

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*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Granting-in-Part Patent Owner's Motion to Amend
35 U.S.C. § 328(a)

I. INTRODUCTION

A. Procedural Background

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 was the only remaining challenged claim. Prelim. Resp. 1; Ex. 2001. With our authorization (Paper 11), Petitioner filed a Reply to the Preliminary Response (Paper 12); Patent Owner filed a corresponding Sur-reply (Paper 13). Taking into account the arguments and evidence presented, we determined the information presented in the Petition established that Petitioner satisfied the burden, under 35 U.S.C. § 324(a), to show that it was more likely than not that Petitioner would prevail with respect to at least one of the challenged claims. Accordingly, we instituted a post-grant review of claim 3 on all the asserted grounds. Paper 14 (“DI”), 37.

After institution, Patent Owner declined to file a Response to the Petition. Patent Owner instead filed a Non-Contingent Motion to Amend requesting cancelation of claim 3 in favor of proposed substitute claim 22 (“claim 22”). *See* Paper 17 (“MTA”). Petitioner opposed the Motion (Paper 18, “Opp. MTA”), and we provided Preliminary Guidance (Paper 20). Patent Owner subsequently filed a Reply in support of its motion (Paper 22, “Reply MTA”); Petitioner responded with an authorized Sur-reply (Paper 29, “Sur-reply MTA.”).

On October 27, 2022, the parties presented arguments at oral hearing, the transcript of which is of record. Paper 32 (“Tr.”).

B. 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.

C. 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 27, 1. Patent Owner, however, identifies four *inter partes* review proceedings “that relate to patents that share a common specification and priority claim with the [’069 Patent].” Paper 27, 1. The following table identifies these related proceedings by case numbers and their respective patent numbers:

Case No.	U.S. Patent No.
IPR2021-01477	10,653,871
IPR2021-01478	10,653,871
IPR2021-01564	10,639,460
IPR2021-01565	10,639,460

D. 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.

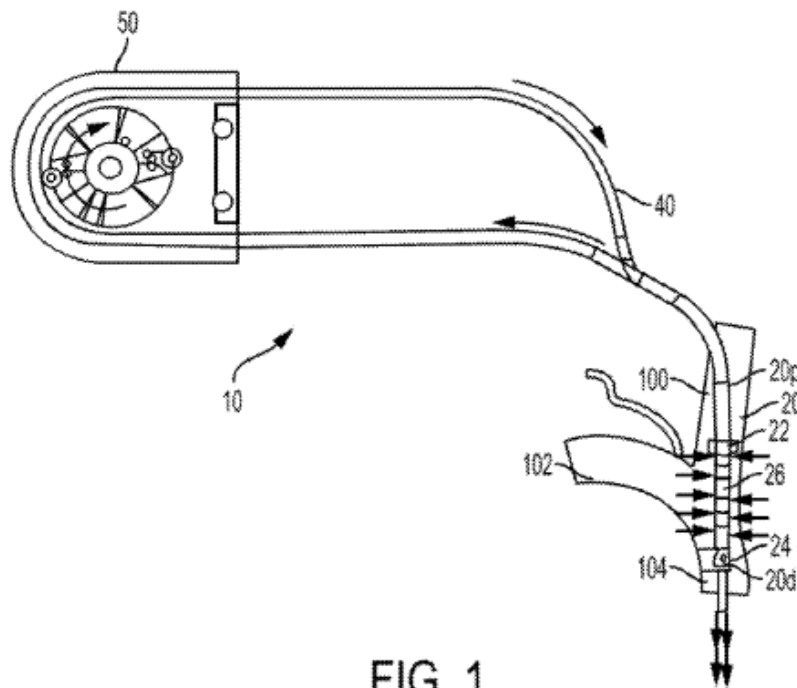


FIG. 1

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.

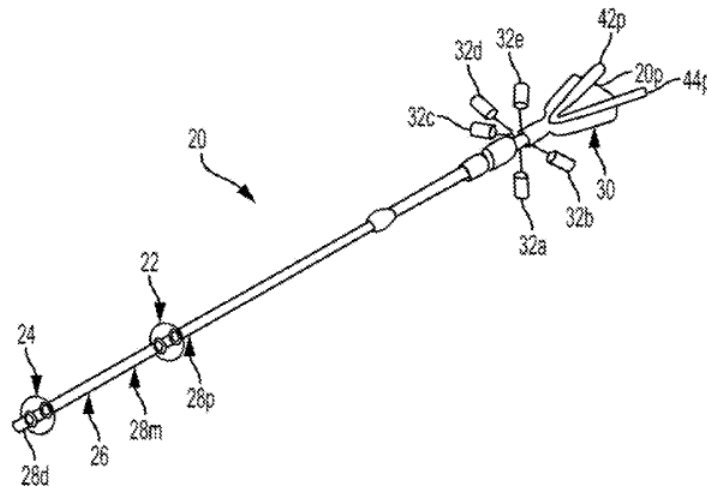


FIG. 2

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.

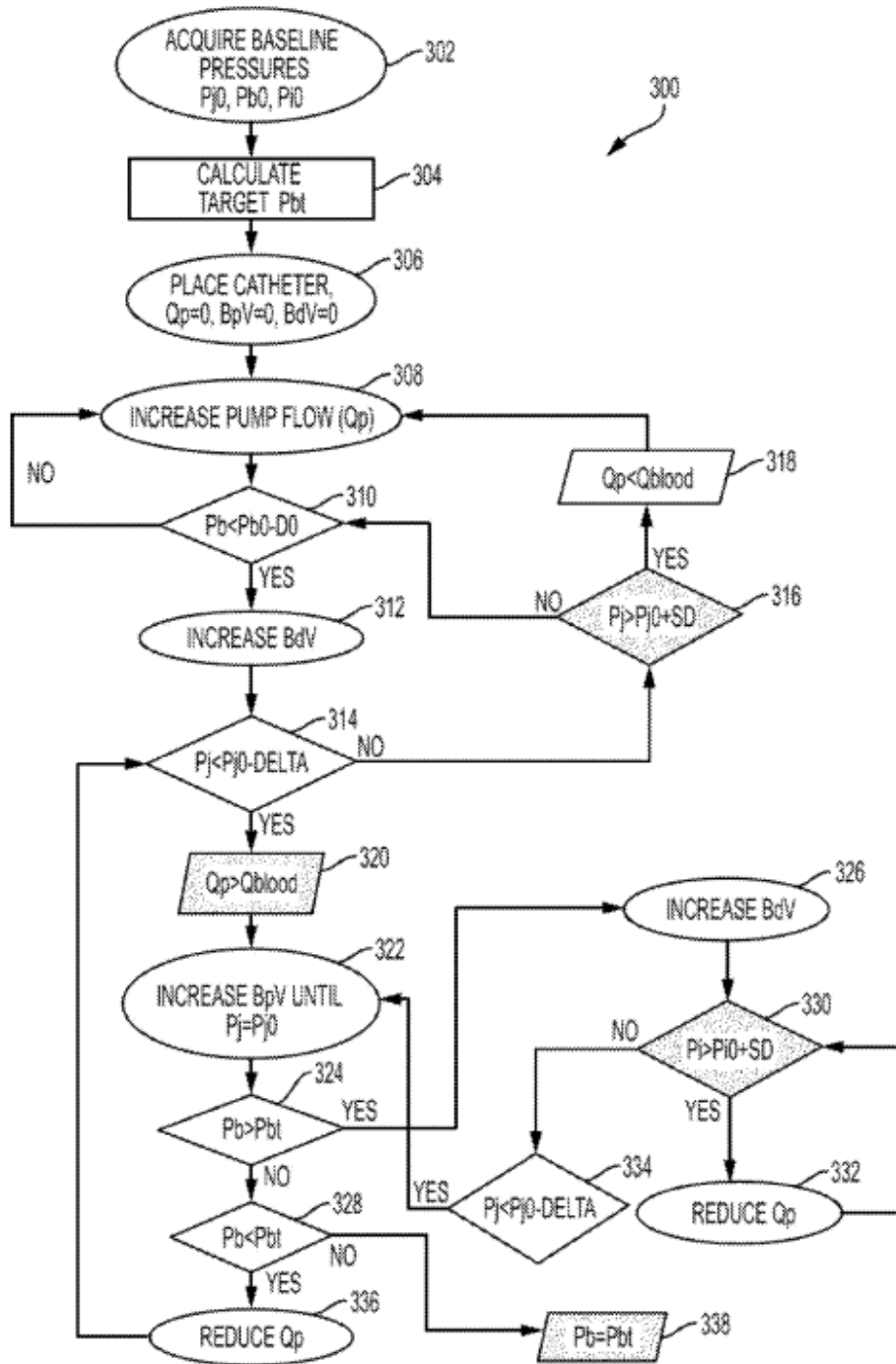


FIG. 11A

Figure 11A shows “a flow diagram for operation of a control module for a system of treating edema.” *Id.* at 5:10–12. “The control module 200 can include multiple feedback loops to adjust performance of the system.” *Id.* at 15:25–26.

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. For example, “[a]t step 310 the control module determines if the [bifurcation] pressure is less than the baseline bifurcation pressure minus the pressure drop indicator. If this proves to be the case, the control process advances to step 312 and increases the volume of the second restriction.” *Id.* at 15:37–46. And at step 314, “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 BdV ”).

“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 the 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 $P_j = P_{j0} + SD$ ”).

E. Challenged Claim

For the reasons noted in Section I.A, above, claim 3 (as it depended from claims 1 and 2) was the only challenged claim addressed in our Institution Decision. *See* DI 2, 8. After institution, Patent Owner requested cancelation of claim 3 and entry of proposed substitute claim 22. MTA. Patent Owner’s request to cancel claim 3 is *granted*. *See* 37 C.F.R. § 42.221(a)(3) (“A motion to amend may cancel a challenged claim”). As such, claim 22 is the sole claim at issue in this proceeding.

Incorporating language from original claims 1, 2, and 3, claim 22 recites:

± 22. 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[.]],

~~2. The device of claim 1,~~ wherein the one or more sensors comprise pressure sensors[.]]; and

~~3. The device of claim 2, further comprising~~ a control module for processing the data provided by the sensors, wherein the ~~data relates~~ control module compares a blood pressure measurement provided by the sensors to a baseline blood pressure measurement to ~~a detected a~~ detected a change in blood pressure[.]] and ~~the control module processes the data to~~ directly adjusts a volume of the first restrictor in response to the detected change in blood pressure.

MTA, 29–30 (Appendix A) (strike-outs and brackets indicating deleted text; added text underlined).

For clarity and ease of discussion, we also reproduce proposed claim 22 with paragraphing and lettering added, deletion and insertion markings omitted, and disputed elements indicated by italics.

22. A device comprising:

[a] a catheter;

[b] a first restrictor operably associated with the catheter,

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

[d] one or more sensors positioned on the catheter and

[e] 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*,

- [f] wherein the one or more sensors comprise pressure sensors; and
- [g] a control module for processing the data provided by the sensors,
- [h] *wherein the control module compares a blood pressure measurement provided by the sensors to a baseline blood pressure measurement to detect a change in blood pressure, and*
- [i] *directly adjusts a volume of the first restrictor in response to the detected change in blood pressure.*

See id.

F. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claim 22 on the following grounds:

Claim Challenged	35 U.S.C §	Reference(s)
22	102	Gille503 ¹
22	102	Gille501 ²
22	103	Gille501, Gille503
22	103	Mohl996 ³
22	103	Levin ⁴
22	103	Levin
22	103	Mohl302 ⁵

Opp. MTA 7–25.

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 et al., US Pat. No. 4,934,996, issued June 19, 1980. Ex. 1016.

⁴ Levin, US Publication No. 2006/0100639 A1 (May 11, 2006). Ex. 1015.

⁵ Mohl302, US Publication No. 2011/0295302 A1 (Dec. 1, 2011). Ex. 1006.

Petitioner relies on the Declaration of Steven W. Day, Ph.D. Ex. 1002; *see also* Ex. 1025 (Dr. Day's updated curriculum vitae); Ex. 2002 (transcript of Dr. Day's deposition); Ex. 1026 (errata to transcript). Patent Owner relies on the Declaration of Mr. Boris Leschinsky. Ex. 2006; *see also* Ex. 1035 (transcript of Mr. Leschinsky's deposition).

G. 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). By way of background, "[P]ost - conditioning treatment is a procedure that is performed after a vessel that was previously occluded (such as due to a myocardial infarction ("MI")) is reopened in order to reduce what is known as reperfusion injury." Ex. 2006 ¶ 41.

Dr. Day provides the following overview of reperfusion and reperfusion injury:

"Reperfusion" is the process of restoring blood flow to body tissues or organs, especially ischemic tissues. "Ischemic" tissues are tissues that have been deprived of blood for some period of time, usually because the vessels that supply blood to the tissue were partially or fully blocked. Sudden restoration of circulation to ischemic tissues may lead to inflammation and other damage, which is known as "reperfusion injury." Post conditioning treatment seeks to avoid reperfusion injury by using a balloon catheter or similar device to variably or intermittently occlude a blood vessel to or from the ischemic tissue, thereby controlling the blood flow to the treated area and reducing the risk of damaging that area.

Ex. 1002 ¶ 29.

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.” Ex. 1004, 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 transplanted organs or tissue, and as a means to deliver drug to a vessel. *See e.g., id.* ¶¶ 16, 18, 10, 20, 22, claims 9, 11.

Figure 1 of Gille503 is reproduced below.

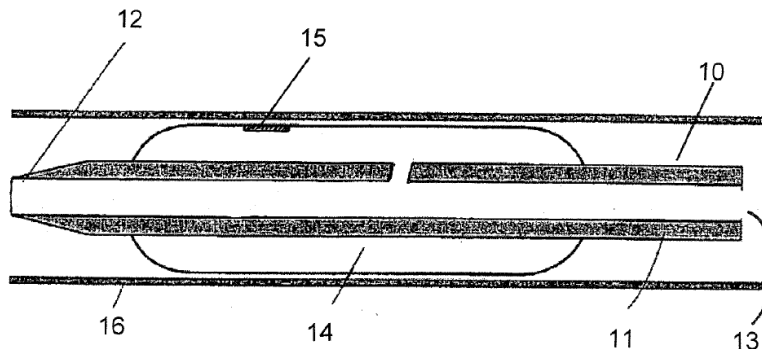


Fig. 1

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.

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.

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

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 discloses that “the catheter comprises means for a local delivery of a drug,” which may involve delivery via “a separate lumen in the tubular body or a coating on the balloon or a delivery via pores in the balloon.” *Id.* ¶ 21. 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. Gille503 explains that the dual balloon embodiment may also be used for drug delivery. *See id.* ¶ 16 In particular,

adjusting the inflation of the two balloons to just seal the vessel in the area between the two balloons allows the exact targeted application of a drug to the area and at the same time controlling the application time of the drug as well as the subsequent transport of the drug downstream when the balloons are (slowly) deflated.

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. Despite its title, Gille501 is not limited to post-conditioning, and its balloon 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 Gille501 is reproduced below.

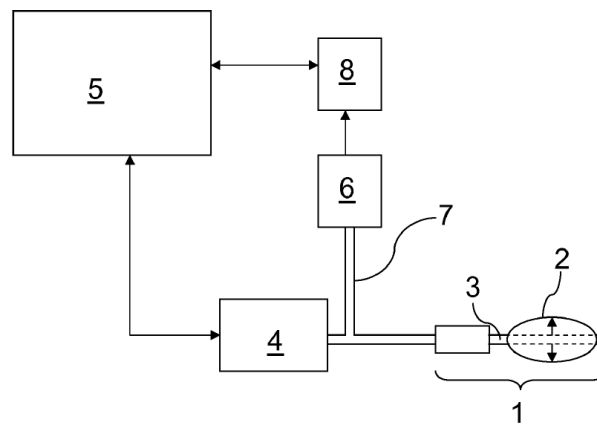


Fig.1

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.* “The control unit may advantageously be capable of storing data, for example relevant parameters of the performed procedure, especially the intermittency patterns, or for example data of physiological parameters of the treated patient.” *Id.* ¶ 9.

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.”

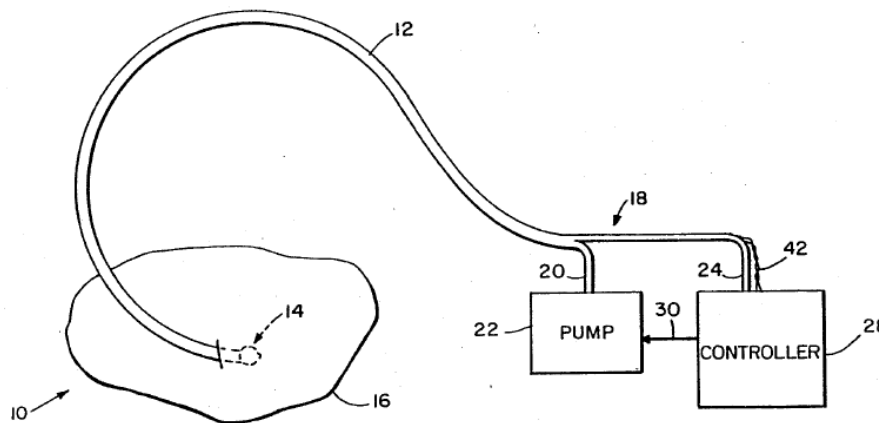
Id. ¶ 17. “[B]alloon inflation may be controlled, based on the systemic blood pressure or on other above mentioned physiological parameters or catheter specific parameters or a combination of two or more thereof.” *Id.*

“[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. Mohl996 (Ex. 1016)

Mohl996 is directed to a “Pressure-Controlled Intermittent Coronary Sinus Occlusion Apparatus and Method.” Ex. 1016; *see generally* Ex. 1014 ¶¶ 143–154, 211–213. Mohl996 discloses “means for occluding the sinus, a pressure transducer for sensing the fluid pressure within the sinus and providing corresponding fluid pressure signals, and a controller responsive to the transducer and arranged to provide trigger signals to the occluding means to trigger an occlusion and to interrupt the occlusion.” Ex. 1016, 1:51–57.

Mohl996’s Figure 1 is reproduced below.



Id. at Fig. 1. Figure 1 is a diagrammatic view of a heart with an intermittent coronary sinus occlusion apparatus. Ex. 1016, 3:33–34. Figure 1 shows

intermittent coronary sinus occlusion apparatus 10 includ[ing] multi-lumen catheter 12 having its distal end 14 inserted into the coronary sinus of heart 16 via the right atrium. The proximal end 18 of catheter 12 has a balloon inflation lumen 20 connected to pump 22. A second lumen 24, coaxial with lumen 20, and wires 42 are connected to controller 28 which contains

circuitry for delivering control signals over line 30 to trigger the starting and stopping of pump 22.

Id. at 3:62–4:2. Referring to Figure 2A [not shown], at distal end 14 of catheter 12, lumen 20 communicates with inflatable balloon 34 via proximal aperture 32. Lumen 24 passes through the balloon and exits distally via aperture 36. *Id.* at 4:3–8. “Changes in blood pressure in the sinus are transmitted to the proximal end of lumen 24, and are sensed at controller 28.” *Id.* at 4:11–13.

Figure 1A of Mohl996 is reproduced below.

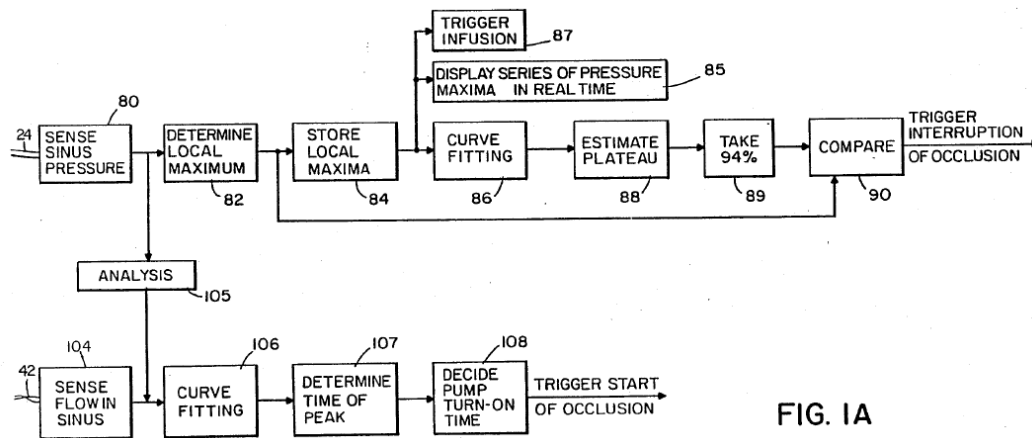


FIG. 1A

Id. at Fig. 1A. Figure 1A shows a flow chart for the operation of the apparatus of Figure 1A. *See id.* at 3:62–4:3. “[P]rocessor 56 samples (80) the output of interface 54 many times in each heart pulse . . . and stores the pressure samples in RAM 60. It then compares successive samples to determine the local maximum pressure for each heartbeat.” *Id.* at 5:13–18. Processor 56 then performs a curve fitting routine . . . [and] compares (90) each newly calculated local maximum with the 94% value and when a local maximum first reaches at least that 94% value, (e.g., at time 92 in FIG. 4) processor 56 triggers the pump to evacuate, or provide negative pressure to, lumen 20, thus interrupting the inflation of balloon 34 before the plateau is

reached. *Id.* at 5:18–34. “[A]fter pump cutoff, the curve of the local pressure maxima falls off to its baseline level 40 until, at time 100, the pump is turned on again and the cycle repeats.” *Id.* at 5:39–42.

Consistent with the above, Mohl996 claims

12. A method for intermittently occluding a coronary sinus, comprising
providing means for occluding said sinus and for measuring the local pressure maximum within said sinus during each heartbeat,
causing occlusion of said sinus,
measuring the local pressure maxima for successive heartbeats during said occlusion, said method being characterized by the steps of
estimating the plateau level of said local pressure maxima,
and
interrupting said occlusion on the basis of said estimate.

Id. at 9:30–42; *see also id.* at 8:33–47 (claim 1).

4. Levin (Ex. 1015)

Levin discloses “a method for reducing reperfusion injury after therapeutic reperfusion of an infarct of a heart or other organ.” Ex. 1015 ¶ 2; *see also id.* at code (54), ¶ 11 (disclosing methods and systems “to reduce the severity and complications of MI [myocardial infarct] by . . . moderating reperfusion injury”). Levin explains that acute myocardial infarction can result in irreversible damage to the heart where the heart muscle is deprived of adequate levels of oxygenated blood. *Id.* ¶ 3.

Treatment of acute myocardial infarction or myocardial ischemia often comprises performing angioplasty or stenting of the vessels to increase the size of the vessel opening to allow increased blood flow. . . . [T]herapeutic strategies that restore

blood flow, as opposed to just letting the patient rest, are called reperfusion. *Id.*

But “[i]f the ischemic episode has been of sufficient severity and/or duration to cause significant changes in the metabolism and the structural integrity of heart muscle, reperfusion may paradoxically result in a worsening of heart function.” *Id.* ¶ 4. This “[r]eperfusion injury occurs in the short period of time immediately following the transition from the metabolic famine to feast.” *Id.* ¶ 5. Levin explains that reperfusion injury can be reduced by “ischemic preconditioning, in which repetitive brief periods of ischemia protect[] the myocardium from a subsequent longer ischemic insult.” *Id.* ¶¶ 7–11.

Accordingly, Levin discloses “[a] method and apparatus for the prevention and treatment of reperfusion injury following the reperfusion of acute MI [myocardial infarct] which includes modulation of coronary blood flow or oxygen delivery following the reperfusion of the infarct with a catheter placed in the coronary artery or vein.” *Id.* code (57). In particular,

the flow of blood to the ischemic and infarct effected regions of the heart is modulated by graded, partial and/or intermittent obstruction of the coronary artery that supplies blood to the infarct area or by partial, and/or graded and/or intermittent obstruction of the coronary sinus or major coronary veins that drain into the coronary sinus.

Id. ¶ 86.

Levin teaches that it may be advantageous “to post-condition[] the heart by obstructing the venous coronary blood flow. It is generally safer and does not interfere with other therapeutic manipulations associated with the catheterization of the coronary artery.” *Id.* ¶ 50. Thus, and referring to Figure 5 (not shown), Levin teaches that, “[i]n the preferred embodiment the

catheter 501 with an occluding or partially occluding balloon 502 mounted close to the distal catheter tip 505 of the catheter is used to cannulate the Coronary Sinus (CS) 504 of the heart.” *Id.* ¶ 52.⁷ In this embodiment, “the catheter tip balloon can be manipulated to create graded (partial) occlusion or to intermittently occlude CS [coronary sinus].” *Id.* ¶ 53; *see also id.* ¶ 35 (“FIG. 10 further illustrates post-conditioning by gradual occlusion of the coronary sinus using pressure feedback.”).

Levin’s Figure 6 is reproduced below.

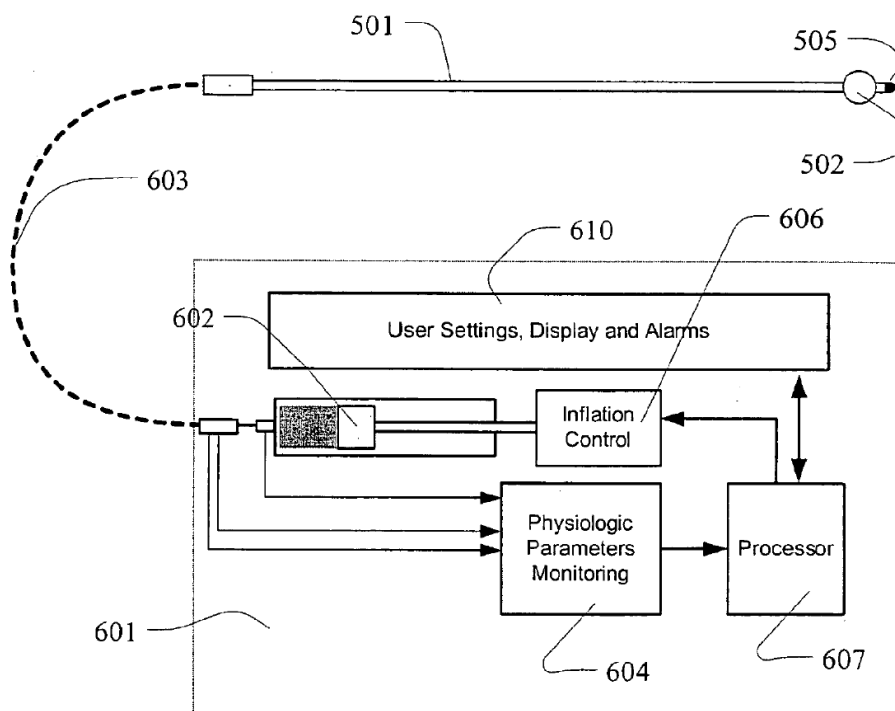


Figure 6 is a schematic representation of “of the preferred embodiment of the invention related to the monitoring of the patient’s CS or Coronary Artery pressure and controlling of the occlusion balloon inflation and

⁷ Dr. Day explains that “[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. 1014 ¶ 135; *see* Ex. 1015 ¶ 86.

deflation.” *Id.* ¶¶ 31, 56. Figure 6 shows “Catheter 501 . . . equipped with the expandable balloon 502.” “Controller console 601 includes the balloon inflation device 602.” *Id.* ¶57. “Inflation and deflation of the balloon 502 by the inflation device 602 is controlled by the inflation control electronics 606.” *Id.* ¶ 58. “Pressure can be measured using an invasive blood pressure sensor mounted on the tip 505 of the catheter 501.” *Id.* ¶ 54; *see also* ¶ 59 (“Advanced micro tip catheter blood pressure transducers . . . can be integrated with the catheter to obtain reliable and accurate measurements of pressure in the CS of the heart.”). “The balloon 502 inflation and consequently the degree of obstruction to blood flow can be controlled continuously based on the CS pressure feedback to maintain CS pressure within desired physiologic limits.” *Id.* “[A]lgorithms such as Proportional Integral (PI) feedback controller can be used to maintain a physiologic parameter (such as CS pressure or CSvO₂) or a calculated index at the target level or within the desired range.” *Id.* ¶ 61.

5. Mohl302 (Ex. 1006)

Mohl302 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. Mohl302’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.” *Id.* ¶ 6.

Mohl302's Figure 1 is reproduced below.

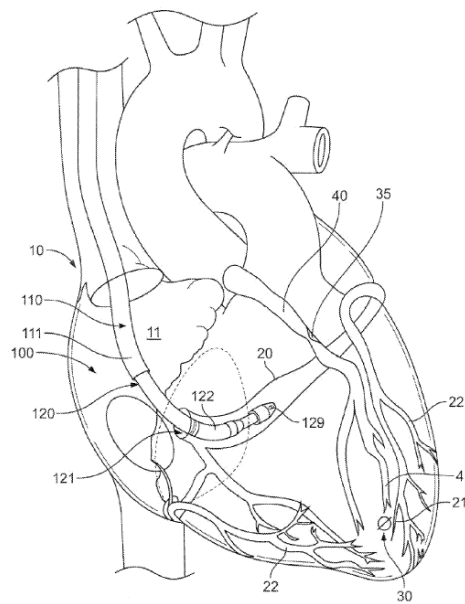


FIG. 1

Figure 1 shows a perspective view of a portion of Mohl302'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 Mohl302 is reproduced below.

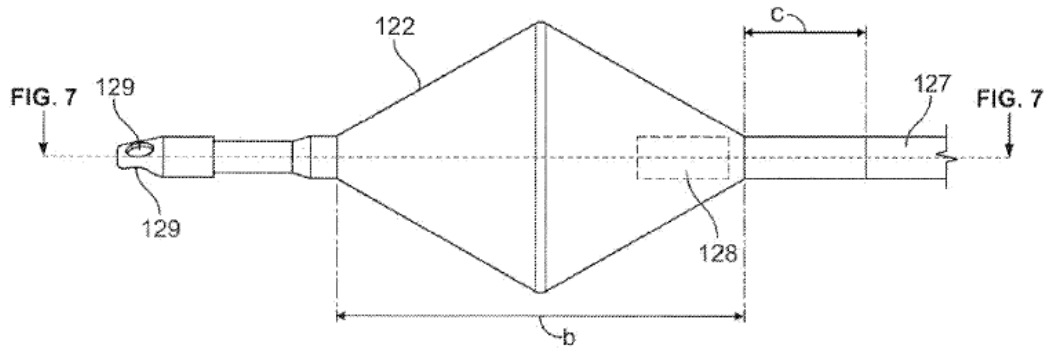


FIG. 5

Figure 5 shows a side view of a portion of Mohl302's catheter device. *Id.*

¶ 15. Inflatable balloon device 122 of Mohl302's catheter device is shown in an inflated condition. *Id.* ¶¶ 15, 49.

Figure 3 of Mohl302 is reproduced below.

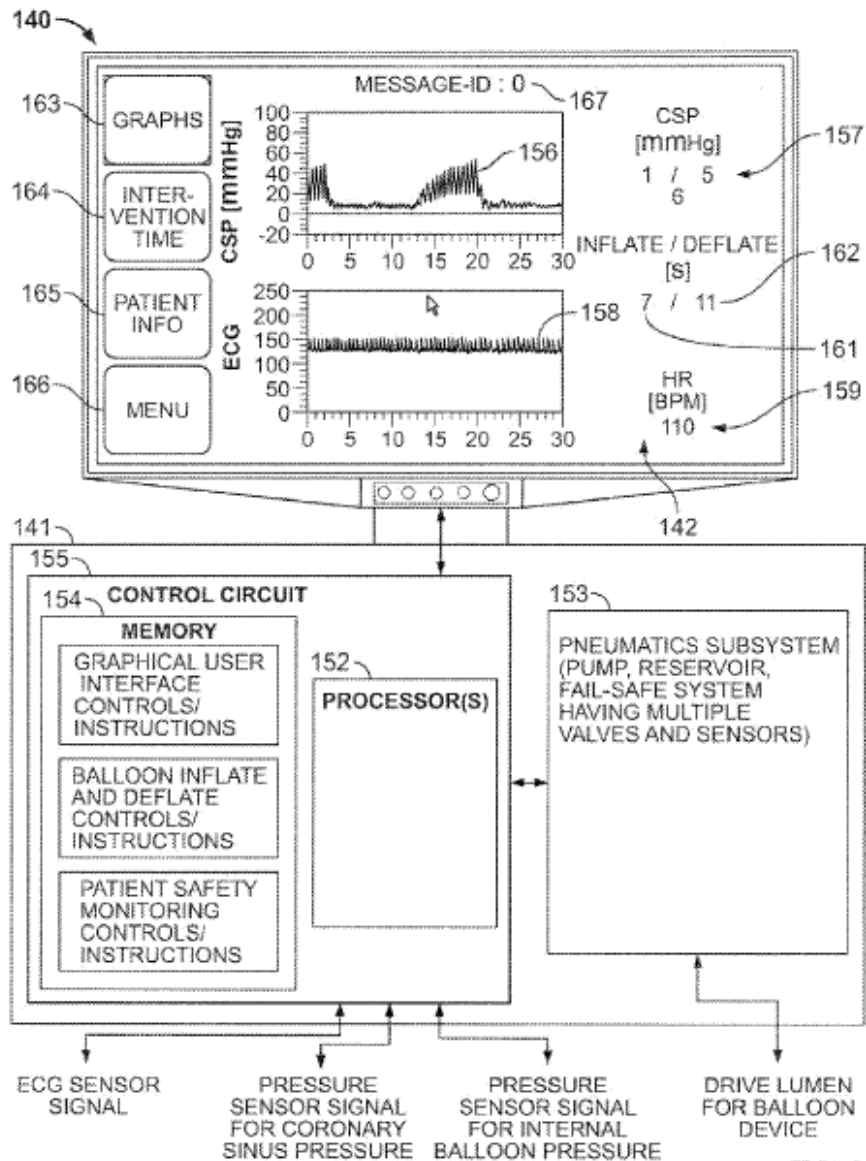


FIG. 3

Figure 3 shows a diagram of an exemplary control system of Mohl302'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).”).

II. ANALYSIS

In a post-grant review, amended claims are not added to a patent as of right, but rather must be proposed as a part of a motion to amend.

35 U.S.C. § 326(d). Ordinarily, the petitioner “bears the burden of persuasion to show, by a preponderance of the evidence, that any proposed substitute claims are unpatentable.” 37 C.F.R. § 42.21(d)(2); *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15, 3–4 (PTAB Feb. 25, 2019) (precedential); *Bosch Auto. Serv. Sols. LLC v. Matal*, 878 F.3d 1027, 1040 (Fed. Cir. 2017). Patent Owner, however, bears the burden of persuasion to

show that the MTA meets the statutory and regulatory requirements set forth in 35 U.S.C. § 326(d) and 37 C.F.R. § 42.221.

A. Statutory and Regulatory Requirements

For the reasons discussed below, Patent Owner has satisfied the statutory and regulatory requirements associated with filing a motion to amend.

1. Reasonable Number of Substitute Claims

A motion to amend must “propose a reasonable number of substitute claims.” 35 U.S.C. § 326(d)(1)(B); *see* 37 C.F.R. § 42.221(a)(3) (“A motion to amend may cancel a challenged claim or propose a reasonable number of substitute claims.”). Patent Owner proposes the same number of substitute claims as the original challenged claims that are canceled, i.e., a one-to-one substitution of claim 3 with proposed substitute claim 22. MTA 1. “There is a rebuttable presumption that a reasonable number of substitute claims per challenged claim is one (1) substitute claim.” *Lectrosonics*, Paper 15 at 4. Petitioner does not argue otherwise.

2. Support in the Original Disclosure

A motion to amend may not present substitute claims that introduce new subject matter. 35 U.S.C. § 326(d); 37 C.F.R. § 41.221(a)(2)(ii). New matter is any addition to the claims without support in the original disclosure. *See TurboCare Div. of Demag Delaval Turbomach. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) (“When [an] applicant adds a claim . . . the new claim[] . . . must find support in the original specification.”); *see also Lectrosonics*, Paper 15 at 7 (“the Board requires

that a motion to amend set forth written description support in the originally filed disclosure of the subject patent for each proposed substitute claim”).

Patent Owner has pointed to adequate written description support for proposed substitute claim 22 in U.S. Patent Application No. 16/867,047 (Ex. 1007). MTA 6–12 (citing Ex. 1013 ¶¶ 100, 101, 104–107, 113, 114, Figs. 11A, 11B). Petitioner does not argue otherwise.

3. Respond to a Ground of Unpatentability

Patent Owner responds to a ground of unpatentability at pages 12–13 of the Motion, asserting that proposed substitute claim 22 includes novel and nonobvious feature combinations to distinguish over the instituted grounds. We agree that claim 22 recites new limitations or new combinations of limitations in an attempt to respond to the Petition’s asserted grounds of unpatentability. *See* MTA 29–30 (Claims App.). Petitioner does not argue otherwise.

4. Scope of the Claims

The proposed substitute claim does not enlarge the scope of the original claims. Proposed substitute claim 22 includes narrowing limitations as compared to original claim 3. MTA 24–25. Petitioner does not argue otherwise.

B. Legal Standards

1. Anticipation

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”). “Expert testimony may shed light on what a skilled artisan would reasonably understand or infer from a prior art reference.” *Acoustic Tech., Inc. v. Itron Networked Sols., Inc.*, 949 F.3d 1366, 1373 (Fed. Cir. 2020). A reference, therefore, “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.’” *In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995) (quoting *In re LeGrice*, 301 F.2d 929 (CCPA 1962)) (Emphasis omitted)).

2. Obviousness

In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court reaffirmed the framework for determining obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* (383 U.S. at 17–18) that are applied in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103 as follows: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and

(4) considering objective evidence indicating obviousness or non-obviousness, if present.⁸ *KSR*, 550 U.S. at 406.

“[W]hen a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.” *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). But in analyzing the obviousness of a combination of prior art elements, it can also 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.” *Id.* 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) (quotations and citations omitted).

C. 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

⁸ Patent Owner does not rely on objective indicia of non-obviousness.

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.*).

In our Institution Decision we provisionally adopted Petitioner’s proposed definition of a person of ordinary skill in the relevant art (sometimes referred to herein as a “POSA”) as

having “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.”

DI 10 (citing Pet. 15; Ex. 1002 ¶ 72). This definition is uncontested and we continue to apply it here. *See* MTA 4–5.

D. 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).

1. Applying the Plain and Ordinary Meaning to All Claim Terms

In our Institution Decision we provisionally applied the plain and ordinary meaning to all claim terms. DI 11–12. Subsequent to institution, the parties agreed that no term requires formal construction to resolve the motion to amend. MTA 5; Opp. MTA 7. For the purpose of this Decision, we apply the plain and ordinary meaning to all claim terms. For clarity, however, we address below Patent Owner’s implicit construction of “baseline blood pressure measurement.”

2. Baseline Blood Pressure Measurement

Claim 22 recites a control module that “compares a blood pressure measurement provided by the sensors to a *baseline blood pressure measurement* to detect a change in blood pressure.” Claim 22, element [h] (*italics added*). Patent Owner’s contention that none of the asserted references disclose this element rests on its implicit construction of the claim language “baseline blood pressure measurement.” Patent Owner’s submissions, however, provide little substantive support for limiting the construction of “baseline blood pressure measurement.” *See* MTA 8–13; Opp. MTA 2; Tr. 10:1–15:12, 42:18–49:17.

As we understand the argument, Patent Owner contends that the “baseline blood pressure measurement” of element 22[h] refers to a target blood pressure value comprising a single, native patient measurement assigned prior to or at the start of a procedure, and thus excludes the use of continuous or reiterative measurements, as well as any measurement mathematically calculated from a native measurement. *See* MTA 8–12, 13

(distinguishing art as “disclos[ing] detection of blood pressure change based on a comparison of an instantaneous, measured blood pressure to a predetermined target blood pressure value, not based on a comparison to a measured baseline blood pressure, as required”); Reply MTA 3 (Patent Owner arguing that “A ‘first measurement’ of a series of ‘continuous measurements’ cannot ‘be considered a baseline.’”); Reply MTA 9 (Patent Owner defining a baseline measurement as “the pressure at a single point in time, but not ‘empirical data’”). Addressing our understanding in the Preliminary Guidance that “second or subsequent measurement[s]” updated via a feedback loop may constitute a baseline blood pressure measurement, Dr. Leschinsky similarly states that, “under requirements of [proposed substitute claim 22], the control module must specifically perform a comparison between a baseline measurement and another measurement. . . . [A] measurement taken after the procedure has begun (e.g., the ‘first measurement’ described by the Board) is not a ‘baseline’ measurement.” Ex. 2006 ¶ 69 (citing Preliminary Guidance 6); *see also* Ex. 1035, 99:14–101:15 (Mr. Leschinsky’s opinion that “baseline blood pressure” can only be an actual patient blood pressure, and not a measurement calculated from a patient measurement).

We do not find Patent Owner’s position availing. With respect to Patent Owner’s contention that we should read “baseline blood pressure measurement” as limited to a single measurement determined prior to, or at the beginning of a procedure, nothing in claim 22 prohibits the device from recalculating a baseline blood pressure measurement, or comparing current blood pressure to the updated baseline. Proposed substitute claim 22 is not a method claim, but is directed to a device that is agnostic as to when a

“baseline blood pressure measurement” is determined, as well as its source. Thus, even if the flow diagrams shown in Figure 11A and 11B of the ’069 Patent do not contain instructions to update the baseline pressures acquired in steps 302 and 354, respectively, this is not forbidden by proposed substitute claim 22 as written, and Patent Owner does not persuade us that such a limitation should be imported into the meaning of “baseline blood pressure measurement.”

Nor does our plain reading of claim 22 distinguish between a native sensor reading and a baseline blood pressure measurement calculated or otherwise derived from a native blood pressure measurement. Consistent with our plain reading of the claim, the Specification’s description of Figure 11a exemplifies comparisons of a current blood pressure reading to a target baseline blood pressure *derived from* a patient measurement. “At step 310,” for example,

the control module determines if the [bifurcation] baseline pressure is *less than the baseline bifurcation pressure minus the pressure drop indicator*. If this proves to be the case, the control process advances to step 312 and increases the volume of the second restriction. If the pressure baseline is *greater than the baseline bifurcation pressure minus the pressure drop indicator* then the process returns to step 308 and the pump flow rate is thereby increased.

Ex. 1001, 15:41–49. (emphasis added). Similarly, at step 314,

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*. If the jugular vein pressure is *greater than the baseline jugular pressure minus the minimum significant pressure deviation* process continues to step 316.

Id. at 15:50–56 (emphasis added). Similarly, “[a]t step 316, an algorithm analyzes if the jugular pressure is *greater than the baseline jugular pressure plus the safety delta*.” *Id.* at 15:63–64 (emphasis added); *see also, e.g., id.* at 15:63–16:10, 17:3–8 (“[A]t 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. The safety delta can typically be in the range of about 2-3 mmHg.”); Fig. 11A, element 314 (“ $P_b < P_{b0} - D_0$ ”), element 322 (“INCREASE $B_d V$ ”).

Accordingly, and for the reasons set forth on pages 1–2 of Petitioner’s Sur-reply, which we adopt, we understand that the term “baseline blood pressure measurement” encompasses a calculated target value, i.e., a value based on or derived from a native patient measurement, and that a “baseline blood pressure measurement” may be an updated measurement, rather than a single measurement set at or prior to the beginning of a procedure. *See* Sur-reply MTA, 1–3 (citing e.g., Ex. 1001, 15:25–26, 15:32–37, 15:41–46, 16:23–17:13; 18:56–19:13; 28:21–30:10, 31:3–19; Figs. 11A, 11B).

E. Anticipation by Gille503 (Ex. 1004)

Petitioner contends that proposed substitute claim 22 is unpatentable as anticipated by Gille503. Opp. MTA 7–13; Sur-reply MTA 3–7. Claim 22 incorporates elements of originally challenged claims 1–3, subject to the additions and deletions shown in Section I.E, above. As such, we take note of the arguments and evidence presented in the Petition with respect to the elements of claims 1–3 common to the proposed substitute claim. *See* Pet. 21–32. *See* Opp. MTA 3–4, n.1.

Patent Owner contends that Gille503 does not anticipate claim 22 because the reference does not disclose 1) use of a restrictor in a vein, and 2)

comparing a blood pressure measurement to a baseline blood pressure measurement to detect a change in blood pressure. MTA 13–16; Reply MTA 2–4. We address those arguments in turn.

1. Use of a Restrictor in a Vein

Claim 22 recites that a first restrictor “in the deployed configuration . . . *comprises a diameter of a vein*, and further refers to “the diameter of the first restrictor *inside the vein*.” Claim 22, elements [c], [e] (italics added). Relying on the testimony of Dr. Leschinsky, Patent Owner contends that Gille503 fails to disclose this element. Reply MTA 3–4. In particular, Patent Owner argues that

Gille503[] relates to post-conditioning treatment to avoid reperfusion injuries when blood flow is restored in a blocked artery supplying blood to previously ischemic tissue, such as the heart following a[myocardial infarction / acute myocardial infarction] or organs following transplant. *See* Ex. 2006 at ¶¶ 72–73 (citing Gille503 at ¶¶ 1, 3, 10). This procedure relates to treatments in *arteries*. *Id.*

Gille503 therefore does not disclose that its balloon can “comprise[] a diameter of a *vein*.” *Id.* at ¶¶ 71–74. Gille503 cannot be used for reperfusion, angioplasty, or drug delivery in a vein. *See id.* at ¶¶ 75–78. Gille503 only mentions such treatments in the context of the postconditioning treatment of its invention (*i.e.*, within an *artery*).

Id.

We do not find Patent Owner’s arguments availing. As an initial matter, Gille503 consistently teaches the use of catheter elements in “vessels” rather than in arteries, and we accept Dr. Day’s testimony that the ordinary meaning of “blood vessel” includes both veins and arteries. *See, e.g.*, Ex. 1004 ¶¶ 14–16, Ex. 1002 ¶¶ 23, 80 (“‘Blood vessel’ is a general term for a vessel that carries blood; a blood vessel may be either an artery or

vein.”), 122. Considering the record as a whole, we find that one of ordinary skill in the art would understand the use of “vessel” in Gille503 to likewise refer to veins as well as arteries. *See* Tr. 23:17–19 (Counsel for Petitioner’s summary that “Gille501 and Gille503 bend over backwards to use the term ‘vessel’ indicating that they contemplate the use of the device in veins just as it’s done in the Mohl references and in Levin.”).

Gille503 discloses devices and methods for post conditioning treatments, i.e., for reducing reperfusion injury by controlling blood flow to a previously damaged area, such as following a myocardial infarction. *See generally*, Section I.G.1, above. Although post conditioning reperfusion is often performed in arteries, the record makes clear that one of ordinary skill in the art would have understood that it may also be performed in a vein such as the coronary sinus. *See* Ex. 1002 ¶¶ 82, 123.

In this respect, both Mohl302 and Levin expressly disclose post conditioning reperfusion via occlusion of the coronary sinus. *See id.* ¶¶ 94–103 (citing, e.g., Ex. 1006 ¶¶ 6, 24, 30, 34, 43, 54, 56); Ex. 1014 ¶¶ 135 (citing, e.g., Ex. 1005 ¶¶ 2-4, 11–12, 23, 56). Levin, for example, teaches that “post-condition[ing] the heart by obstructing the venous coronary blood flow,” may be advantageous because [i]t is generally safer and does not interfere with other therapeutic manipulations associated with the catheterization of the coronary artery.” Ex. 1015 ¶ 50. Levin, thus, points to a preferred embodiment in which a catheter balloon tip creates a partial or intermittent occlusion of the coronary sinus. *Id.* ¶ 53; *see also id.* ¶ 35 (“FIG. 10 further illustrates post-conditioning by gradual occlusion of the coronary sinus using pressure feedback.”), ¶ 86 (describing disclosed method as

encompassing “obstruction of the coronary sinus or major coronary veins that drain into the coronary sinus”).

Gille503 is not limited solely to post-conditioning, and more broadly discloses “a catheter with an expandable balloon for use in a medical treatment, especially for dilating a constricted portion generated in a body tissue or body lumen, such as a blood vessel,” which includes the treatment of occluded or stenotic body tissue or body lumens in “procedures like angioplasty.” Ex. 1004 ¶¶ 2, 3, 18, 20, 22. Dr. Day explains that angioplasty is

a procedure for clearing narrowed or blocked blood vessels. In angioplasty, the balloon catheter is inserted into a blood vessel and advanced until the balloon is at the site of the narrowing or blockage. The balloon is then inflated, which can reopen a blocked vessel or widen a narrowed blood vessel.

Ex. 1002 ¶ 33.

Gille503 expressly teaches embodiments of the invention for use in percutaneous transluminal coronary angioplasty to control blood flow in the reperfusion of transplanted organs or tissue. *Id.* ¶¶ 18, 22. Claim 11 of the reference, for example, recites “[t]he catheter according to one of the preceding claims for use in percutaneous transluminal coronary angioplasty.” Both parties’ experts agree that although angioplasty is commonly performed in arteries, the procedure can also be done in veins. Ex. 1002 ¶ 33; Ex. 1014 ¶ 30; Ex. 2006 ¶ 77 n.3; Ex. 1035, 85:14–17; Ex. 1035, 80:11–85:17.

We further do not find availing Patent Owner’s assertion that Gille503’s disclosure of balloon catheter drug delivery is limited to “the context of the postconditioning treatment of its invention (*i.e.*, within an

artery).” Reply MTA 4. As explained by Dr. Leschinsky, Patent Owner’s position is largely predicated on the understanding that Gille503 is limited to post conditioning treatment in an artery. Ex. 2006 ¶ 78. But as noted above, one of ordinary skill in the art would understand Gille503 to encompass the treatment of veins and, thus, the delivery of drugs to those vessels.

Considering the record as a whole, we find that one of ordinary skill in the art would understand the use of “vessel” in Gille503 to indicate the use of balloon catheters in both arteries and veins.

2. Comparing a Blood Pressure Measurement to a Baseline Blood Pressure Measurement

Claim 22 recites a control module that “compares a blood pressure measurement provided by the sensors to a *baseline blood pressure measurement* to detect a change in blood pressure.” Claim 22, element [h] (*italics added*). As noted in Section II.D.2, above, we construe “baseline blood pressure measurement” as encompassing 1) an updated measurement, rather than a single measurement set at or prior to the beginning of a procedure; and 2) a calculated target value, i.e., a value based on or derived from a native patient measurement.

Patent Owner contends that Gille503 does not disclose element 22[h] because it does not use an initial native patient measurement as the baseline. In particular, Patent Owner argues that “Gille503 does not disclose detecting a change in blood pressure by comparing a blood pressure measurement provided by the sensors to a baseline blood pressure measurement,” as required by this element. MTA 13–16. Rather, Patent Owner contends, “comparisons in Gille503 are made between the measured blood pressure

and a ‘target blood pressure’” with no disclosure of “where that target pressure comes from.” *Id.* at 14–15.

Petitioner asserts that “Gille503 [] discloses that balloon inflation can be controlled using blood pressure readings from a sensor.” Opp. 11 (citing Ex. 1004 ¶¶ 6, 13, 19). Gille503 discloses that “in combination with adjustable means for inflating and/or deflating the balloon the . . . pressure sensor can help to adjust the inflation or deflation in speed and extent to the actual needs of the patient.” Ex. 1004 ¶ 6.

According to an example of the invention, the sensed pressure is . . . 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 . . . can be achieved with an adjustment of the inflation extent of the balloon depending on the sensed data.

Id. ¶ 19; *see also* Ex. 1014 ¶ 113. Inflation of the balloon can thereby keep parameters such as “systemic blood pressure” within “desired physiological limits.” *Id.* ¶ 15.

Petitioner contends that one of ordinary skill in the art would understand these teachings to disclose a PCLCS [Physiological Closed-Loop Control System]-type feedback loop that compares pressure sensor readings against a target blood pressure value and adjusts balloon inflation based on that comparison. Opp. MTA 11–12 (citing Ex. 1014 ¶¶ 111–115). As articulated by Dr. Day, “The feedback loop successively compares sensor provided readings of current pressure against the specified target pressure, and then adjusts balloon inflation accordingly—inflating the balloon to increase occlusion, decrease blood flow, increase pressure upstream and decrease pressure downstream, or deflating the balloon to decrease

occlusion, increase blood flow, decrease pressure upstream and increase pressure downstream.” Ex. 1014 ¶ 114.

Petitioner notes that “Gille503 does not require any particular source for the target blood pressure,” but “the only general possibilities are a Measured Value or a Predetermined Value,”⁹ and one of ordinary skill in the art would understand that either could be used as a source of target values. Opp. MTA 12–13 (citing Ex. 1020, 24–25; Ex. 2002, 24:13–15; Ex. 1014, 84–86); Ex. 2022, 28:21–29:15. Petitioner further argues that between these two options, a measured value would be easier to implement, “because it could simply be measured in a patient prior to or during treatment.” Opp. MTA 12. Petitioner further argues that one of ordinary skill in the art would understand that a Measured Value can be used in the context of controlled reperfusion or angioplasty. *Id.* at 13 (citing Ex. 1004 ¶¶ 1–6, 21, 22; Ex. 1014 ¶ 118). As such, we understand Gille503 to encompass detecting change in blood pressure by comparing a current blood pressure measurement provided by the sensors to a continuously updated baseline blood pressure measurement.

Relying on the testimony of Dr. Leschinsky, Patent Owner responds that one of ordinary skill in the art would understand Gille503 to teach that optimal blood pressure can *only* be determined by reference to a predetermined target and, thus, “a baseline measurement is not useful in Gille503.” Reply 2–3 (citing Ex. 2006 ¶¶ 44–56); *see, e.g.*, Ex. 2007 ¶ 49

⁹ We understand the parties to use “Measured Value” to indicate a baseline measurement of the patient (such as from pressure sensors on the catheter), and a “Predetermined Value” as “a generic or arbitrary value not specific to a particular patient.” *See* Ex. 1014 ¶¶ 82–86.

(“A POSA would recognize that only by comparing the sensed blood pressure to a predetermined target could it be determined that the alteration in blood pressure due to the inflation or deflation of the balloon is sufficient for effective post-conditioning.”). Petitioner responds, however, that Dr. Leschinsky’s testimony relating to “optimal pressure” (*see* Ex. 2006 ¶ 49) is based on an embodiment involving a flow sensor, rather than a blood pressure sensor. Sur-reply 6 (citing Ex. 1004 ¶ 14); *see also* Ex. 2006 ¶¶ 58 (“rather than rely on sensing blood pressure at all, Gille503 describes that a sensor for measuring blood *flow*”); *id.* ¶ 59. Petitioner’s argument is well taken as paragraph 14 of Gille503 recites:

According to an aspect of the invention *the flow sensor* is positioned distal from the balloon. Like that, the blood flow in the treated vessel behind the balloon can be controlled during the whole treatment. Optimal 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.

Ex. 1014 ¶ 14 (emphasis added). In contrast to Dr. Leschinsky’s focus on blood flow and flow sensors, Gille503 also discloses embodiments relating to blood pressure and blood pressure sensors. *See, e.g.*, Ex. 1004 ¶¶ 6, 11, 14, 19, 24; *see generally*, section I.G.1. Dr. Leschinsky further bases his argument on the proposition that Gille503 is limited to post-conditioning treatments. *See* Ex. 2006 ¶ 55, n.1. But as discussed in Section I.G.1, above, we find that Gille503 is not limited solely to post-conditioning treatments. *See* Ex. 1004 ¶¶ 2, 3, 18, 20, 22, claim 11.

Petitioner also contends that Dr. Leschinsky provides no support for his “assertion that targets ‘chosen by the medical person’ (*id.* ¶ 18) can only

be predetermined, rather than based on patient values.” Sur-reply 6 (referencing Ex. 2006 ¶ 53). Moreover, Dr. Leschinsky cites only to paragraph 18 of Gille503, which discloses exemplary embodiments of the invention, which as above, relate to embodiments in which “the fluid flow is blood flow,” rather than blood pressure, *per se*. See Ex. 1004 ¶ 18 (“For example, different pre-programmed series of sequential inflation and deflation of the balloon in a targeted extent resulting in full sealing or reduced low pressure blood flow at a time can be stored in the control unit and can thus be chosen by the medical person to fit to the needs of the patient.”). Accordingly, Dr. Leschinsky’s testimony is limited by his reliance specific embodiments of Gille503 as opposed to the teachings of the reference as a whole.

Patent Owner also addresses a passage in our Preliminary Guidance, which we adopt here. Reply MTA 3 (citing Ex. 2006 ¶ 69). In particular, we preliminarily determined that that one of ordinary skill in the art would understand Gille503 to disclose

a feedback loop [that] successively compares sensor-provided readings of current pressure against the specified target pressure, and then adjusts balloon inflation accordingly. Ex. 1014 ¶ 114. Even if Gille503’s target value was *initially* predetermined, because Gille503 discloses “continuous measurement” and adjustment “depending on the sensed data,” a first measurement to determine whether the blood pressure is at the target value could be considered a baseline and then any second or subsequent measurement is used to determine whether the balloon needs to be inflated or deflated based on the difference between the two measurements. See Ex. 1004 ¶ 19. This allows Gille503 to adjust the volume of the balloon as needed “when the constriction of the blood vessel is only partly removed from one inflation step to the next inflation step.” *Id.*

Preliminary Guidance, 6.

Relying on the testimony of Mr. Leschinsky, Patent Owner argues that “[a] ‘first measurement’ of a series of ‘continuous measurements’ cannot ‘be considered a baseline.’ No ‘second or subsequent measurement’ is compared to such a ‘first measurement’ (which, in any event, would not be a ‘baseline’ since it is taken after the beginning of the treatment). Instead, each measurement is independently compared to the original, predetermined target value.” Reply 3 (citations omitted). Focusing on the single use of “optimal” in paragraph 14 of Gille503, Dr. Leschinsky opines that “updating the target value based on one of the successive measurements would defeat the purpose of the use of the target value in Gille503: to set an ‘optimal’ value for the blood pressure to reach through operation of the inflation or deflation of the balloon.” Ex. 2006 ¶ 69.

For the reasons discussed above, we do not read the exemplary embodiments described in paragraph 14 of Gille503 as representative of the reference as a whole. Rather, we find more persuasive Dr. Day’s testimony that Gille503 satisfies Element 22[h] because one of ordinary skill in the art would have understood that “comparisons performed by the feedback loop would detect a change in blood pressure either when current sensed blood pressure ceases to equal the target blood pressure, or when current sensed blood pressure begins to equal target blood pressure after previously not equaling the target pressure.” Ex. 1014 ¶ 114; *see generally, id.* ¶¶ 111–119.

Dr. Leschinsky also opines that the analysis in our Preliminary Guidance fails to satisfy the requirements of claim 22 because “***the control module*** must specifically perform a comparison between a baseline measurement and another measurement.” Ex. 2006 ¶ 69 (emphasis added).

We find it self-evident that this function is carried out by a control module, and agree with Petitioner and its expert that one of ordinary skill would understand Gille503 to describe a feedback loop comprising a control module “controlling balloon inflation based on sensor data to achieve a ‘target’ pressure.” Opp. MTA 13; Ex. 1014 ¶¶ 120–125.

In view of the above, we find that one of ordinary skill in the art would understand Gille503 to disclose the “in a vein” and “comparing” limitations of the proposed substitute claim (elements 22[c]/[e] and 22[h], respectively). We have also considered Petitioner’s arguments and evidence with respect to the uncontested limitations. Considering the record as a whole, Petitioner has shown by a preponderance of the evidence that claim 22 is unpatentable as anticipated by Gille503.

F. Anticipation by Gille501 (Ex. 1005)

Petitioner contends that proposed substitute claim 22 is unpatentable as anticipated by Gille501. Opp. MTA 7–11; Sur-reply MTA 1–3. Patent Owner opposes. MTA 16–18; Reply MTA 4–6. Although Petitioner characterizes Gille501 as “a somewhat broader and, in some respects, more detailed version of Gille503,” Patent Owner argues that “Gille503 and Gille501 are separate, independent references . . . [that] should be considered separately.” Pet. 42; MTA 18 n.7. The parties’ arguments with respect to the two references, however, substantially overlap and their underlying reasoning is substantially the same. Considering the record before us, we similarly agree with and adopt Petitioner’s arguments with respect to

Gille501. *See* Opp. MTA 7–11; Sur-reply MTA 1–3; Ex. 1014 ¶¶ 82–97. We nevertheless note the following with respect to claim element 22[h].¹⁰

According to Patent Owner, “Gille501’s ‘desired physiological limits’ are predetermined values, not baseline measurements,” and the inflation and deflation of Gille501’s balloon catheter is controlled by “a ‘*pre-programmed*’ series . . . in a targeted extent,’ which ‘can be stored in the control unit and can thus be chosen by the medical person to fit the needs of the patient.’” Reply 4 (citing Ex. 2006 ¶¶ 83, 85–95; Ex. 1005 ¶ 8). Patent Owner also contends that the data in Gille501’s parametrization files is “only used *after* the procedure is over, not as a baseline measurement,” and Gille501 does not describe how [blood pressure] can be used to detect a change for the purposes of adjusting a volume of a restrictor.” *Id.* at 5–6 (citing Ex. 1005 ¶¶ 4, 9, 15–17, 25; Ex. 2006 ¶¶ 86–89, 94–97). We do not find Patent Owner’s arguments availing.

As noted by Petitioner, “Gille501 discloses a sensor-controlled balloon catheter to occlude blood vessels for controlled reperfusion, angioplasty and drug delivery.” Opp. MTA; *see generally*, Section I.G.2, above. Gille501 teaches that pressure sensor measurements can be used to control the degree of balloon inflation inside the blood vessel to keep blood pressure “within desired physiological limits”:

the physiological parameter which is chosen to be used in the control of the [balloon] pump is selected from the group

¹⁰ Patent Owner suggests that Gille501 does not disclose element 22[c]/[e] because the reference is limited to post-conditioning treatment restricting arterial flow. Reply MTA 11. We do not find this argument persuasive for essentially the same reasons discussed in section II.E.1, above, and as addressed at pages 9–11 of Petitioner’s Sur-reply to the Motion to Amend.

consisting of systemic blood pressure, blood pressure before the balloon catheter, blood pressure behind the balloon catheter and can advantageously be used to stay *within desired physiological limits*. The measured physiologic signals, for example monitored by pressure sensors . . . can be transmitted to the control unit which in turn controls the pump and thereby the inflation and deflation of the balloon.

Ex. 1005 ¶ 15; *see* Opp. MTA (further citing Ex. 1005 ¶¶ 6, 12, 17, 25).

As with Gille503, Petitioner contends that one of ordinary skill “would understand from these disclosures that Gille501 is referring to a PCLSC-type feedback mechanism that uses comparisons by the control unit (the claimed ‘control module’) against ‘limits,’ *i.e.*, target values, to achieve or maintain those limits.” Opp. MTA 8; Ex. 1014 ¶¶ 79–81. According to Petitioner, one of ordinary skill in the art would understand that these limits could be Measured Values *or* Predetermined Values. Opp. MTA 8 (citing Ex. 1014 ¶¶ 75–91; Ex. 2002, 31:21–34:15, 109:20–24); Ex. 2002, 104:14–107:10 (Dr. Day’s testimony that Gille501 discloses the use of Measured Values). Petitioner further contends that

Gille501 expressly contrasts “beneficial physiological limits” with “beneficial predetermined limits,” *i.e.*, Predetermined Values, and teaches using either type of limit:

repeated 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. (quoting Ex. 1005, 4:34–38) (citing Ex. 1014 ¶ 93; Ex. 2002, 42:16–18).

Petitioner further argues that Gille501 teaches the storage of patient data (including blood pressure data) in parameter files for access by control software. *Id.* (citing Ex. 1005 ¶¶ 9 (“The control unit may advantageously be capable of storing data, for example, relevant parameters of the performed

procedure . . . [such as] data of physiological parameters of the treated patient.”), 10). Accordingly, Petitioner states:

Because the parametrization files can contain patient measurements as parameters, and because Gille501 teaches that any such parameter can be used to automatically control the balloon catheter, a POSA would understand that Gille501 teaches the use of Measured Values—specifically, in the feedback loops that would be used to implement its teaching of keeping blood pressure “within beneficial physiological limits.”

Id. (citing Ex. 1014 ¶¶ 94–95; Ex. 2002, 104:14-107:10).

We find the above arguments of Petitioner and Dr. Day credible and adopt them as our own. Considering the record as a whole, we find that one of ordinary skill in the art would understand Gille501 to disclose the “in a vein” and “comparing” limitations of the proposed substitute claim (elements 22[c]/[e] and 22[h], respectively). We have also considered Petitioner’s arguments and evidence with respect to the uncontested limitations. Considering the record as a whole, Petitioner has shown by a preponderance of the evidence that claim 22 is unpatentable as anticipated by Gille501.

G. Obviousness in view of Gille503 and Gille501

Petitioner contends that proposed substitute claim is unpatentable as obvious in view of Gille503 and/or Gille501. Opp. MTA 13–20; Sur-reply MTA 11–12. Patent Owner opposes. Reply MTA9–11.

In short, Petitioner asserts that even if Gille501 and/or Gille503 only disclose using predetermined blood pressure values, it would have been obvious to use measured values instead, as the only alternative to a predetermined value. Opp. MTA 13; *see* Ex. 1014 ¶¶ 159–164. As discussed in Section II.E.2, above, Gille503 discloses a feedback loop to compare

sensor-provided current pressure with a target pressure, and then adjust balloon inflation. *See* Ex. 1004 ¶ 19. Gille501 discloses a similar feedback loop to control balloon inflation and keep blood pressure “within beneficial physiological limits.” *See, e.g.,* Opp. MTA 7–9; Ex. 1005 ¶¶ 15–17; Ex. 1014 ¶¶ 79–81, 94–95. Petitioner argues that one of ordinary skill in the art “would know that the Gille references’ comparison algorithms would work regardless of the source of the target value,” whether the comparison is based on a Measured Value or Predetermined Value, “the balloon is simply inflated or deflated to the extent specified in the algorithm, and the comparison is repeated.” Opp. MTA 13–14; Sur-reply MTA 11; Ex. 1014 ¶ 161.

Petitioner further argues that one of ordinary skill in the art would have been motivated to use “Measured Values instead of (or in addition to) Predetermined Values.” Opp. MTA 14. As articulated by Dr. Day, [u]sing a Measured Value as a target value for blood pressure is a readily apparent choice because normal blood pressure varies from person to person (and can vary in a given person) and because this is analogous to homeostasis.” Ex. 1014 ¶ 161. Dr. Day further opines that one of ordinary skill in the art would have had a reasonable expectation of success in modifying the Gille algorithms to use a Measured Value as this would involve “rudimentary changes . . . well within the skill of a POSA.” *Id.* ¶ 162. Accordingly, Dr. Day states, “in the absence of any teachings that Measured Values could not or should not be used in the feedback loops of either Gille balloon catheter (and I see no such teachings), it would be obvious to a POSA from this knowledge alone that a Measured Value could be used in a feedback loop if appropriate for a particular therapeutic objective.” *Id.* ¶ 161.

Dr. Day further opines that “Gille501 and Gille503 disclose that their respective devices are suitable for both controlled reperfusion and angioplasty.” *Id.* ¶ 163; According to Dr. Day, one of ordinary skill in the art would understand

from Levin, Mohl996 and Mashimo^[11] that Measured Values could be used in the feedback loops of sensor-controlled balloon catheters for either purpose. Because all of these catheters have the same basic components and operate under the control of software, a POSA would also know that the balloon catheters disclosed in the Gille references could be used in place of the balloon catheter of either Levin or Mohl996 to perform the reperfusion control algorithms of those references, as well as in place of the balloon catheter of Mashimo to perform angioplasty.

Id.; see Opp. MTA 15–21. Dr. Day further states that one of ordinary skill in the art “would have a reasonable expectation of success because of the structural and functional similarity of the devices and because using a different feedback loop algorithm in the Gille devices, for example, the algorithm of Levin, would simply entail programming that algorithm into the control units of the Gille devices.” *Id.*

Patent Owner contends, however, that one of ordinary skill in the art would not have been motivated to use a measured baseline value with the Gille catheters because “there are no flaws or downsides to the algorithms of Gille501 or 503 that would cause a POSA to modify them,” but admits that “there are many potential algorithms that could be used . . . in [] a post-conditioning treatment as taught by Gille501 and 503.” Reply MTA 10 (citing Ex. 2006 ¶¶ 151–152). Patent Owner further argues that Gille501,

¹¹ Mashimo and Goyal, WO 2008/042347 A2, publ. April 10, 2008. (Ex. 1017).

Gille503, and Levin all employ predetermined targets, and that Mohl996 and Mashimo relate to retro-perfusion, rather than to the post-conditioning taught in the Gille references. In any event, Patent Owner argues, “Gille503 teaches away from modifications based on other devices because ‘there is no standard to the components of a catheter’” and Gille503 states “that ‘it might be *more feasible* to sense the pressure of the balloon itself.’” *Id.* at 10–11 (citing Ex. 2006 ¶¶ 157–159; Ex. 1004 ¶ 19).

Patent Owner’s arguments are not availing for the reasons set forth in Petitioner’s briefing. *See* Opp. MTA 13–20; Sur-Reply MTA 11–12. We note in particular, that the Gille references are not limited to post-conditioning treatments, nor to the use of balloon catheters in arteries, as opposed to veins. *See, e.g.*, Sections I.G.1–2, above. Nor does Gille503’s disclosure that an alternate embodiment “might be more feasible” constitute a teaching away. *See, e.g., Galderma Labs., LP v. Tolmar, Inc.*, 737 F.3d 731, 738–39 (Fed. Cir. 2013) (finding that “[a] teaching that a composition may be optimal or standard does not criticize, discredit, or otherwise discourage investigation into other compositions” and thus the prior art “do[es] not teach away from the claimed invention”).

Patent Owner’s argument that motivation is lacking because “there are no flaws or downsides to the algorithms of Gille501 or 503” is likewise unavailing because, as noted by Petitioner, “when ‘there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.’” Opp. MTA 14 (citing *KSR*, 550 U.S. at 421). Finally, and with respect to Patent Owner’s argument that catheters suffer from a lack of standardization, we credit Dr. Day’s opinion that all of the catheters disclosed in the cited art

“have the same basic components and operate under the control of software.” Ex. 1014 ¶ 163.

Considering the record as a whole, we conclude that one of ordinary skill in the art would understand that, to the extent proposed substitute claim 22 is not anticipated by Gille501 or Gille503, it would have been obvious in light of either or both of these references.

H. Anticipation by Mohl996 (Ex. 1016)

Petitioner contends that proposed substitute claim 22 is unpatentable as anticipated by Mohl996. Opp. MTA 17–18, 23–25; Sur-reply MTA 10. Petitioner and its expert present element by element analyses comparing substitute claim 22 with Mohl996. Opp MTA 24–25; Ex. 1014 ¶¶ 214–224. Relying on the testimony of Dr. Leschinsky, Patent Owner opposes solely on the ground that Mohl996 fails to disclose comparing a blood pressure measurement to “a baseline blood pressure measurement,” as required by element 22[h]. Reply MTA 6–7; Ex. 2006 ¶¶ 112–119.

With respect to element 22[h], Petitioner points to Mohl996’s disclosure of “means for occluding the sinus, a pressure transducer for sensing the fluid pressure within the sinus and providing corresponding fluid pressure signals, and a controller responsive to the transducer and arranged to provide trigger signals to the occluding means to trigger an occlusion and to interrupt the occlusion.” Opp. MTA 17 (citing Ex. 1016, 1:52–57; *id.* at 3:65–4:2, 4:3–33, 4:51–56, Figs. 1, 2A). Petitioner further states that,

the processor in Mohl996’s controller senses coronary sinus pressure in a given patient, compares successive readings to determine the maximum local pressure at each heartbeat, stores those maxima, and then uses them to calculate a target that is 94% of the plateau above which measured pressure likely

cannot rise. [Ex. 1016,] 4:59–65, 5:13–28, Fig. 1A. The controller then repeatedly compares the sensed maximum pressures to the target; when they match, the controller directly deflates the balloon. *Id.* at 5:28–34. *See generally* Ex. 1014 at ¶¶ 143–53.

Id. at 18. Petitioner further relies on Mohl996 claims 1 and 12. *Id.* at 2.

Consistent with the above, the method of Mohl996’s claim 12, for example, includes the steps of:

measuring the local pressure maxima for successive heartbeats during said occlusion, said method being characterized by the steps of
estimating the plateau level of said local pressure maxima,
and
interrupting said occlusion on the basis of said estimate.

Ex. 1016 at 9:30–42.

Patent Owner argues that in relying on an “*estimated* plateau level,” Mohl996 fails to disclose comparison to a baseline blood pressure “measurement” as required by element 22[h]. Reply MTA 6 (citing Ex. 2006 ¶¶ 112–118); *see also id.* (further arguing that Mohl996’s plateau “represents a pressure that in fact never occurs”). As articulated by Dr. Leschinsky, Mohl996’s

“estimated plateau level” (or 94% thereof) is not a baseline blood pressure measurement, or even a series of baseline blood pressure measurements. Instead, a POSA would understand that the plateau is an *estimate* (not a measurement) of a maximum safe future pressure that is based on multiple measurements taken during the course of the treatment.

Ex. 2006 ¶ 113 (citing Ex. 1016, 5:3–8. 30–34); *see* Ex. 1035, 92:4–93:22, 96:23–97:24. Moreover, Dr. Leschinsky opines, “because the plateau level is repeatedly recalculated on a beat-to-beat basis throughout the treatment, it

also does not represent a baseline because it is not determined at the start of the treatment.” Ex. 2006 ¶ 113.

Patent Owner’s arguments are not availing. First, as discussed above, we do not read claim 22 as limited to a single baseline blood pressure determined prior to, or at the beginning of a treatment. *See* Section II.E.2, above. Accordingly, whether or not Mohl996’s device updates its estimated plateau level during the course of a treatment has no bearing on whether it anticipates proposed substitute claim 22.

We also interpret the term “baseline blood pressure measurement” as encompassing a calculated value, i.e., a value based on or derived from a native patient measurement. *See id.* As such, we find unavailing Patent Owner’s argument that Mohl996 calculates a baseline blood pressure (i.e., “estimated plateau level”) based on patient data.

Finally, we fail to see the relevance of Patent Owner’s argument that Mohl996’s plateau “represents a pressure that in fact never occurs.” *See* Reply MTA 6. In this respect, Mohl996 discloses that the processor calculates a plateau blood pressure “and when a local maximum first reaches at least that 94% value . . . processor **56** triggers the pump to evacuate, or provide negative pressure to, lumen **20**, thus interrupting the inflation of balloon **34** before the plateau is reached.” Ex. 1016, 5:13–34. Proposed substitute claim 22 similarly requires that “the control module compares a blood pressure measurement provided by the sensors to a baseline blood pressure measurement to detect a change in blood pressure, and directly adjusts a volume of the first restrictor in response to the detected change in blood pressure.” Proposed substitute claim 22 merely requires a *comparison* of blood pressure to a baseline blood pressure measurement.

Nowhere does it suggest that blood pressure must meet or exceed the baseline, or that meeting or exceeding the baseline is a predicate to triggering adjustment of the restrictors.

In view of the above, we find that one of ordinary skill in the art would understand Mohl996 to disclose the “comparing” limitation element 22[h], the only contested limitation of the proposed substitute claim. We have also considered Petitioner’s arguments and evidence with respect to the uncontested limitations. Considering the record as a whole, Petitioner has shown by a preponderance of the evidence that claim 22 is unpatentable as anticipated by Mohl996.

I. Grounds Based on Levin (Ex. 1015) and Mohl302 (Ex. 1006)

Petitioner “is entitled to a final written decision addressing all of the claims it has challenged.” *SAS Inst. Inc.*, 138 S. Ct. at 1359. Because we determine that the sole claim before us, proposed substitute claim 22, is unpatentable as anticipated by Gille503, Gille501 and Mohl996, and in the alternative, obvious in view of Gille503 and/or Gille501, we do not reach the Petition’s grounds of unpatentability involving Levin or Mohl302. *See Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App’x 984, 990 (Fed. Cir. 2020) (non-precedential) (recognizing that the “Board need not address issues that are not necessary to the resolution of the proceeding” and, thus, agreeing that the Board has “discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims”).

III. CONCLUSION

As noted in Section I.A, above, Petitioner filed a Petition for Post-Grant Review of claims 1–9 and 19–21. Prior to institution, Patent Owner statutorily disclaimed claims 1–9 and 19–21 such that only claim 3 remained. Patent Owner later filed a Non-Contingent Motion to Amend requesting cancelation of claim 3 in favor of proposed substitute claim 22. Because we granted Patent Owner’s request to cancel claim 3, proposed substitute claim 22 is the only claim now before us.

For the foregoing reasons, Petitioner has shown by a preponderance of the evidence that proposed substitute claim 22 is unpatentable, as summarized in the following table:¹²

Claim	35 U.S.C §	Reference(s) / Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
22	102	Gille503	22	
22	102	Gille501	22	

¹² Should Patent Owner wish to consider amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

22	103	Gille501, Gille503	22	
22	102	Mohl996	22	
22	102	Levin ¹³		
22	103	Levin ¹⁴		
22	103	Mohl302 ¹⁵		
Overall Outcome			22	

Motion to Amend Outcome	Claim(s)
Original Claims Cancelled by Amendment	3
Substitute Claims Proposed in the Amendment	22
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	22
Substitute Claims: Not Reached	

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner's request to cancel claim 3 of U.S.

¹³ As noted in Section II.I, above, we did not reach challenges based on Levin.

¹⁴ As noted in Section II.I, above, we did not reach challenges based on Levin.

¹⁵ As noted in Section II.I, above, we did not reach challenges based on Mohl302.

Patent No. 10,926,069 B2 in its Non-Contingent Motion to Amend is
granted;

FURTHER ORDERED that proposed substitute claim 22 has been
shown to be unpatentable;

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

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