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Paper 13
Date: April 11, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABIOMED, INC.,
Petitioner,

v.

WHITE SWELL MEDICAL LTD.,
Patent Owner.

IPR2021-01477
Patent 10,653,871 B2

Before ROBERT A. POLLOCK, TIMOTHY G. MAJORS, and CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

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

I. INTRODUCTION

Abiomed, Inc. ("Petitioner") filed a Petition for *inter partes* review of claims 1–16 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 121 ("Prelim. Resp.").

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has demonstrated a reasonable likelihood that at least one claim of the '871 Patent is unpatentable, we institute an *inter partes* review of all challenged claims on each of the Grounds raised in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *see also* Guidance on the Impact of SAS on AIA Trial Proceedings (April 26, 2018).[1]

A. Real Parties-in-Interest

Petitioner identifies itself as the real party-in-interest. Pet. 7. Patent Owner identifies itself as the real party-in-interest. Paper 8, 1.

B. Related Matters

In its Mandatory Notice, Patent Owner stated that it "is not aware of any judicial or administrative matters that could affect, or could be affected by, a decision in this proceeding." Paper 8. Petitioner has, however, filed IPR2021-01477, 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").

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

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

C. The ’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. Accumulation of this excess fluid in the air spaces of the lungs may lead to respiratory failure. *Id.* at 1:46–48.

The ’871 Patent explains that current treatments for pulmonary edema employ loop diuretics or vasodilators, but these treatments are not ideal because the “edema is not always alleviated rapidly enough and for many patients renal function is adversely affected.” *Id.* at 1:49–55. The ’871 Patent purports to resolve this problem by providing a system for treating edema using an implanted “indwelling catheter within a vein of a patient” with a

"first restriction." *Id.* at 2:6–12. 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 such a system.

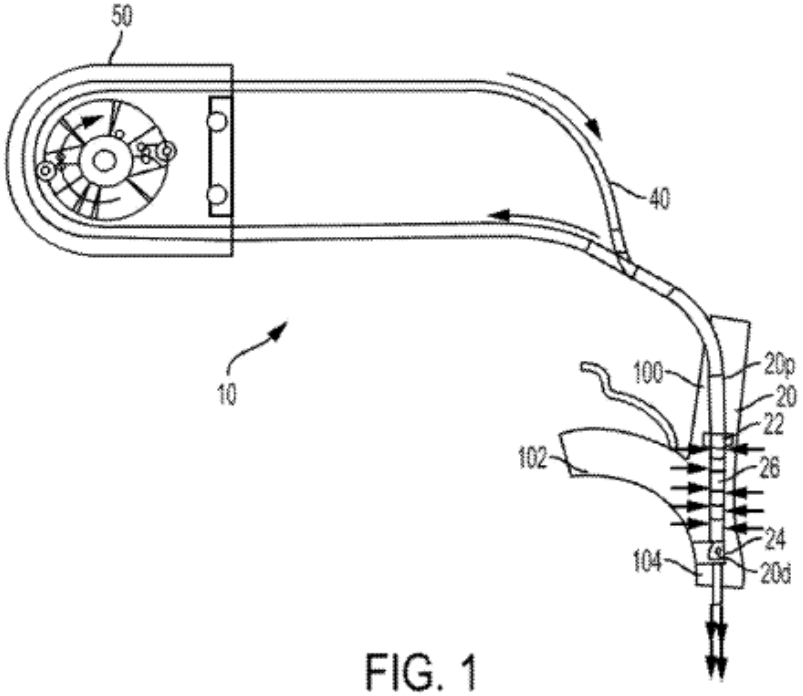


FIG. 1

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

Figure 2 of the ’871 Patent is reproduced below.

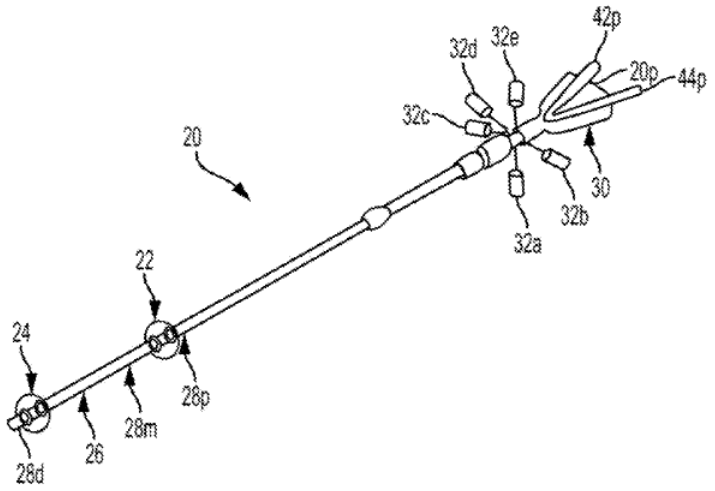
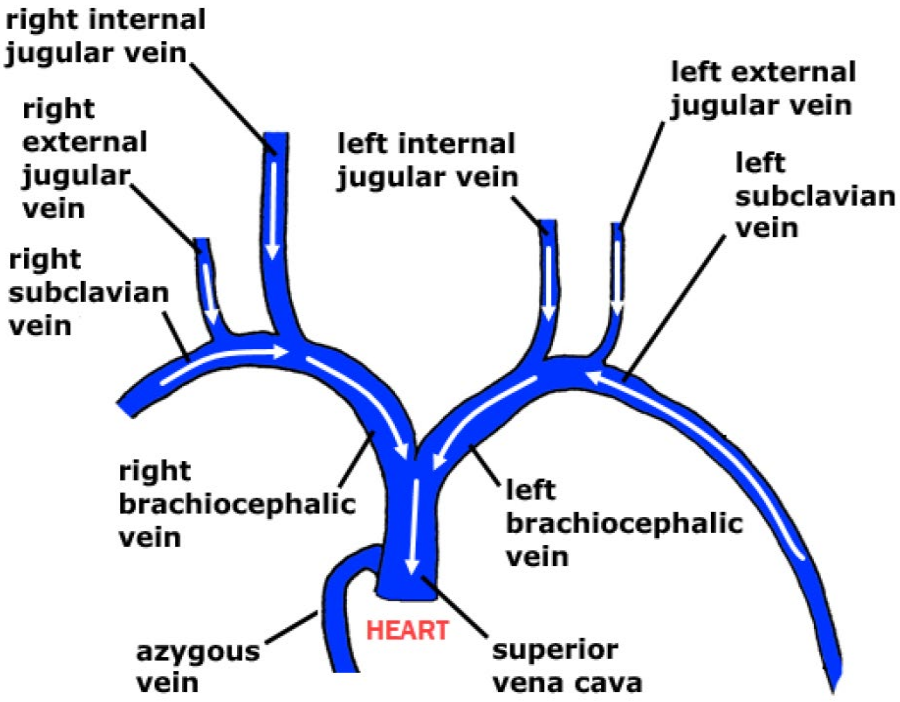


FIG. 2

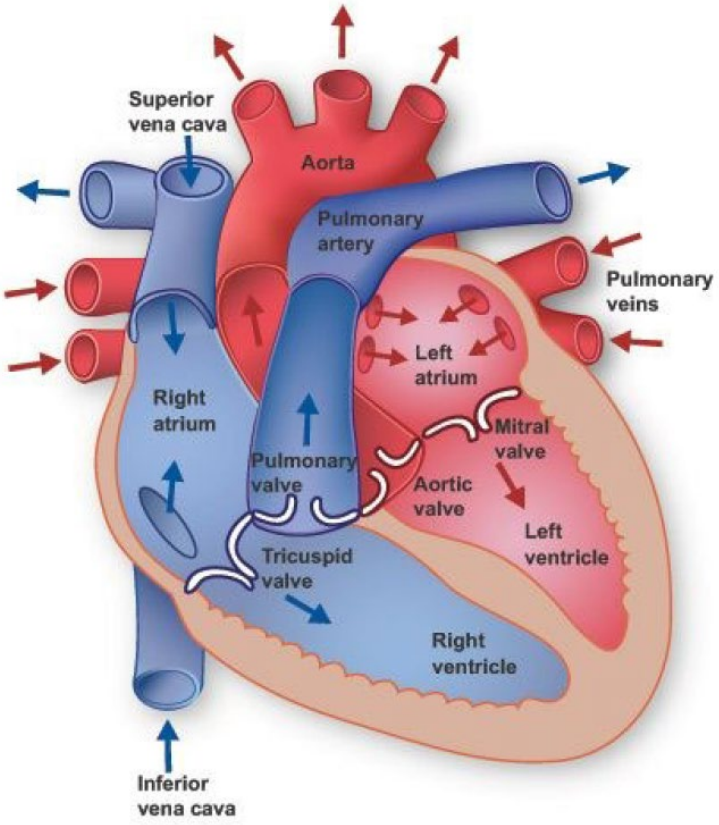
Figure 2 is a perspective view of the indwelling catheter of Figure 1. *Id.* at 4:39–40. Port 32d is used to deliver fluid to restriction 22 and port 32a is used to deliver fluid to restriction 24. *Id.* at 9:7–15. Within lumens inside catheter 20, pressure sensors can be positioned “to be used for sensing pressure at various locations along the vein in which the catheter is implanted.” *Id.* at 9:15–19.

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. Upon receiving this information, “the control module can be configured to actuate the pump function” and alter “the first or second restriction volume.” *Id.* at 15:20–32.

A catheter such as illustrated in Figure 1 may be placed, for example, in a jugular, subclavian, or innominate vein using a "placement technique . . . well known to those skilled in the art." *See, e.g.*, *id.* at 8:3–15, 10:1–11, 12:50–54, 13:39–43, 17:36–44. 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.



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.



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.

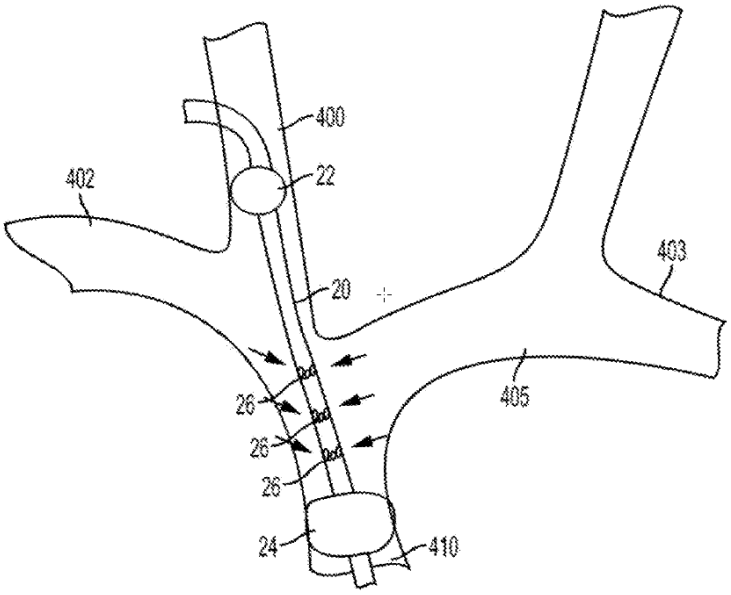


FIG. 27

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.

D. 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, the Examiner's "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,

> The 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 (bolding omitted).[2]

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 or more restrictors for regulating blood flow. However, Callaghan does not teach or suggest one or more sensors, wherein the catheter is operated 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.

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[2] 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).

Ex. 1008, 102 (bolding 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.

E. Priority date of the '871 Patent

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 first filed on February 19, 2015, as the '930 Application. Ex. 1001, codes (21), (60), (63); *see* section I.B, above. Petitioner argues that multiple elements of independent 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 declines to address whether the challenged claims are supported in the '206 Provisional Application, and argues that we need not reach the issue "[b]ecause the references relied on by the Petition are each dated before the June 1, 2014 filing date of the provisional application" and, thus, necessarily predate the filing date of the '206 Provisional Application. *See* Prelim. Resp. 9–10.

As the parties agree, at least implicitly, that the asserted references are prior art with respect to the challenged claims, we need not presently consider whether the '871 Patent is entitled to the priority date of the '206 Provisional Application. Based on the present record, it is not apparent that there is any material difference between a POSA's skill level or understanding whether June 1, 2014, or February 19, 2015, is the applicable priority date. To the extent either party contests the understanding of one of

ordinary skill as of a specific critical date, the parties are welcome to revisit the priority issue at trial.

F. Challenged Claims

Petitioner challenges claims 1–16 of the '871 Patent. Pet. 9. Claim 1, the sole independent claim, is reproduced below:

[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) (limitations contested in Patent Owner's Preliminary Response bolded); *see* Prelim. Resp. 14.

G. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–16 of the '871 Patent on the following grounds (Pet. 9):

Ground	Claim Challenged	35 U.S.C §	Reference(s)/Basis
1	1, 3–16	102	Gelfand[3]
2	1–16	103	Gelfand, Kaiser[4]
3	3, 16	103	Gelfand, Bannon[5]
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

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

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. Because Ground 6 is, therefore, duplicative of Ground 2, we refer to them collectively as Ground 2/6, as convenient.

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. (Ex. 1004). Considering the record before us, we determine that Drs. Day and Garcia are qualified to offer testimony on the knowledge of one of ordinary skill in the art at the time of the invention. *See* Ex. 1002 ¶¶ 3–15, 27–46, 94–97 (Dr. Day's statements as to his background and qualifications, background on the relevant technology, and definition of the person of ordinary skill in the art); Ex. 1003 (Dr. Day's *curriculum vitae*); Ex. 1004, ¶¶ 4–15, 28–32, 54–57 (Dr. Garcia's statements as to his background and qualifications, background on the relevant technology, and definition of the person of ordinary skill in the art); Ex. 1005 (Dr. Garcia's *curriculum vitae*); section II.B, below (provisionally adopting Petitioner's definition of one of ordinary skill in the art).

H. Overview of Asserted References

1. Overview of Gelfand (Ex. 1006)

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

changes in that tissue." *Id.* "The area of actual destruction, or necrosis, of myocardial tissue is called the infarct size." *Id.* ¶ 7.

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

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

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

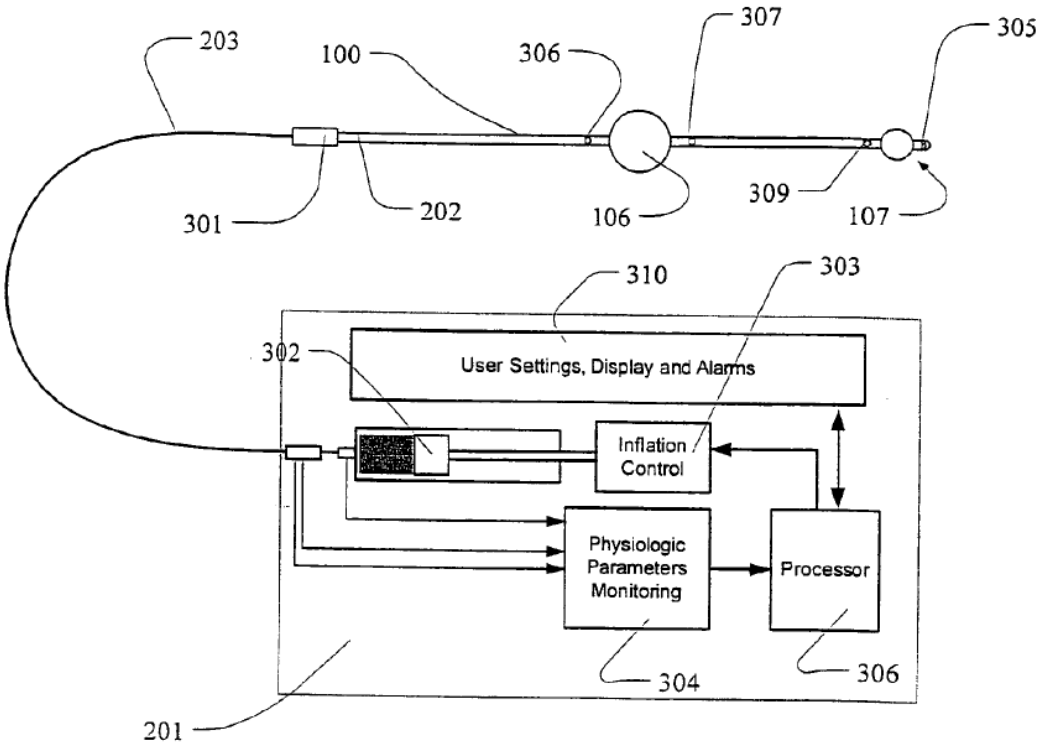
> Gelfand explains that venous blood returns to the heart
>
> predominantly via the Inferior Vena Cava (IVC) and to lesser extent via the Superior Vena Cav[a] (SVC) and coronary veins. IVC and SVC converge into the Right Atrium (RA) of the heart. If the amount of venous blood returning to the heart is 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").

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] According to Gelfand, the catheter "basically consists of the vascular catheter 100, inflatable occlusion balloon 106 proximal to the distal tip 108 of the catheter and the controller 201." *Id.* ¶ 31. Figure 3, reproduced below, shows Gelfand's catheter and associated hardware.

[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



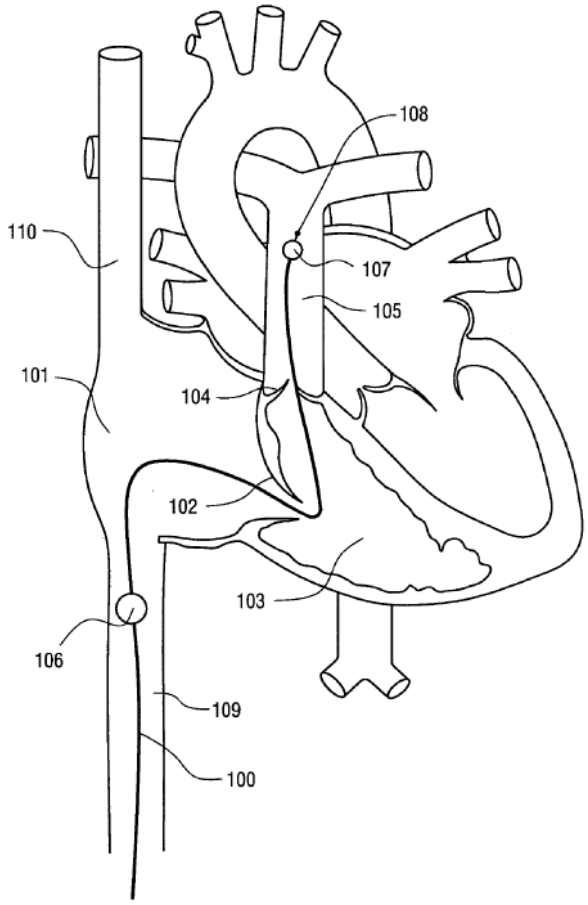
Id. ¶ 23, Fig. 3.

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

"Physiologic signals from the monitoring sub-system 304 are transmitted to the processor 306 that in turn controls the deflation and (optionally) the inflation of the balloon 106 b[]y controlling the inflation control system 302." *Id.* ¶ 51. Figure 4 (not shown) further illustrates an algorithm embedded in the software of processor 306 that uses catheter sensor information to automatically control and adjust balloon inflation to keep physiologic parameters such as blood pressure within safe limits. *See id.* ¶¶ 24, 53–54, Fig. 4.

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

Figure 1



Id. ¶ 21. Figure 1 shows catheter 100 threaded through the right atrium 101 with a distal PA balloon 107 positioned in the pulmonary artery and occlusion balloon 106 positioned in the inferior vena cava 109. *See id.* ¶¶ 28–29. Gelfand indicates that the orientation shown in Figure 1 is a preferred embodiment, but expressly teaches that

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

Id. ¶ 29 (emphasis added).

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 impendence device to "control the intra - cardiac filling pressures by creating a pressure differential in a vessel such as the inferior vena cava." *Id.* at 4:56–59, 6:49–59. Kaiser teaches that this "pressure differential may sequester extraneous blood to . . . the venous system. . . . [and] manifest an effective 'mechanical diuresis.'" *Id.* at 4:59–62. Kaiser teaches additional benefits of reducing cardiac pressure including as an aid in "remodeling that improves myocardial function and hemodynamics." *Id*. at 5:8–25.

Kaiser discloses an exemplary embodiment comprising a "catheter, lead, or elongate member"[7] and at least one adjustable component[8] (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.

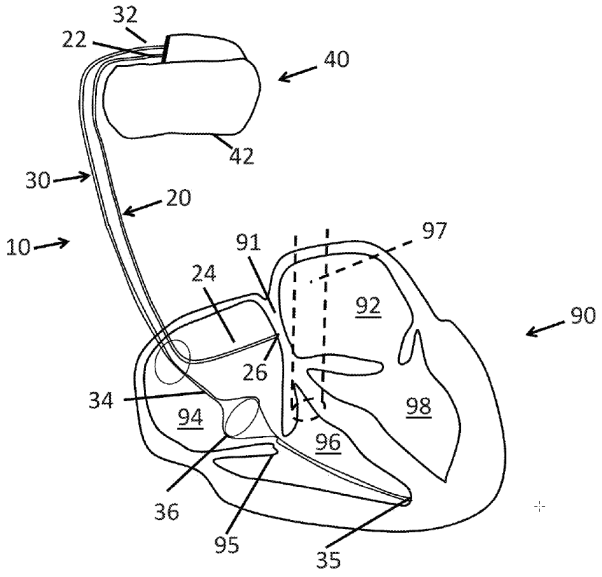


FIG. 1

[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. We note Dr. Day's umbrella terms "expandable member" or "adjustable component" as referring to any or all of these terms. *See* Ex. 1002 ¶¶ 200, 243.

Id. at 8:57–58.

Figure 1 shows a two-lead system including leads/catheters 10 and 20 connected to controller 40 at their proximal ends. Lead/catheter 30 "includes an expandable member 36 on the distal end 34, e.g., offset proximally by a predetermined distance from distal tip 35 . . . such that the expandable member 36 is located within the right atrium 94 and /or the tricuspid valve 95." *Id.* at 9:53–62; *see id.* at 10:26–29 (defining "lead 30" as a "catheter including an inflation lumen"). Kaiser teaches "expandable member 36 may be a compliant balloon configured to . . . at least partially fill right atrium 94 (or other body lumen) and/or occlude flow into or through a body lumen within or adjacent the heart." *Id.* at 10:10–15. In other embodiments, the inflatable device may be positioned to cause a pressure drop in, for example, the pulmonary artery, IVC, or SVC. *Id.* at 6:60–64, 5:64–6:2, claim 5 (reciting a "flow impedance device implantable within a patient's inferior vena cava"), claim 17 ("The method of claim 10, wherein the body lumen within which the adjustable component is positioned is one of an inferior vena cava, a superior vena cava, a right atrium, and a right ventricle of the patient's heart.").

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

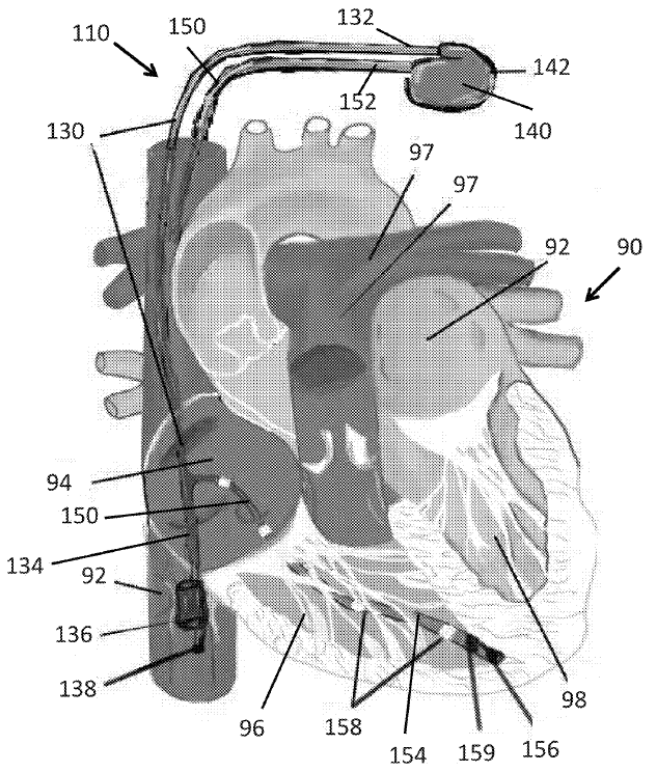


FIG. 2

Figure 2 shows an embodiment of a two-lead system similar to that depicted in Figure 1. *See generally id.* at 8:59–60, 12:7–15. In this embodiment, lead/catheter 130 includes impedance flow device 136 positioned in the inferior vena cava 92. *Id.* at 12:52–64. Figure 2 further shows sensor 138 on the distal end of lead/catheter 130, "coupled to controller 140 to measure the pressure of blood beyond the flow impedance device 136." *Id.* at 12:65–13:2. 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.

3. Overview of Bannon (Ex. 1012)

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

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

Id. at 29.

Further comparing these two preferred procedures, Bannon states that "[t]he internal jugular vein is often the access site of choice for central venous cannulation. Advantages include a superficial location, easy ultrasonic visualization, and a straight course to the superior vena cava (on the right)." *Id.* at 30. Alternatively, Bannon states that "[t]he subclavian vein, long favored by surgeons, offers an alternative to the internal jugular vein for central venous access. It may be associated with fewer infectious complications than the internal jugular vein, and will remain accessible after localized thrombosis of the internal jugular vein." *Id.* at 33 (internal footnote numbering omitted).

In contrast, Bannon teaches that "[f]emoral vein catheters are associated with higher rates of infection and thrombosis than subclavian catheters or internal jugular vein catheters. Therefore, the femoral vein is considered the third choice for catheterization and is used only when

subclavian and internal jugular approaches are not feasible." *Id.* at 37 (internal footnote numbering omitted).

II. ANALYSIS

A. Legal Standards

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

To show anticipation under 35 U.S.C. § 102, each and every claim element, arranged as in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008). The prior art need not, however, use the same words as the claims to find anticipation. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). In evaluating anticipation, it is permissible to take into account not only the literal teachings of the prior art reference, but also the inferences the skilled artisan would draw from it. *Eli Lilly and Co. v. Los Angeles Biomedical Res. Inst. at Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017) (holding that the "dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer from a prior art reference that every claim element is disclosed in that reference"); *In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995) ("A reference anticipates a

claim if it discloses the claimed invention 'such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention.'" (quoting *In re LeGrice*, 301 F.2d 929 (CCPA 1962)) (Emphasis omitted)). Moreover, "a reference can anticipate a claim even if it does not expressly spell out all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would at once envisage the claimed arrangement or combination." *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (internal quotation marks and alterations omitted). However, a patent claim "cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003).

"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) (internal quotations omitted).

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

B. Person of Ordinary Skill in the Art

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

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

> a multidisciplinary team consisting of at least (1) a person ("Engineer POSA") with either (a) a bachelor's or master's degree in mechanical engineering, biomedical engineering or a similar field, as well as two or more years of work experience with catheters or similar medical devices, or (b) a Ph.D. in mechanical or biomedical engineering, or in a similar field; working with (2) a person with an M.D. or analogous degree and five or more years of work experience in interventional cardiology, hemodynamics or a similar discipline ("Clinician POSA").

Pet. 23; Ex. 1002 ¶¶ 94–95; Ex. 1004 ¶¶ 54–55. In the second, Petitioner recasts the above team as a collection of skilled artisans in complementary fields, specifically,

> an Engineer POSA receiving assistance from, or equivalent to that provided by, a Clinician POSA; a Clinician POSA receiving assistance from, or equivalent to that provided by, an

> Engineer POSA; or a single person with the qualifications of both an Engineer POSA and a Clinician POSA.

Pet. 23; Ex. 1002 ¶ 96; Ex. 1004 ¶ 56. However phrased, Petitioner's proposed definition indicates a high level of skill in the relevant art.

Patent Owner does not presently contest the above definitions, but argues that we need not address them "[b]ecause no issue that must be decided by the Board depends on the level of ordinary skill." PO Resp. 10–11. We do not agree with Patent Owner's reasoning insofar as the perspective of one of ordinary skill in the art is critical to our patentability analyses. Our reviewing court has made clear that an understanding of a patent's claims, the teachings of the prior art, and whether a claim would have been obvious in light of those references, are all determined from the perspective of one of ordinary skill in the relevant art. *See, e.g.*, *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1360, 1361, n.3 (Fed. Cir. 2008) (citations omitted).

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

C. Claim Construction

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

Petitioner contends that one of ordinary skill in art would understand "maintaining intravascular pressure," as used in claim 5, to mean "maintaining pressure within blood vessels or a blood vessel;" "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." Pet. 23–27 (emphasis and citations omitted).

Patent Owner "does not take a position on the constructions of these terms for the purposes of this Preliminary Response because no issue that must be decided by the Board depends on them." Prelim. Resp. 11. While we agree with Patent Owner that our Decision on Institution does not depend

on a precise meaning of these claim terms, Petitioner presents reasoned argument and evidence as to their meaning, which we find useful in understanding the claims as a whole, and Petitioner's proposed definitions appear consistent with the intrinsic evidence of record. In the interest of clarity, we provisionally adopt Petitioner's proposed definitions, and invite Patent Owner to address the meaning of any relevant claim term at trial.

D. The Parties' Contentions

Petitioner contends that claims 1 and 3–16 are anticipated by Gelfand (Ground 1) (Pet. 27–54), and that claims 1–16 are rendered obvious by Gelfand alone (Ground 5), or in combination Kaiser (Ground 2/6), Bannon (Ground 3), or Kaiser and Bannon (Ground 4) (Pet. 55–101). In each case, Petitioner presents reasoned arguments for unpatentability supported by the testimony of Drs. Garcia and Day. *See generally id*. at 27–101.

In response, Patent Owner argues that the cited references do not teach elements 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 one or more sensors" (element [1f]). PO Resp. 14–25. For these elements Petitioner relies on Gelfand and Kaiser, which we address in turn.

1. Gelfand

Petitioner relies on Gelfand as supporting all asserted Grounds. Pet. 9. 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 removed). Petitioner further notes Gelfand's disclosure that "it is understood that the occlusion balloon 106, shown in the IVC 109, can be positioned in other places within the right heart and great veins such as . . . Superior Vena Cava (SVC) . . . [without] substantially chang[ing] the invented method, system or device." Pet. 38–39 (citing Ex. 1006 ¶ 29; Ex. 1002 ¶ 135) (emphasis removed). According to Petitioner, "Gelfand thus discloses advancing its catheter in the superior vena cava of a patient." *Id.* at 39 (referencing Ex. 1002 ¶¶ 131–135).

In response, Patent Owner contends that the reference "only teaches that restrictors can be used within the IVC, which is separate from and biologically different to the SVC, and which would require the use of devices and techniques that are not disclosed by Gelfand." Prelim. Resp. 15. Patent Owner argues that there are "significant biological differences between the IVC and the SVC including that the IVC is significantly larger, both in terms of its length and diameter." *Id.* at 15, 18; *see id*. at 6, 18 (asserting that the IVC has a diameter of 27–36 mm as compared to the "substantially smaller" 18–22 mm diameter of the SVC). Thus, Patent Owner argues, the IVC has "significantly more capacity to store excess

blood (known as 'capacitance') than the SCV." *Id.* at 6 (citing Ex. 2001,[9] 2002[10]); *see id.* at 18. Relying on these differences, Patent Owner concludes:

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

Id. at 18.

As an initial matter, Patent Owner's conclusion is contrary Gelfand's express teaching that the catheter's occlusion balloon can be positioned in the superior vena cava (SVC). Ex. 1006 ¶ 29; *see* Ex. 1004 ¶ 82. Moreover, we observe that "anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabling to one of skill in the art." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001) (citing *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985) ("It is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.")).[11] We further note the

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[9] Lakna, "*Difference Between Superior and Inferior Vena Cava*," Pediaa (Aug. 28, 2018), https://pediaa.com/difference-between-superior-andinferior-vena-cava/.

[10] Tucker *et al.*, "*Anatomy, Abdomen and Pelvis, Inferior Vena Cava*," (July 27, 2021), *available at* https://www.ncbi.nlm.nih.gov/books/NBK482353/.

[11] Although not expressly raised by Patent Owner, the parties are encouraged to address whether Gelfand and/or Kaiser sufficiently enables the use of a catheter balloon in the SVC. *See*, *e.g.*, *Raytheon,* 314 F.3d at 1354. ("a reference that does not provide an enabling disclosure for a particular claim

"presumption . . . that both the claimed and unclaimed disclosures in a prior art patent are enabled." *Amgen*, 314 F.3d at 1355*; see also In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012) (extending presumption to prior art printed publications). Moreover, at this stage of the proceedings, Patent Owner's conclusion is based entirely on attorney argument, which "is no substitute for evidence." *See Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989).

In contrast, Petitioner's argument that one of ordinary skill in the art would understand Gelfand to disclose the positioning requirements of elements [1d] through [1f], is supported by the testimony of Drs. Day and Garcia. Dr. Day is a biomedical engineer, focusing on "medical devices that interact with the circulatory system," and having experience with "blood flow and fluid dynamics, as well as medical devices inserted through or attached to blood vessels for cardiovascular treatment and blood flow modulation." Ex. 1002 ¶ 3; *see* Ex. 1003. Dr. Garcia is a heart surgeon with a "primary focus as an interventionalist on catheter based therapies for acute myocardial infarction, unstable coronary syndromes, classic stable angina." Ex. 1004 ¶ 6; *see* Ex. 1005.

Considering Gelfand's express teaching that the catheter balloon may be positioned in the SVC, Dr. Day testifies that, "[h]aving reviewed Gelfand's methods, systems and devices, I find that they could be used in the SVC without any substantial modification other than the catheter potentially being inserted into a vein upstream of the SVC." Ex. 1002 ¶¶ 131–135; *see also id.* ¶¶ 136–145 (similar testimony relating to elements [1e] and [1f]).

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limitation may . . . be used to supply claim elements enabled by other prior art or evidence of record").

Dr. Garcia similarly opines that "Gelfand discloses occluding the SVC or IVC with a balloon catheter device to reduce blood flow to the heart. Gelfand's catheter is a type of Swan-Ganz catheter, a commonly used catheter with which I and other clinicians are very familiar, and Gelfand discloses that its catheter can be inserted and placed using conventional techniques." Ex. 1004 ¶ 60 (citing Ex. 1006 ¶¶ 26–28 (Dr. Day's overview of therapeutic balloon catheters). Referencing Dr. Day's testimony, Dr. Garcia further states that

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

Id. ¶ 119; *see also id.* ¶¶ 83–85, 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").

With respect to the presently contested limitations of elements [1d] through [1f], Petitioner has the better position on this record. Considering the arguments and evidence presently before us, Petitioner has shown sufficiently for purposes of institution that a skilled artisan would understand Gelfand as disclosing these elements.

2. Kaiser

In addition to the teachings of Gelfand, Petitioner's Grounds 2/6 and 4 further rely on Kaiser for elements [1d] through [1f]. *See*, *e.g.*, Pet. 69–71.

As we understand Petitioner's supporting evidence, Drs. Day and Garcia explain why one of ordinary skill in the art would have recognized that Kaiser's catheter balloon or "adjustable component" can be used to occlude blood flow in the SVC. *See, e.g.*, Ex. 1002 ¶¶ 239–245, 201 (citing Ex. 1007, 5:64–6:2, 6:60–64, claims 10, 17), 277 (citing same); Ex. 1004 ¶¶ 114–118. Petitioner's declarants further testify that although Kaiser and Gelfand focus on different medical objectives, both disclose "essentially the same components" to occlude the SVC. Ex. 1002 ¶¶ 239–247, 272–282; Ex. 1004 ¶¶ 98, 110.

Focusing on Kaiser's more preferred embodiments—those having a catheter balloon in the IVC—Patent Owner argues, for example, that "Kaiser does not include any teachings whatsoever that its flow impedance device 136 may be positioned within the SVC, as required by claim element 1[d]." Prelim. Resp. 21.

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

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

> 10. A method for treating a patient with conduction disease and/or heart failure configured to monitor and/or treat the patient, comprising:
>
> **introducing a distal end of an elongate member into a venous side of a patient's heart, the distal end carrying** at least one sensor configured to provide sensor data corresponding to pressures within or near the patient's heart and **an adjustable component configured to create a pressure gradient to blood flow within or near the patient's heart**;
>
> manipulating the elongate member to position the adjustable component within a body lumen of the venous side of the patient's heart;
>
> introducing at least one pacing component into or adjacent the patient's heart;
>
> implanting **a housing containing a controller** within the patient's body adjacent the heart; and
>
> coupling the controller to the at least one sensor and the adjustable component;
>
> **wherein the controller is programmed to adjust the adjustable component based at least in part on sensor data from the at least one sensor to create a desired pressure gradient to blood flow within the patient's heart** to reduce intracardiac filling pressures within the patient's heart.
>
> 17. The method of claim 10, **wherein the body lumen within which the adjustable component is positioned in** one of an inferior vena cava, **a superior vena cava**, a right atrium, and a right ventricle of the patient's heart.

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

As indicated above, Kaiser discloses and claims a method for "introducing a distal end of an elongate member [i.e., a catheter] into a venous side of a patient's heart . . . the distal end [of the catheter] carrying . . . an adjustable component configured to create a pressure gradient to

blood flow within or near the patient's heart" (i.e., an expandable balloon or other adjustable restrictor), wherein the catheter is in communication with a "controller . . . programmed to adjust the adjustable component based at least in part on sensor data . . . to create a desired pressure gradient to blood flow within the patient's heart," and wherein "the adjustable component [e.g., balloon]" is positioned in . . . a superior vena cava." *See id.* As such, the plain language of Kaiser's claim 17, as it depends from claim 10, satisfies at least elements [1d] through [1f] of the challenged claims.

In section II.D.1, we determined Petitioner has shown sufficiently for purposes of institution that Gelfand teaches and/or suggests elements [1d] through [1f]. In light of the above, we find Petitioner has shown sufficiently for purposes of institution that Kaiser also teaches and/or suggests these elements.

III. CONCLUSION

Each of Petitioner's Grounds rely on Gelfand or Gelfand in combination with Kaiser with respect to elements [1d] through [1f]. As discussed above, Petitioner has shown sufficiently for the purpose of institution that both Gelfand and Kaiser disclose or suggest these elements. With respect to the remaining elements of claims 1–16 challenged under Grounds 1, 2/6, and 3–5, Petitioner presents reasoned arguments for unpatentability supported by the testimony of Drs. Garcia and Day, which Patent Owner does not presently contest. *See generally* Pet. 27–101; Prelim. Resp.

Having considered the record before us, we conclude that the information presented in the Petition establishes that Petitioner has shown a reasonable likelihood of prevailing in showing that claims 1–16 of the

’871 Patent are unpatentable. Accordingly, we institute *inter partes* review of the challenged claims on all grounds presented in the Petition.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is granted; and

FURTHER ORDERED that the requested *inter partes* review is instituted with respect to claims 1–16 of the ’871 Patent.

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