 as obvious in view of Gelfand alone. *Id.* at 99–100. As Ground 3, Petitioner challenges claims 3 and 16 as obvious in view of Gelfand and Bannon. *Id.* at 94–98. And as Ground 4, Petitioner challenges claims 3 and 16 as obvious in view of Gelfand, Kaiser, and Bannon. *Id.* at 98. Petitioner provides an element-by-element comparison of the asserted art to the challenged claims.

With respect to the combinations of Gelfand and Kaiser (Grounds 2–4 and 6), Petitioner argues that Kaiser discloses a method to treat heart failure using a device with components and features analogous to those of Gelfand’s device. Pet. 61. “While Gelfand aims to reduce heart wall stress and Kaiser aims to optimize intracardiac pressures and induce ‘mechanical diuresis,’ these effects are all obtained through the common mechanism of

sensor-controlled SVC occlusion.” *Id.* at 62. According to Petitioner, one of ordinary skill in the art would understand that

Gelfand’s vein-occluding device could be used not only to treat MI complications according to Gelfand’s method, but also heart failure according to Kaiser’s method, *i.e.*, by controllably reducing venous blood return to the heart to regulate intracardiac filling pressure and induce “mechanical diuresis.” A POSA would be motivated to use Gelfand’s device because it uses conventional, off-the-shelf components familiar to clinicians—catheters, balloon pumps and sensors (Ex. 1006, ¶¶ [0026]–[0028], [0030], [0036]–[0045], [0049])—and describes features such as sensor operation or balloon operation in greater detail, making Gelfand’s device potentially easier to implement and use. *See generally* Ex. 1002, ¶ 248; Ex. 1004, ¶¶ 97–98, 110–12.

Id. According to Petitioner, “[a] POSA would have every expectation of success because Gelfand’s device has the features of Kaiser’s device and the functionality required by Kaiser’s method, including percutaneous placement and computerized sensor-controlled occlusion of the SVC.” *Id.* Petitioner further relies on Bannon with respect to claims 3 and 16 as providing additional motivation “to insert the catheter into the right internal jugular or left subclavian vein.” *See* Pet. 96–98. Considering the record as a whole, we find that Petitioner has adequately shown that claims 1–16 are unpatentable as obvious under at least Grounds 2–4, and 6.

We further note that, other than as argued under Grounds 1 and 2, Patent Owner does not argue the merits of Grounds 3–6, asserting instead that “Grounds 3–6 fail for the same reasons as Grounds 1–2.” POR 71 (capitalization normalized). Patent Owner further asserts that Grounds 3 and 5 fail “because Gelfand does not anticipate claim 1.” *Id.* at 72. But as discussed in Section II.D, above, we find that Gelfand *does* anticipate claim

1, which would seem to render at least Grounds 3 and 5 moot. For completeness, however, we address below Patent Owner's arguments with respect to the merits of Ground 2 as applied to all obviousness grounds.

In addressing Ground 2, Patent Owner states:

because neither Gelfand's device, as described above, nor Kaiser's method disclose each limitation of independent claim 1, from which each of the remaining claims depend, the combination of Gelfand and Kaiser does not render obvious any of these claims. In addition, because neither Gelfand's device, as described above, nor Kaiser's method disclose the additional limitation of dependent claim 5, the combination of Gelfand and Kaiser does not render obvious claim 5 for that reason as well.

Id. at 58–59. We are not persuaded by Patent Owner's arguments for two reasons. First, because we determined in Section II.D, above, that Gelfand's device does disclose each limitation of claims 1 and 5, and considering the absence of argument or evidence for secondary considerations of non-obviousness, we also find that claims 1–16 are rendered obvious by, e.g., Gelfand alone (Ground 5, claim 15) or Gelfand and Kaiser (Ground 2, claims 1–16).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). Second, we are not persuaded by the merits of Patent Owner's arguments not previously addressed with respect to Ground 1.

²⁴ Patent Owner does not separately argue the elements of dependent claim 15, which recites, "[t]he method of claim 1, wherein the catheter comprises an opening that is configured to facilitate pressure monitoring." Ex. 1001, 24:43–45; POR.

Patent Owner contends that Kaiser fails to disclose occluding the SVC, and to the extent it does, Kaiser's disclosure "is insufficient to enable such use by a POSA." POR 59–67; Sur-reply 19–23 (citations omitted). We do not find these arguments persuasive for the reasons set forth at pages 24–28 of Petitioner's Reply, which we adopt. Thus, assuming Gelfand alone does not enable placing a flow-restricting device in the SVC (contrary to our findings above), we find Kaiser enables doing so.

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* Ex. 1002 ¶¶ 239–249 (Dr. Day's explanation that Kaiser, like Gelfand, discloses sensor-controlled occlusion of the SVC). Accordingly, we find that Kaiser discloses occluding the SVC.

Patent Owner further argues 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 61 (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.” POR 62–64 (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 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.” Sur-reply 19–20; POR 64–65 (citing Ex. 2005 ¶¶ 113–114); *see id.* at 13–15 (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 or address significant differences between SVC and IVC in terms of capacitance of 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 Clinical POSA [would] require additional disclosure regarding how Kaiser could be used safely and successfully in the SVC.” *Id.* at 65–67 (citing, e.g., Ex. 2005 ¶¶ 112, 114). We do not find Patent Owner’s argument persuasive.

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, Section II.D.1, above (citing, *e.g.*, *Amgen*, 314 F.3d at 1354–55). 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 25–28 of Petitioner’s Reply, which we adopt in full.²⁵

In particular, 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. Ex. 1002 ¶ 205 (annotated version of Kaiser Fig 2 showing that the lead/catheter passes through the SVC to reach the IVC); Ex. 2006, 218:6–220:13. With respect to enablement of Kaiser’s method in the SVC, we find that Dr. Brecker’s analysis also falls short of overcoming the presumption that Kaiser is enabling for the reasons set forth at pages 27–28 of the Reply and as further discussed in Section II.D, above, with respect to Gelfand.

We find particularly persuasive 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 27–28 (citing Ex. 1007,

²⁵ Although, for completeness, we address Patent Owner’s arguments that Kaiser is not enabled, this property is not required with respect to the Gelfand/Kaiser Grounds because Petitioner has shown that Gelfand is enabled with respect to the limitation at issue. *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”).

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.

Patent Owner also contends that Kaiser does not describe that its method can be performed “while maintaining intravascular pressure” as required by claim 5. POR 67–71 (citing Ex. 2005 ¶¶ 131–37, 139, 141(f)). Patent Owner’s contention, however, is premised on a construction that requires maintaining a non-hypotensive systemic arterial pressure. As discussed in Section II.C, however, our construction is not so limited. Applying our broader construction, we agree with Petitioner that Kaiser satisfies the limitation of dependent claim 5 for the reasons of record. *See* Pet. 76–78; Reply 29; Exhibit 1004 ¶¶ 128–130.

III. CONCLUSION²⁶

For the foregoing reasons, we determine that Petitioner has established by a preponderance of the evidence that claims 1–16 of the ’871 Patent are unpatentable.

²⁶ 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

In summary:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1, 3–16	102	Gelfand	1, 3–16	
1–16	103	Gelfand, Kaiser	1–16	
3, 16	103	Gelfand, Bannon	3, 16	
3, 16	103	Gelfand, Kaiser, Bannon	3, 16	
15	103	Gelfand	15	
15	103	Gelfand, Kaiser	15	
Overall Outcome			1–16	

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–16 of U.S. Patent No. 10,653,871 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.

or a request for reexamination of the challenged patent, we remind Patent 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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