

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABIOMED, INC.,
Petitioner,

v.

WHITE SWELL MEDICAL LTD.,
Patent Owner.

PGR2021-00107
Patent 10,926,069 B2

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

POLLOCK, *Administrative Patent Judge*.

DECISION
Granting Institution of Post-Grant Review
35 U.S.C. § 324

I. INTRODUCTION

Abiomed, Inc. (“Petitioner”) filed a Petition for Post-Grant Review of claims 1–9 and 19–21 of U.S. Patent No. 10,926,069 B2 (Ex. 1001, “the ’069 Patent”). Paper 1 (“Pet.”). White Swell Medical Ltd. (“Patent Owner”) timely filed a Preliminary Response to the Petition. Paper 9 (“Prelim. Resp.”). Patent Owner filed a Statutory Disclaimer of claims 1, 2, 4–9, and 19–21 such that claim 3 remains as the only challenged claim. Prelim. Resp. 1; Ex. 2001. With our authorization (Paper 11), Petitioner filed a Reply to the Preliminary Response (Paper 12, “Prelim. Reply”); Patent Owner filed a corresponding Sur-reply (Paper 13, “Prelim. Sur-reply”).

Institution of post-grant review is authorized by statute only when “the information presented in the petition . . . demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” 35 U.S.C. § 324; *see* 37 C.F.R. § 42.4. Upon considering the Petition, the Preliminary Response, the additional briefing, and the cited evidence, we conclude that Petitioner has satisfied its burden under 35 U.S.C. § 324 to show that it is more likely than not that claim 3 is unpatentable.

A. Real Parties-in-Interest

Petitioner identifies itself as the real party-in-interest. Pet. 3. Patent Owner identifies itself as the real-party-in-interest. Paper 6, 1.

B. Related Matters

The parties indicate that they are not aware of any judicial or administrative matter that would affect, or be affected by, a decision in the proceeding. Pet. 3; Paper 6, 1.

C. The '069 Patent (Ex. 1001)

The '069 Patent is directed to “System and Method for Treatment of Pulmonary Edema” and describes “a method for implanting an indwelling catheter within a vein of patient,” which can create a restriction with the vein to define a localized low pressure zone adjacent to an outflow port.

Ex. 1001, code (54), Abstr.

According to the '069 Patent, under normal circulatory conditions of the arterial and venous systems, “the lymph fluid is cleared back through the lymphatic system.” *Id.* at 1:27–30. However, in pathological conditions, a pressure gradient is reduced such that the lymphatic system cannot clear additional fluid. *Id.* at 1:30–38. 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.* Accumulation of this excess fluid in the air spaces of the lungs may lead to respiratory failure. *Id.*

The '069 Patent explains that current treatments for edema employ loop diuretics or vasodilators, but these treatments are not ideal because “edema is not always alleviated rapidly enough.” *Id.* at 1:41–46. The '069 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 1:66–2:6. 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 2:6–13.

Figure 1 shows such a system of the '069 Patent and is reproduced below.

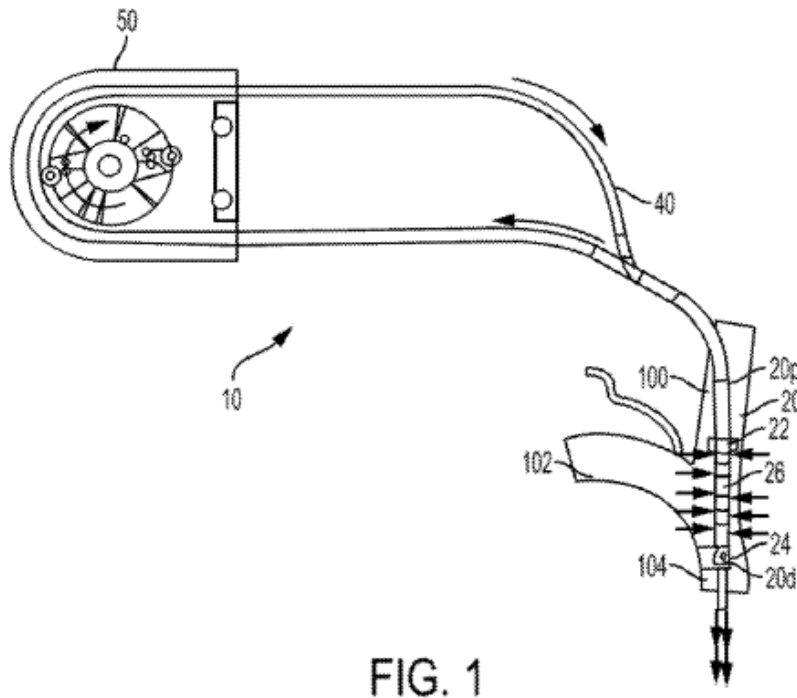


FIG. 1

Figure 1 is a schematic view of a system 10 for treating pulmonary edema. *Id.* at 4:28–29. 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 7:8–12, 49–56. 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 7:22–27. 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 7:27–31.

Figure 2 of the '069 Patent is reproduced below.

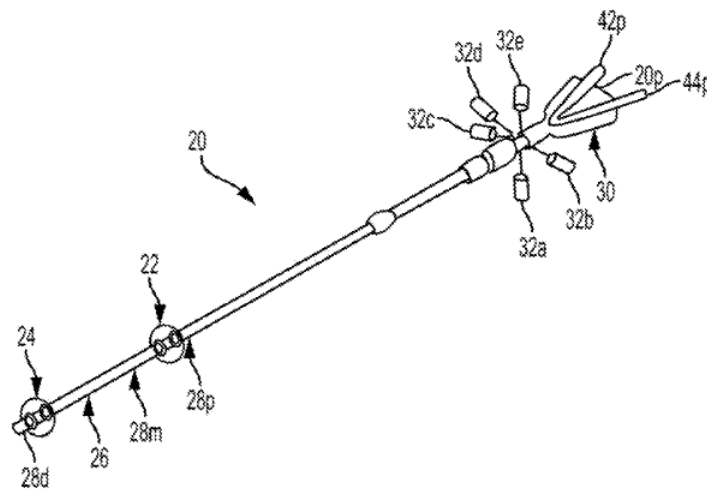


FIG. 2

Figure 2 is a perspective view of the indwelling catheter of Figure 1. *Id.* at 4:30–31. Port 32d is used to deliver fluid to restriction 22 and port 32a is used to deliver fluid to restriction 24. *Id.* at 9:1–6. 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 9:8–11.

According to the '069 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 15:9–11. Control module 200 (shown in Figure 10) receives information regarding the pressure from various locations with the veins. *Id.* at 15:12–18. 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 15:18–23.

In one embodiment, control module 200 may be configured to execute process 300, as shown in Figure 11A, reproduced below.

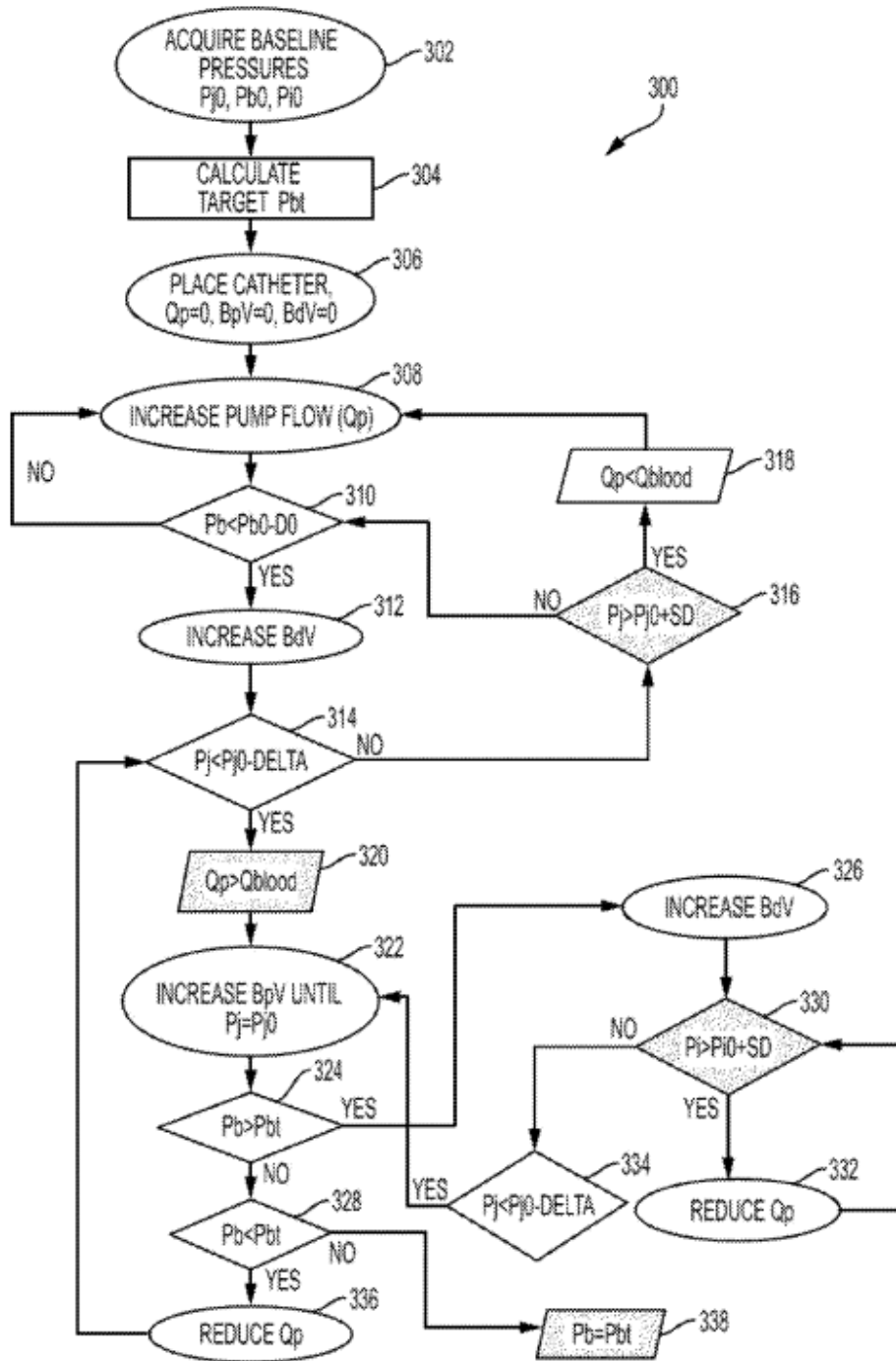


FIG. 11A

Figure 11A shows “a flow diagram for operation of a control module for a system of treating edema.” *Id.* at 5:10–12. As illustrated in Figure 11A, “at step 302 the control module can acquire the baseline measurement for the jugular pressure, the bifurcation pressure and the innominate pressure. The control module at step 304 can then calculate the target bifurcation pressure to a value typically in the range of about 3-5 mmHg.” *Id.* at 15:32–37. The process includes steps of comparing baseline pressure measurements to venous pressures and adjusting restriction inflation volumes accordingly. *See id.* at 15:15–16:34. At step 314, for example, “data from the jugular vein pressure is analyzed to determine if the jugular vein pressure is less than the baseline jugular pressure minus the minimum significant pressure deviation.” *Id.* at 15:50–54. “[I]f the jugular pressure is less than the baseline jugular pressure minus the minimum significant pressure deviation . . . [t]he process then advances to step 322 where the first restriction volume is increased until the jugular pressure is greater than the baseline jugular pressure.” *Id.* at 15:50–16:10, Fig. 11A, element 314 (“ $P_b < P_{b0} - D_0$ ”), element 322 (“INCREASE B_dV ”).

“Figure 11B is a flow diagram for an alternative technique for placing a catheter within a patient,” based on the diameter of the innominate vein. *Id.* at 5:13–15, 16:35–44. As with example illustrated in Figure 11A, the control module can measure baseline pressure data and calculate target pressure. *See id.* at 16:44–48.

At step 364, if the jugular pressure is less than the baseline jugular pressure . . . the control module applies an algorithm to analyze whether the pump flow rate is greater than the natural blood flow rate into the innominate view. Thereafter, at step 370, the proximal balloon inflation volume can be increased

until the jugular pressure is equal to the baseline jugular pressure plus a safety delta.

Id. at 16:66–17:6, *see also* Fig. 11B, element 364 ($P_j < P_{j0}$), element 370 (“INCREASE BpV UNTIL $P_j = P_{j0} = SD$ ”).

D. Challenged Claims

Petitioner challenges claim 3 of the '069 Patent. Pet. 1; Prelim. Resp.

1. Claim 3 depends from claim 2, which in turn, depends from claim 1, and claims 1–3 are reproduced below (paragraphing added).

1. A device comprising:

a catheter;

a first restrictor operably associated with the catheter

wherein the first restrictor comprises a retracted and deployed configuration and in the deployed configuration, the first restrictor comprises a diameter of a vein; and

one or more sensors positioned on the catheter and

in operable communication with the first restrictor, the one or more sensors operable to provide data that is used to alter the diameter of the first restrictor inside the vein.

Ex. 1001, 23:27–38.

2. The device of claim 1, wherein the one or more sensors comprise pressure sensors.

Id. at 23:39–40.

3. The device of claim 2, further comprising a control module for processing the data provided by the sensors, wherein

the data relates to a detected change in blood pressure, and the control module processes the data to adjust a volume of the first restrictor in response to the detected change in blood pressure.

Id. at 23:41–46.

E. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claim 3 of the '069 Patent on the following grounds:

Ground	Claim Challenged	35 U.S.C §	Reference(s)/Basis
1	3	§ 102(a)(1)	Gille503 ¹
2	3	§ 102(a)(1)	Gille501 ²
3	3	§ 102(a)(1)	Mohl ³

Pet. 5.

Petitioner submits the Declaration of Steven W. Day, Ph.D. (Ex. 1002) in support of institution of post-grant review. Based on the preliminary record before us, Dr. Day is qualified to offer testimony on the knowledge of one of ordinary skill in the art as of any of the asserted priority dates of the '069 Patent. *See, e.g., id.* ¶¶ 3–15, 23–34 (Dr. Day's statements as to his background and qualifications, and background on the relevant technology); ¶¶ 72–73 (Dr. Day's opinion regarding the definition of one of ordinary skill in the art); Ex. 1003 (Dr. Day's curriculum vitae); *see also* section II.A (discussing applicable priority dates).

F. 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.

¹ Gille et al., EP Publication No. 2353503 A1 (Aug. 10, 2011). Ex. 1004.

² Gille et al., EP Publication No. 2353501 A1 (Aug. 10, 2011). Ex. 1005.

³ Mohl, US Publication No. 2011/0295302 A1 (Dec. 1, 2011). Ex. 1006.

Cl. 1975); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*).

According to Petitioner, a person of ordinary skill in the relevant art would have “an M.D. or 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 would have “a Ph.D. in mechanical or biomedical engineering, or in a similar field.” Pet. 15 (citing Ex. 1002 ¶ 72).

Patent Owner asserts that “[b]ecause no issue that must be decided by the Board depends on the level of ordinary skill, the Board need not decide (and the Patent Owner, without waiver or disclaimer, does not address) it.” Prelim. Resp. 8.

We adopt Petitioner’s proposed level of ordinary skill to determine whether it is more likely than not that Petitioner would prevail with respect to claim 3. The parties are welcome to revisit this definition at trial.

G. 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 (2020). 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 proposes constructions for the claim terms “a retracted and deployed configuration,” and “sensors . . . in operable communication with the first restrictor.” Pet. 15–21. Petitioner draws the definitions for these terms from the description provided in the '069 Patent. *Id.* Patent Owner states that it “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. 8.

At this stage of the proceeding, we determine that construction of the identified claim terms is not necessary for purposes of this Decision. *See Vivid Techs.*, 200 F.3d at 803 (only terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy). As is evident in sections II.D and II.E, below, however, Patent Owner implicitly construes language of the asserted claims when responding to Petitioner’s anticipation arguments. We consider the meaning of that language in connection with the parties’ anticipation arguments. Although, for the purpose of institution, we provisionally apply the plain and ordinary

meaning to all disputed terms, the parties are encouraged to formally address the construction of any disputed terms at trial.

II. ANALYSIS

A. Eligibility for Post Grant Review

The post-grant review provisions set forth in Section 6(d) of the AIA⁴ apply only to patents subject to the first-inventor-to-file provisions of the AIA. *See* AIA § 6(f)(2)(A) (“The amendments made by subsection (d) . . . shall apply only to patents described in section 3(n)(1).”). Patents subject to the first-inventor-to-file provisions are those that issue from applications “that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after” March 16, 2013. *Id.* § 3(n)(1). Our rules require that each petitioner for post-grant review certify that the challenged patent has an effective filing date that renders the patent available for post-grant review. 37 C.F.R. § 42.204(a) (“The petitioner must certify that the patent for which review is sought is available for post-grant review . . .”). In addition, “[a] petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent or of the issuance of a reissue patent (as the case may be).” 35 U.S.C. § 321(c); *see also* 37 C.F.R. § 42.202(a) (accord).

Consistent with the above, Petitioner states that the ’069 Patent is eligible for post-grant review because “the ’069 Patent is a first-to-file patent having an effective filing date no earlier than June 1, 2014” and that “this

⁴ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”).

petition is being filed within nine months of the patent's issuance.” Pet. 4. Petitioner also “certifies that it is not barred or estopped from requesting such review on the identified grounds.” *Id.* Patent Owner does not dispute post-grant review eligibility for the '069 Patent. *See* Prelim. Resp., *generally*.

On this record, we determine that the '069 Patent is eligible for post-grant review. The application leading to the '069 Patent was filed on May 5, 2020, and claims priority to a series of non-provisional applications and a provisional application which was filed on June 1, 2014. Ex. 1001, (22), (63), (60). All these dates fall after March 16, 2013.⁵ Also, this Petition was filed in August, 2021, which is within nine months after the February 23, 2021, issue date of the '069 Patent. *Id.* at (45); Pet. 4.

B. Principles of Law

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). An anticipatory reference must, moreover, disclose those elements arranged as in the claim. *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 in order to find anticipation. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). It is also permissible to take into account not

⁵ Petitioner contends that the '069 Patent claims are not entitled to the priority benefit of U.S. Provisional Application No. 62/006,206, filed on June 1, 2014. Pet. 13. We need not decide this issue, however, because neither PGR eligibility, nor the prior art status of the asserted references, turns on this issue. *See* Prelim. Resp. 7.

only the literal teachings of the prior art reference, but also the inferences an ordinarily skilled person would draw from the reference. *Eli Lilly and Co. v. Los Angeles Biomedical Res. Inst.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017).

We analyze the asserted grounds of unpatentability in accordance with the above-stated principles. We begin our analysis with an overview of the asserted references.

C. Overview of Asserted References

1. Gille503 (Ex. 1004)

Gille503 is a 2010 European Patent Application for a “Catheter adapted for use in post conditioning treatment” listing Andreas Gille and Matthias Schafer as inventors. Ex. 1004, code (22), (72), (54).

Gille503 discloses a catheter having at least one balloon disposed on the exterior of a tubular body, means for inflating and deflating the balloon[s], and at least one flow or pressure sensor “chosen from sensors well known in the art.” *Id.* at Abstr., ¶¶ 5, 11, 12, claim 1. The treatment includes “dilating a constricted portion generated in a body tissue or body lumen, such as a blood vessel.” *Id.* ¶ 2.⁶ According to Gille503, embodiments of the invention may be used in percutaneous transluminal coronary angioplasty, to control blood flow in the reperfusion of

⁶ Gille503 and Gille501 are amenable to citation by paragraph and by column and line. Although both formats are used in the parties’ briefs, we generally apply the column and line format only where specifically cited by a party.

transplanted organs or tissue, and as a means to deliver drug to a vessel. *See e.g., id.* ¶¶ 16, 18, 10, 20, claims 9, 11.

Figure 1 of Gille503 is reproduced below.

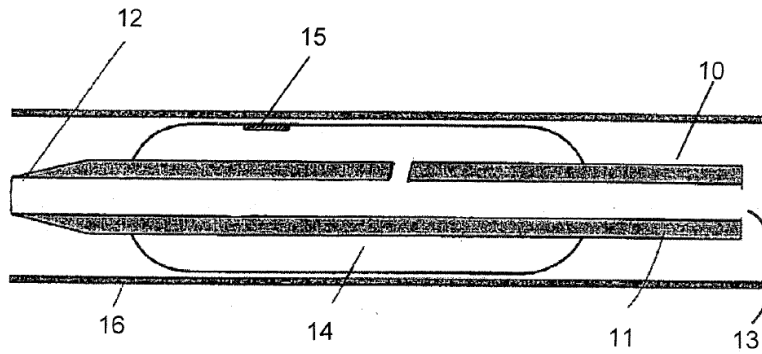


Fig. 1

Figure 1 shows catheter 10 “placed inside blood vessel 16.” *Id.* ¶ 24.

Catheter 10 includes elongated tubular body 11 and inflatable and deflatable balloon 14 which is in fluid connection to the lumen inside tubular body 11.

Id. Pressure sensor 15 is positioned on a surface of balloon 14 “facing the interior wall of the vessel.”

Gille503 discloses that

[e]specially in combination with adjustable means for inflating and/or deflating the balloon[,] the flow and/or pressure sensor can help to adjust the inflation or deflation in speed and extent to the actual needs of the patient. For example, with the inventive provision of a sensor integrally on the catheter it is possible to allow a reduced and low blood flow through the vessel during the post conditioning treatment which is found to be beneficial in comparison to a series of full inflation and deflation of the balloon and the resulting on/off behaviour of the normal blood flow in the vessel.

Id. ¶ 6. Gille503 further discloses that “[s]ignals from sensors can be transmitted to a control or a processor that in turn displays and/or controls the inflation or deflation of the balloon by influencing the inflation/deflation

means.” *Id.* ¶ 13. In one embodiment, “[o]ptimal blood flow and blood pressure in the targeted area in risk of reperfusion injury can be achieved by adjusting pre-programmed inflation and deflation series of the balloon in accordance with the actual measurements of the sensor.” *Id.* ¶ 7.

Gille503 discloses that the catheter may be “functionally connected to a controlling device for controlling the inflation or deflation of the balloon in relation to the sensed flow of a fluid and/or in relation to the sensed pressure.” *Id.* ¶ 18. In some embodiments,

the sensed pressure is the inflation pressure of the balloon or the blood-pressure. Sensing the blood pressure, especially in a continuous measurement, can give important information about the actual situation directly at the site of the treatment. In particular, a target low blood pressure during the post conditioning treatment avoiding a full sealing of the vessel can be achieved with an adjustment of the inflation extent of the balloon depending on the sensed data.

Id. ¶ 19.

Gille503 further teaches that the catheter “can comprise at least a second balloon disposed on the exterior of the tubular body.” *Id.* ¶ 20.

The sensor measurements can help to determine the exact pressure of the balloons to just seal the vessel from the blood flow without risking injury of the vessel by overexpansion or by applying too much pressure to the vessel. In addition, the provision of the second balloon can help to create a well defined passage reducing the immediate blood pressure at the first balloon when positioned proximal to the first balloon.

Id.

2. Gille501 (Ex. 1005)

Gille501 is a European Patent Application for “Computer Controlled Post-Conditioning Device,” filed the same day as Gille503 and listing the same two inventors. *See* Ex. 1005, codes (22), (72), (54).

As with Gille503, Gille501 discloses a balloon catheter, but further describes a related pump and a control unit, where control of the pump depends “on at least one physiological parameter and/or catheter specific parameter and/or in correspondence to a predefined, time-dependent algorithm according to a pre-established post conditioning perfusion protocol.” Ex. 1005, Abstr. Gille501’s ballon catheter “may be . . . suitable to perform angioplasty-like treatments, comprising at least one dilatation balloon disposed on a flexible tubular catheter body.” *Id.* ¶ 5. In some embodiments the device may be used “for the local delivery of a drug,” “in the treatment of infarctions of organs, for example lung, kidney, liver or splenic infarctions, myocardial infarct or other occlusions of body vessels or body tissues,” and “in the reperfusion of transplanted organs or tissues.” *Id.* ¶¶ 22–23, claims 12, 13.

Figure 1 of Gill501 is reproduced below.

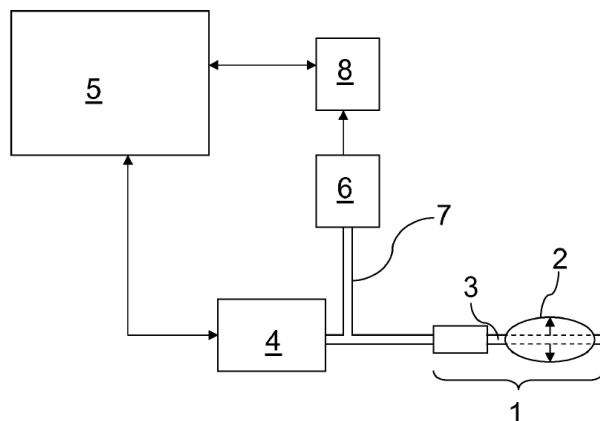


Fig.1

Figure 1 shows schematically the components of a medical device of Gille501. *Id.* ¶ 24. Balloon catheter 1 includes at least one inflatable and deflatable balloon 2 that is fluidly connected to first lumen 3 for inflation and deflation. *Id.* ¶ 25. Pump 4 is fluidly connected to balloon catheter 1. *Id.*

According to Gille501,

the physiological parameter which is chosen to be used in the control of the pump is selected from the group consisting of systemic blood pressure, blood pressure before the balloon catheter, blood pressure behind the balloon catheter, blood flow before the balloon catheter, blood flow behind the balloon catheter, the heart rate and/or electrocardiogram and can advantageously be used to stay within desired physiological limits.

Id. ¶ 15. “The measured physiologic signals, for example monitored by pressure sensors and/or flow sensors integrated in the balloon catheter, or positioned on the balloon catheter, can be transmitted to the control unit which in turn controls the pump and thereby the inflation and deflation of the balloon.” *Id.*

Gille501 further states that in some embodiments,

the catheter-specific parameter is the inflation pressure of the balloon and/or the perfusion pressure of a pumped fluid and/or the volume of the pumped fluid. The balloon inflation and therefore also the degree of obstruction of the blood flow can be controlled, for instance, periodically or continuously based on the pressure signal.

Id. ¶ 16. Gille501 teaches that such a device may comprise “at least one pressure transducer for measuring the physiological parameter and/or catheter-specific parameter and for submitting a signal to the control unit.”

Id. ¶ 17. “[B]alloon inflation may be controlled, based on the systemic blood pressure or on other above mentioned physiological parameters or catheter

specific parameters or a combination of two or more thereof.” *Id.*

“[R]epeated inflation and deflation of the balloon can be performed with continuous or periodic adjustment and/or maintenance of beneficial physiological limits or in beneficial predetermined limits.” *Id.*

3. Mohl (Ex. 1006)

Mohl is directed to systems and methods for treating heart tissue, including “instruments for intermittently occluding the coronary sinus using a coronary sinus occlusion catheter device.” Ex. 1006, Abstr. As explained by Dr. Day, “[t]he coronary sinus is a vein through which blood flows from other veins on the outside of the heart muscle (the myocardium) into the right atrium of the heart.” Ex. 1002 ¶ 96.

Mohl’s systems include a control system that activates an inflatable balloon device “as part of a predetermined pattern of occlusion periods and release periods that is independent of the coronary sinus pressure or as part of a pressure-dependent pattern that is at least partially defined by the coronary sinus pressure readings during the procedure.” Ex. 1006 ¶ 6.

Mohl’s Figure 1 is reproduced below.

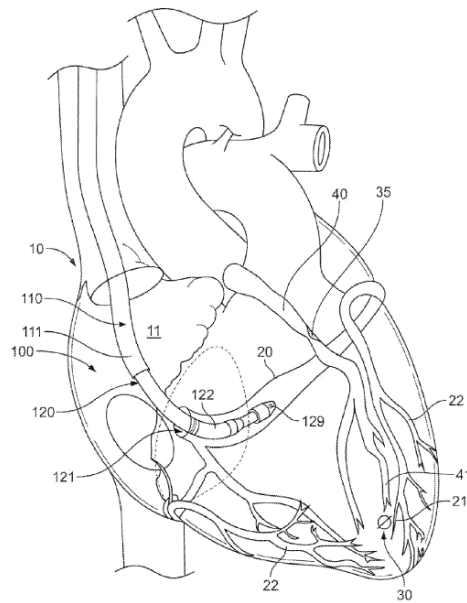


FIG. 1

Figure 1 shows a perspective view of a portion of Mohl's system for treating heart tissue. *Id.* ¶ 11. System 100 includes sinus occlusion catheter 120 that can be arranged in and to occlude a coronary sinus 20 such that “the venous blood flow that is normally exiting from the coronary sinus 20 may be redistributed into a portion of heart muscle tissue 30 that has been damaged due to blood deprivation or loss of functional myocardium.” *Id.* ¶¶ 23–24. Occlusion is accomplished using occlusion component or inflatable balloon device 122 that is positioned at distal tip portion 121 of sinus occlusion catheter 120. *Id.* ¶ 30. Inflatable balloon device 122 is in fluid communication with the internal lumen of sinus occlusion catheter 120, which is in turn, in communication with a control system to inflate inflatable balloon device 122. *Id.* Distal tip 121 includes one or more distal ports 129 that may be “in fluid communication with a single pressure sensor lumen extending through the coronary sinus occlusion catheter 120” such that “the

coronary sinus pressure can be monitored via a pressure sensor device that is in fluid communication with the distal ports 129.” *Id.* ¶ 31.

Figure 5 of Mohl is reproduced below.

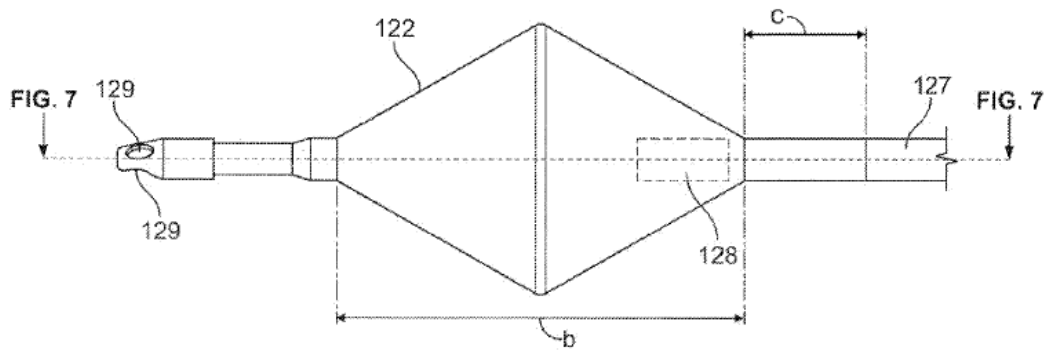


FIG. 5

Figure 5 shows a side view of a portion of Mohl's catheter device. *Id.* ¶ 15. Inflatable balloon device 122 of Mohl's catheter device is shown in an inflated condition. *Id.* ¶¶ 15, 49.

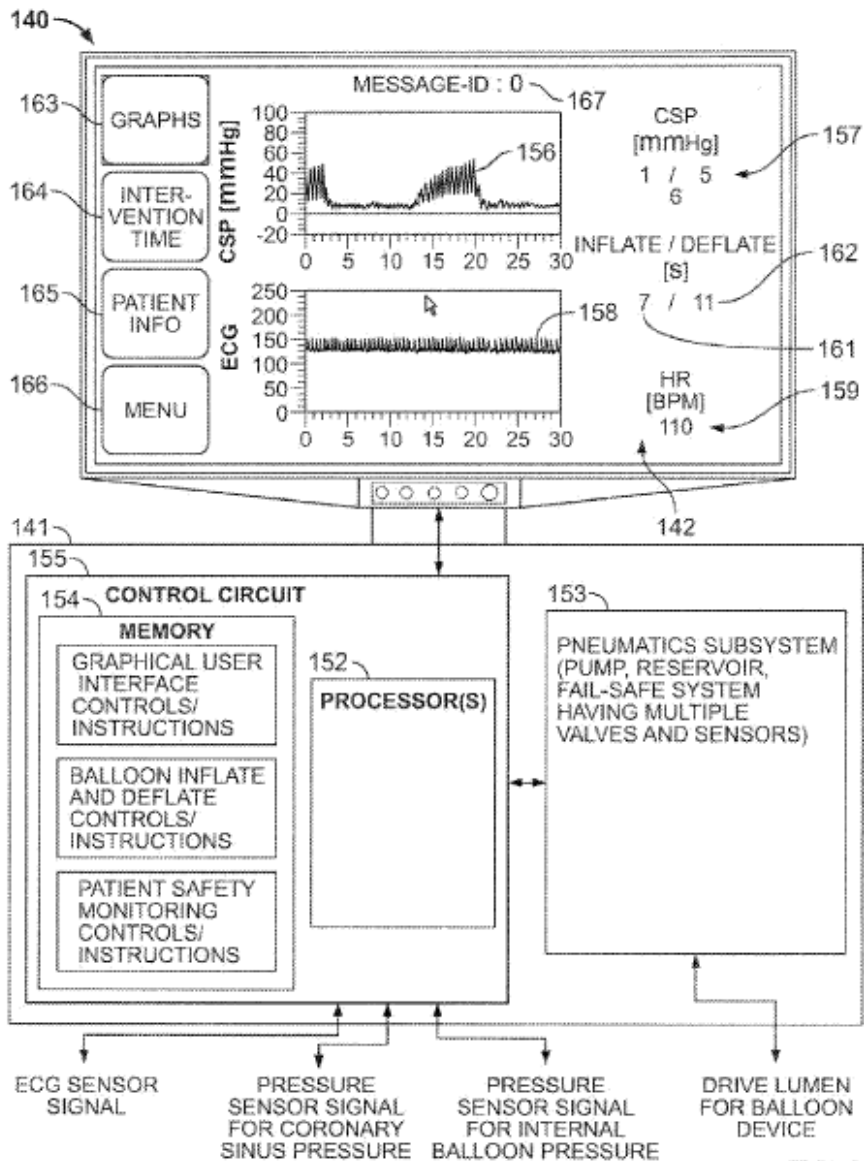


FIG. 3

Figure 3 shows a diagram of an exemplary control system of Mohl's system for treating heart tissue. *Id.* ¶ 13. Control system 140 is used to “activate or deactivate the occlusion component 122 at the distal tip portion 121 of the coronary sinus occlusion catheter 120 while also receiving one or more sensor signals that provide data indicative of heart characteristics (e.g.,

coronary sinus pressure, electrocardiogram (ECG) information, and the like).” *Id.* ¶ 33.

As shown in Figure 3, control system 140 contains a control circuit 154 that includes balloon inflate and deflate software to implement “a customized algorithm that calculates and updates the time periods during which the coronary sinus is in an occluded state and in a non-occluded state based upon the coronary sinus pressure measurements.” *Id.* ¶ 43. Control circuit 154 may, therefore “execute the balloon inflate and deflate software module and communicate with the pneumatic subsystem 153 so as to inflate and deflate the balloon device 122 according to the customized algorithm that is dependent upon the coronary sinus pressure measurements in the patient.” *Id.*; *see also id.* ¶ 56 (“In particular embodiments, the control system 140 (FIGS. 2–3) can activate and deactivate the balloon device 122 (causing inflation and deflation) according to . . . a pressure-controlled intermittent coronary sinus occlusion (time periods are dependent upon the coronary sinus pressure measurements).”).

D. Anticipation by Gille503 (Ex. 1004) and Gille501 (Ex. 1005)

In Ground 1, Petitioner asserts that claim 3 is unpatentable under 35 U.S.C. § 102(a)(1) as being anticipated by Gille503. Pet. 5, 21–32; Prelim. Reply 1–3. Patent Owner opposes. Prelim. Resp. 10–14; Prelim. Sur-Reply 1–3. In Ground 2, Petitioner similarly asserts that claim 3 is unpatentable as anticipated by Gille501. Pet. 5, 40–53; Prelim. Reply 1–3. Patent Owner opposes. Prelim. Resp. 15–18; Prelim. Sur-Reply 1–3. Petitioner characterizes Gille501 as “a somewhat broader and, in some respects, more detailed version of Gille 503” (Pet. 42) and the parties present essentially the same arguments for Grounds 1 and 2. *See e.g.*, Prelim. Reply 1–3

(consolidated arguments for Grounds 1 and 2); Prelim. Sur-Reply (same). Considering the overlap in disclosure and argument, we focus on Gille503 and Ground 1 in deciding whether to institute trial.

Claim 3—as it depends from claims 1 and 2—requires a catheter comprising “one or more sensors operable to provide data that is used to alter the diameter of the first restrictor inside the vein,” wherein “the data relates to a detected change in blood pressure,” and “[a] control module processes the data to adjust a volume of the first restrictor in response to the detected change in blood pressure.” With respect to these elements, Petitioner asserts that Gille503 discloses a catheter comprising “at least one flow sensor and/or at least one pressure sensor.” Pet. 29 (citing Ex. 1004, 1:55–2:10, 2:12–17, 3:15–16, 3:18–19, 4:6–7; Ex. 1002 ¶¶ 124–125). Petitioner contends that Gille503 discloses “a first restrictor operably associated with the catheter” and, in particular, an “inflatable and deflatable” balloon disposed in a blood vessel. *See, e.g., id.* at 25–26 (citing Ex. 1004, 1:56–2:5, 5:27–29, 6:6–8, Fig. 1; Ex. 1002 ¶¶ 110–112). Petitioner further contends that Gille503 discloses a control module for processing data provided by the pressure sensors to control inflation or deflation of the balloon. Pet. 29–32 (citing, *e.g.*, Ex. 1004, 2:18–22, 3:30–33, 4:33–37, 4:56–5:7, Ex. 1002 ¶¶ 126–129, 133–136). And although Gille503 does not expressly refer to operation of the balloon catheter in a patient’s “vein,” as recited in independent claim 1, Petitioner contends that Gille503’s repeated use of the term “blood vessel” encompasses the use of the device in both arteries and veins. Pet. 27–28 (citing Ex. 1004, 1:5–9, 2:12–17, 2:24–25, 3:1–5, 5:44–49, 5:50–52; Ex. 1002 ¶¶ 80, 122–123).

1. *“wherein the data relates to a detected change in blood pressure, and the control module processes the data to adjust a volume of the first restrictor in response to the detected change in blood pressure”*

Patent Owner contends that Ground 1 fails because “Gille503 does not describe sensors that provide data that relates to a detected change in blood pressure,” and adjust the volume of a catheter balloon (restrictor) in response to those changes, as claim 3 requires. Prelim. Resp. 11. Moreover, Patent Owner asserts, Gille503 “do[es] not disclose detecting a change in blood pressure *at all*.” Prelim. Sur-reply, 1.

Gille503 discloses sensors continuously measuring blood pressure and adjusting the inflation of the balloon depending on that sensed data. *See* Ex. 1004, 4:56–5:7. According to Patent Owner, Gille503’s sensor data does not “relate[] to a detected change in blood pressure,” as required by claim 3 because “inflation or deflation of [the] balloon [is] based on the instantaneous blood pressure meeting a certain condition, not in response to a detected change in blood pressure.” Prelim. Resp. 11. More specifically, Patent Owner argues that

measuring something continuously is not the same as detecting a change in what is being measured. Gille503 does not disclose that any comparison is ever made between an earlier measured blood pressure and a later measured blood pressure, as would be required to detect a change based on continuous measurements. Rather, all Gille503 describes is taking continuous measurements, one after the other, and acting on each measurement independently.

Id. at 12 (citing Ex. 1004, 4:56–5:15). Thus, according to Patent Owner, rather than detecting a “change in blood pressure,” the passages in Gille503 relied on by Petitioner merely describe “a comparison [of instantaneous

blood pressure readings] to an arbitrary and artificial target.” *See* Prelim. Sur-reply 1 (further arguing that “Gille503 and Gille501 are not able to detect any changes in pressure that do not result in the pressure deviating from the predetermined target”).

We do not find Patent Owner’s argument availing on the present record. While we do not fault its assertion that “the plain language of claim 3 expressly requires that the collected data ‘relates to a *detected change* in blood pressure,’” nothing in the record persuades us that this term excludes detecting a change in blood pressure based on a comparison to some predetermined target, as is taught in Gille503. Moreover, as noted by Petitioner, claim 3 recites that the sensor data “‘*relates to* a detected change in blood pressure.’ Claim 3 does not say the data *comprises* ‘a detected change in blood pressure.’” Prelim. Reply 1. And though Patent Owner asserts that this claim term is supported by the ’069 Patent’s teaching that “changes can be detected, for example, by using the sensors to establish a ‘baseline measurement’ and then comparing subsequent measurements to the baseline,” we decline to read this exemplary embodiment into the challenged claim. Prelim. Sur-reply 1 (citing Ex. 1001, 15:25–16:10, Fig. 11A).

In similar respect, we also note Patent Owner’s argument that Gille503 is

not able to detect changes in pressure that do not result in the pressure deviating from the predetermined target. If the pressure is above the target and then drops (or increases) but still remains above the target, comparisons to the target value will not enable the detection of those changes, and no adjustments will be able to be made based on them.

Id. at 2–3. Nothing in claim 3 requires that all pressure changes are detected, or that every detected pressure change results in adjustment of the balloon.

Our understanding of the plain language of claim 3 is supported by the '069 Specification, which discloses adjustment of balloon pressure upon detecting a “minimum significant pressure deviation” and, thus, implies a minimum activation threshold for responding to a detected pressure change. *See* Prelim. Reply 4–5 (citing Ex. 1001, 16:3–10; Prelim. Resp. 5). Accordingly, we decline to import elements of Patent Owner’s hypothetical into the challenged claim.⁷

By way of clarification, we note that both Gille503 and '069 Specification teach the use of conventional pressure sensors. *See* Prelim. Reply, 1 (citing Ex. 1001, 9:24–25; Ex. 1004, 3:12–13). According to claim 1, from which claim 3 depends, such sensors are “operable to provide data that is used to alter the diameter of the first restrictor inside the vein,” whereas claim 3 adds that “the control module processes the data to adjust a volume of the first restrictor in response to the detected change in blood pressure.” The challenged claim thus indicates that although the sensor “data relates to a detected change in blood pressure,” it is the control module that is responsible for processing the data received from the sensors. *See id.* at 2 (discussing, *e.g.*, Ex. 1001, Fig. 11A); Prelim. Resp. 10. In this respect, it would appear that the blood pressure sensors detect blood pressure and any

⁷ Patent Owner also appears to suggest that Ground 1 fails because Gille503 “does not describe whether the pressure signal needs to be measured continuously.” Prelim. Resp. 16. Again, we do not recognize such a requirement in claim 3. *But see* Ex. 1004 ¶19 (“Sensing the blood pressure, especially in a continuous measurement, can give important information about the actual situation directly at the site of the treatment.”), ¶16 (embodiment providing “continuous information” regarding blood pressure readings at proximal and distal sensors).

change in blood pressure is assessed by the control module. In any event, and considering the preliminary record before us, we do not read claim 3 to require either the blood pressure sensors or control module to make a direct comparison of sequential blood pressure readings as Patent Owner appears to propose.

In light of the above, we find unavailing Patent Owner's argument that because Gille503 "do[es] not detect any changes in pressure," any adjustments to "the inflation of the balloon [are] based on the relation of the measured pressure to the desired limit, not based on any change in the pressure." Prelim. Resp. 17; Prelim. Sur-reply 1–2. To the contrary, Petitioner has sufficiently shown that Gille503 discloses sensor "data relat[ing] to a detected change in blood pressure," and that a control module "processes the data to adjust a volume of the first restrictor in response to the detected change in blood pressure," as required by claim 3. *See, e.g.*, Ex. 1004 ¶¶ 7, 19–20.

2. *"one or more sensors operable to provide data that is used to alter the diameter of the first restrictor inside the vein"*

Claim 1, from which claim 3 depends, requires "one or more sensors operable to provide data that is used to alter the diameter of the first restrictor inside the vein." With respect to this limitation, Patent Owner argues that Gille503 fails to disclose adjustment in the volume of the balloon "inside [a] vein" as required by the challenged claim. Prelim. Resp. 13–14; Prelim. Sur-reply 3. Noting that Gille503 does not use the word "vein" and states that its device was "developed . . . for revascularization of stenotic and occluded body vessels, *such as coronary arteries*," Patent Owner argues

that Gille503 neither describes nor suggests that it could be used in veins.
Prelim. Resp. 14.

Patent Owner’s argument is unavailing on the present record. As set forth in section II.C.1, above, Gille503 teaches that its balloon catheter has broad application in angioplasty, reperfusion of organs or tissue, and the delivery of drugs to blood vessels. And although Gille503 uses the general term “blood vessel,” we do not read the reference as excluding the use of the catheter in veins. Further considering Dr. Day’s presently unopposed testimony, we accept for the purpose of institution that (1) the ordinary meaning of “blood vessel” includes both veins and arteries; and (2) one of ordinary skill in the art would understand that the angioplasty, reperfusion, and drug delivery techniques disclosed in Gille503 could be performed in veins. *See* Ex. 1002 ¶¶ 80, 122–123. As such, Petitioner has sufficiently shown that Gille503 discloses “one or more sensors operable to provide data that is used to alter the diameter of the first restrictor inside the vein,” as required by the challenged claim.

In sum, Petitioner has shown sufficiently that one of ordinary skill in the art likely would have considered claim 3 of the ’069 Patent anticipated by Gille503 for the reasons set forth in Ground 1. Considering the similarities between Gille503 and Gille501, and the parties’ arguments thereon, Petitioner has likewise satisfied this threshold with respect to Ground 2.

E. Anticipation by Mohl (Ex. 1006)

In Ground 3, Petitioner asserts that claim 3 is unpatentable under 35 U.S.C. § 102(a)(1) as being anticipated by Mohl. Pet. 5, 63–84; Prelim.

Reply 4–6. Patent Owner opposes. Prelim. Resp. 19–21; Prelim. Sur-Reply 1–3.

1. “*wherein the data relates to a detected change in blood pressure*”

Relevant to claim 3’s recital of sensor data “relat[ing] to a detected change in blood pressure,” Mohl discloses a control system that activates an inflatable balloon device “as part of a predetermined pattern of occlusion periods and release periods that is independent of the coronary sinus pressure *or as part of a pressure-dependent pattern that is at least partially defined by the coronary sinus pressure readings during the procedure.*” Ex. 1006 ¶ 6 (italics added). In arguing anticipation, Petitioner points, in particular, to Figure 3 of Mohl, wherein control circuit 155 within control system 140 receives ECG signals, and pressure sensor signals for internal balloon pressure and coronary sinus pressure. *See* Pet. 82–84. As highlighted by Petitioner, Mohl states that “control system 140 can activate or deactivate the occlusion component 122 at the distal tip portion 121 of the coronary sinus occlusion catheter 120 while also receiving one or more sensor signals that provide data indicative of heart characteristics (e.g., coronary sinus pressure, electrocardiogram (ECG) information, and the like.” Ex. 1006 ¶ 33; Pet. 83. Petitioner further points to Mohl’s teaching that, also within control system 140, software “stored on the memory device 154 can implement a customized algorithm that calculates and updates the time periods during which the coronary sinus is in an occluded state and in a non-occluded state *based upon the coronary sinus pressure measurements.*” Pet. 84 (quoting Ex. 1006 ¶ 43). Relying on the testimony of Dr. Day, Petitioner concludes that “[b]ecause the sensor on Mohl’s catheter monitors

coronary sinus blood pressure, it can detect any change in blood pressure, and this data is sent to the control system.” Pet. 83 (citing Ex. 1002 ¶ 248).

Patent Owner responds that, as with “Gille503 and Gille501, measuring blood pressure is not the same as detecting a change in blood pressure” and Ground 3 fails because “the Petition fails to establish that Mohl describes sensors that provide data that relates to a detected change in blood pressure.” Prelim. Resp. 19. We do not find Patent Owner’s argument persuasive. *See, generally*, section II.D.1, above.

As noted above, Mohl discloses that an algorithm directs the timing for inflation and deflation of the balloon “based upon the coronary sinus pressure measurements,” *i.e.*, based on changes in blood pressure data provided by the sensors. Ex. 1006 ¶ 43. As we read Mohl, there would be no need for such an algorithm if the system did not detect—and subsequently respond to—changes in blood pressure. But because Mohl does teach adjusting the balloon “based on” blood pressure measurements provided by blood pressure sensors, we presently understand Mohl as disclosing sensor data that “relates to a detected change in blood pressure,” as required by the challenged claim.

In addition to the arguments raised with respect to Gille503 and Gille501, Patent Owner raises a claim differentiation argument:

Claim 2 of the ’069 patent requires that the data used to alter the diameter of the claimed first restrictor comes from “pressure sensors.” If data from pressure sensors necessarily related to detected changes in blood pressure, it would not have been necessary for claim 3 to separately recite this requirement. Thus, if Petitioner’s reasoning were correct that Mohl’s disclosure of a pressure sensor that monitors blood pressure is sufficient to disclosure that the pressure sensor detects changes in blood pressure, the language of claim 3 of the ’069 patent

requiring that the data from the claimed pressure sensors “relates to a detected change in blood pressure” would be superfluous, which is disfavored.

Prelim. Resp. 20 (citing *Comark Commc’ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998)); *see* Prelim. Sur-reply 4. For the reasons set forth on pages 3 and 4 of Petitioner’s Preliminary Reply, we do not agree with Patent Owner that its claim differentiation argument is determinative here. As noted by Petitioner, claim 3 recites a “control module” that processes a subset of the sensor data that can be provided by the sensors introduced in claim 1. *See* Prelim. Reply 4. In particular, claim 1 broadly recites “one or more sensors operable to provide data,” claim 2 limits the genus of sensors to “pressure sensors,” and claim 3 discloses that a control module processes a subset of the data provided by the pressure sensors that “relates to a detected change in pressure.” As such, we need not resort to claim differentiation in determining the scope of the challenged claim.

2. *“the control module processes the data to adjust a volume of the first restrictor in response to the detected change in blood pressure”*

In addressing claim 3, Petitioner relies, in part, on Mohl’s teaching that “the **balloon inflate and deflate software module** stored on the memory device 154 can implement a customized algorithm that calculates and updates the time periods during which the coronary sinus is in an occluded state and in a non-occluded state **based upon the coronary sinus pressure measurements.**” *See* Pet. 84 (quoting Ex. 1002 ¶ 43); Ex. 1002 ¶¶ 250–252. As articulated by Petitioner’s expert:

Because Mohl’s pressure sensor monitors blood pressure in the coronary sinus, it detects any change in that blood pressure. (Ex-1006 at ¶¶ [0033], [0043].) Mohl’s “control system” (the

claimed “control module”) receives this sensor data, and its processor(s) uses the data in executing the software module that controls balloon inflation and deflation, which adjusts when the balloon inflates and deflates. (*Id.* at ¶¶ [0040], [0043].) Adjusting inflation or deflation of the balloon results in adjusting its volume, as stated in Claim 1[e].

Ex. 1002 ¶ 252 (further referencing Ex. 1002 ¶¶ 27, 235–236).

Patent Owner contends, however, that Petitioner’s evidence “fails to establish that Mohl discloses adjusting the volume of a restrictor *in response to* a detected change in blood pressure,” as required by claim 3. Prelim. Resp. 20; *see* Prelim. Sur-reply 5–6. Patent Owner first argues that “updat[ing] the time periods during which the coronary sinus is in an occluded state and in a non-occluded state based upon the coronary sinus pressure measurements,” as taught by Mohl, “does not adjust the volume of the restrictors,” but only “updates [] time periods.” Prelim. Resp. 21; Prelim. Sur-reply 5; Ex. 1006 ¶ 43.

We do not find Patent Owner’s argument availing on the present record. Claim 3 does not state that “the control module processes the data to *directly* adjust a volume of the first restrictor in response to the detected change in blood pressure,” and Patent Owner provides no justification for reading this limitation into the claim. Applying the plain and ordinary meaning to the language of claim 3, we consider Dr. Day’s presently undisputed testimony that processors in Mohl’s control module use data from blood pressure sensors in executing software that controls balloon inflation and deflation, which adjusts when the balloon inflates and deflates. Ex. 1002 ¶ 252 (citing Ex. 1002 ¶¶ 40, 43). Considering the disclosed process as a whole, Dr. Day reasonably concludes that “[a]djusting inflation or deflation of the balloon results in adjusting its volume.” *Id.* Accordingly,

Petitioner has sufficiently shown that Mohl’s “control module processes the data to adjust a volume of the first restrictor,” as required in claim 3.

We further understand Patent Owner to argue that each time Mohl’s software updates the time period for coronary sinus to be in the occluded or non-occluded state, “the volume of the balloon does not necessarily change”—i.e., not *every* update will initiate a change between inflation states. Prelim. Resp. 21. But as explained in section II.D.1, above, we do not read claim 3 as requiring every detected pressure change to result in adjustment of the balloon. Accordingly, Patent Owner’s argument is unavailing.

Patent Owner next argues that Mohl fails to disclose a catheter balloon adjusted “in response to the detected change in blood pressure,” because its “time periods for the coronary sinus to be maintained in an occluded or non-occluded state are determined based on signals from *multiple* sensors.” Prelim. Resp. 21–22 (emphasis added); *see* Prelim. Sur-reply 5–6. Patent Owner references, for example, Mohl’s disclosure that “a control circuit that activates a pneumatic subsystem to inflate or deflate the inflatable balloon device of the coronary sinus occlusion catheter for a selected period of time based at least in part on the pressure signal indicative of the coronary sinus pressure,” and that Mohl’s “control system 140 may . . . receiv[e] one or more sensor signals that provide data indicative of heart characteristics (e.g., coronary sinus pressure, electrocardiogram (ECG) information, and the like).” *See id.*; Ex. 1006 ¶¶ 9, 23.

On page 6 of its Preliminary Sur-reply, Patent Owner further references Mohl’s teaching that in some “embodiments, the control system 140 (FIGS. 2–3) can activate and deactivate the balloon device 122 (causing

inflation and deflation) according to . . . a pressure-controlled intermittent coronary sinus occlusion (time periods are dependent upon the coronary sinus pressure measurements).” Ex. 1006 ¶ 56. Summarizing its position, Patent Owner contends that Mohl does not adjust the time periods for balloon inflation “in response to” detected changes in blood pressure but “in response to a multi-part algorithm.” Accordingly, “[t]hat the time periods are ‘dependent’ (in part) on the coronary sinus pressure measurements according to [Mohl’s] ¶ 56 does not establish that they are adjusted ‘in response to’ changes in such measurements.” Prelim. Sur-reply 6.

Patent Owner’s argument is unavailing on the present record. Patent Owner fails to explain why we should read claim 3 to require that “the control module processes the data to adjust a volume of the first restrictor [*solely*] in response to the detected change in blood pressure.”⁸ We also recognize Petitioner’s arguments that in teaching embodiments where balloon inflation is “at least partially” controlled by coronary sinus pressure, the reference implicitly “contemplates that inflation may be controlled solely by such readings.” *See* Pet. Reply 5–6. While we do not make a final determination on this record, Petitioner’s argument is sufficient for institution and has not been rebutted on the present record.

In a related argument, Patent Owner contends that Ground 3 is defective because “Mohl discloses that the actual timing of the inflation or

⁸ To the extent we may be persuaded otherwise on a fuller record, a discussion of how one of ordinary skill in the art would understand Mohl’s teaching that in some embodiments, “time periods [controlling balloon inflation/deflation states] are *dependent upon* the coronary sinus pressure measurements),” would be helpful. *See* Ex. 1006 ¶ 56 (*italics added*).

actual inflation or deflation of the balloon is determined by data from the *ECG* sensors, not the pressure sensors” and, thus, fails to disclose inflation or deflation of the balloon “in response to the detected change in blood pressure,” as recited in claim 3. Prelim. Resp. 22; *see* Prelim. Sur-reply 6. In this respect, Patent Owner relies on the embodiment set forth in paragraph 37 of Mohl, which “may include one or more ECG sensors 139 to output ECG signals to the control system 140.” Ex. 1006 ¶ 37. We note, however, that the reference repeatedly suggests that ECG is an *optional* component of the described system. *See id.* ¶ 9 (“The system may also include . . . an electrocardiogram (ECG) signal input”), ¶ 23 (“control system 140 may . . . receiv[e] one or more sensor signals . . . e.g., . . . electrocardiogram (ECG) information”), ¶ 33 (same). As such, and for the additional reasons described above, Patent Owner’s argument is not availing on the present record.

We further note Mohl’s teachings that inflation and deflation of the catheter balloon is controlled “at least partially . . . by the coronary sinus pressure readings during the procedure.” Ex. 1006 ¶ 6; *see id.* ¶ 56 (“In particular embodiments, the control system 140 (FIGS. 2–3) can activate and deactivate the balloon device 122 (causing inflation and deflation) according to . . . a pressure-controlled intermittent coronary sinus occlusion (time periods are dependent upon the coronary sinus pressure measurements).”). As discussed above, we do not read claim 3 to require detected changes in blood pressure be the sole determinant for adjusting the claimed restrictor. Thus, irrespective of whether Mohl requires the use of ECG sensor signals to contribute “to properly time the start” of the inflation and deflation periods of the balloon, Petitioner has sufficiently established that Mohl teaches

“adjust[ment] of a volume of the first restrictor in response to the detected change in blood pressure,” as required by claim 3.

In sum, Petitioner has shown sufficiently that one of ordinary skill in the art would have considered claim 3 of the '069 Patent anticipated by Mohl for the reasons set forth in Ground 3.

III. CONCLUSION

For the foregoing reasons, we conclude that the information presented in the Petition establishes that it is more likely than not that Petitioner would prevail in showing that claim 3 of the '069 Patent is unpatentable. Accordingly, we institute post grant review of challenged claim 3 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 post-grant review is instituted with respect to claim 3 of the '069 Patent.

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