

UNITED STATES PATENT AND TRADEMARK
OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VIVITRO LABS INC.,
Petitioner

v.

BIOMEDICAL DEVICE CONSULTANTS & LABORATORIES OF
COLORADO, LLC,
Patent Owner.

Case IPR2024-00320
Patent 9,237,935

PATENT OWNER PRELIMINARY RESPONSE

TABLE OF CONTENTS

I.	Introduction	1
II.	Background	3
III.	The '935 Patent	9
	A. Overview	11
	B. Prosecution History	15
	C. Procedural History.....	16
IV.	Person of Ordinary Skill in the Art	18
V.	Claim Construction	18
	A. “in fluid communication” (Claim 1)	20
	B. “excess volume area” (Claim 1).....	25
	C. “under compression” (Claim 1)	28
VI.	Petitioner Fails To Demonstrate a Reasonable Likelihood of Prevailing On Any of Its Asserted Grounds	30
	A. The Petition Fails To Show That Xi Anticipates Claim 1 (Ground A)	31
	1. Xi Teaches Oscillating the Test Valve; It Does Not Teach a Distribution Chamber on a First Side of the Valved Prosthetic Device.....	31
	2. ViVitro Improperly Relies on the Test Valve to Satisfy Two Separate Elements of Claim 1	35
	3. Xi Teaches an Open System That Is Not a Pressurizable Test Chamber	36
	4. Xi’s Compliance Chamber Does Not Include An Excess Volume Area That Provides A Volume For Storing A Volume Of A Test System Fluid When The Test System Fluid Is Under Compression.....	41

B.	The Petition Fails To Show That Claim 1 Is Obvious In View Of Dynatek & Xi (Ground B).....	44
1.	Dynatek Does Not Teach a Pressure Source in Fluid Communication with a Fluid Distribution Chamber or an Excess Volume Area in Fluid Communication with the Fluid Return Chamber	45
2.	Dynatek Lacks an Excess Volume Area	48
3.	Xi Does Not Remedy the Deficiencies of Dynatek	51
4.	A POSA Would Not Be Motivated To Combine Dynatek with Xi	53
C.	The Petition Fails To Show That Claim 1 Is Obvious In View Of Goldstein and Lu (Ground C)	56
1.	Goldstein Discloses A Real-Time Pulse Duplicator Incapable Of Operating At Accelerated Rates.....	57
2.	It Is Not Obvious To Operate Goldstein’s Real-Time Pulse Duplicator At Accelerated Rates.....	60
VII.	Conclusion.....	63

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>BDC v. Vivitro Labs, Inc.</i> , No. 2023-2393, 2024 U.S. App. LEXIS 7312 (Fed. Cir. Mar. 28, 2024)	17, 23
<i>Bicon, Inc. v. Straumann Co.</i> , 441 F.3d 945 (Fed. Cir. 2006)	28
<i>Bio-Sys., Inc. v. Illumina Cambridge Ltd.</i> , 821 F.3d 1359 (Fed. Cir. 2016)	36
<i>CCS Fitness, Inc. v. Brunswick Corp.</i> , 288 F.3d 1359 (Fed. Cir. 2002)	19
<i>Helmsderfer v. Bobrick Washroom Equip., Inc.</i> , 527 F.3d 1379 (Fed. Cir. 2008)	19
<i>Laryngeal Mask Co. v. Ambu</i> , 618 F.3d 1367 (Fed. Cir. 2010)	21
<i>In re Magnum Oil Tools Int’l, Ltd.</i> , 829 F.3d 1364 (Fed. Cir. 2016)	53
<i>Parus Holdings, Inc. v. Google LLC</i> , No. 2022-1269, 2023 WL 3939532 (Fed. Cir. June 12, 2023).....	37
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (en banc)	18, 19
<i>In re Suitco Surface, Inc.</i> , 603 F.3d 1255 (Fed. Cir. 2010)	19
<i>Virtek Vision International ULC v. Assembly Guidance System, Inc.</i> , 97 F.4th 882 (Fed. Cir. 2024)	53, 60
<i>Vitronics Corp. v. Conceptronic, Inc.</i> , 90 F.3d 1576 (Fed. Cir. 1996)	19

Westminster Pharmaceuticals, LLC, v. LPRI France,
IPR2022-00677, Paper 7, Patent 8,183,227 B1,
2022 Pat. App. LEXIS 4312 (P.T.A.B. August 24, 2022) 17

Statutes

35 U.S.C. § 314(a) 30

Other Authorities

37 C.F.R. § 42.24(a).....66
37 C.F.R. § 42.24(b) 66
37 C.F.R. § 42.107(a).....1
37 C.F.R. § 42.108(c).....30
37 C.F.R. § 42.6(a)(3).....37
MPEP § 2111.01 19

LIST OF PATENT OWNER EXHIBITS

- Ex. 2003 Declaration of Michael J. Girard
- Ex. 2004 *Communicate*, MERRIAM WEBSTER DICTIONARY,
<https://www.merriam-webster.com/dictionary/communicate> (last
visited May 4, 2024)
- Ex. 2005 Declaration of Craig Weinberg, Ph.D, *Biomedical Device
Consultants & Laboratories of Colorado, LLC v. ViVitro Labs,
Inc.*, No. 2:23-cv-04291-RGK-E, Dkt. 61 (C.D. Cal 2023)

I. Introduction

Pursuant to 37 C.F.R. §42.107(a), Biomedical Device Consultants & Laboratories of Colorado, LLC (“Patent Owner”) submits this Preliminary Response to the Petition for *Inter Partes* Review (“IPR”) of U.S. Patent No. 9,237,935 (“the ’935 Patent”) filed by ViVitro Labs Inc. (“Petitioner”).

Institution must be denied because Petitioner fails to meet its burden of showing a reasonable likelihood that it would prevail with respect to claims challenged in the Petition for at least two reasons.

First, none of the cited references, or their combination, disclose the claimed “excess volume area capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid communication with the fluid return chamber providing a volume for storing a volume of a test system fluid when the test system fluid is under compression” within a pressurizable test chamber. Petitioner incorrectly substitutes “excess volume area,” and the unique function of receiving the volume of fluid displaced during a compression stroke that the excess volume area performs within a pressurized test chamber, with the genericized term “compliance.” In fact, the Petition does not even discuss the portion of the ’935 Patent that explains how the term “compliance” is used in the patent. *See* ’935 Patent, 9:11-16 (“As used herein, ‘compliance’ refers to ...”). Thus, the Petition is deficient on its face, even under Petitioner’s flawed proposed substitution of terms. As

discussed below, while the excess volume area does provide compliance, not all compliance chambers provide an excess volume area or satisfy the claim limitations. Thus, none of the references anticipate or render obvious any claim.

Second, Petitioner fails to provide any reasonable rationale for combining Xi with Dynatek or for combining Goldstein with Lu. Instead, Petitioner makes generalized statements such as “a compliance chamber was a known technique to address water hammer” (Petition at 49) and “a POSA would be motivated by (at least) Lu to speed up the rate.” *Id.* at 60. But conclusory statements are insufficient to prove motivation for combining references or, more specifically, for modifying prior art to incorporate compliance that operates as an “excess volume area” in an accelerated system. Moreover, Petitioner attempts to combine incompatible accelerated (Goldstein) and non-accelerated (Lu) testers, while also discussing dissimilar compliance (Xi, Dynatek) that fails to address the distinct function served by the claimed excess volume area. Even still, Petitioner argues to combine Xi’s oscillating valve in an open system with Dynatek’s stationary valve in a closed system, despite their fundamental difference in operation. Essentially, petitioner is throwing various inapt references together to see if a combination will “stick.” That is improper.

Accordingly, the Petition and accompanying evidence do not establish a reasonable likelihood that Petitioner will prevail. Thus, the Board should deny

institution of all grounds asserted in the Petition.

II. Background

Heart disease remains the leading cause of death in the U.S., killing more than 600,000 Americans each year. More than five million Americans are diagnosed with heart valve disease each year. While heart valve disease can occur in any of the four heart valves, most commonly the aortic and mitral valves are diseased.

The International Organization for Standardization (“ISO”) establishes verification testing and reporting guidelines for prosthetic heart valves in ISO 5840¹. Ex-1017. ISO 5840 sets forth two types of *in vitro* verification tests for prosthetic heart valves. *Id.* at 11 (Section 7.2 *In vitro assessment*).

One type is hydrodynamic performance assessment. *Id.* at 12 (Section 7.2.3). Hydrodynamic testing provides information on the fluid mechanical performance of the heart valve and indicators of its performance in terms of load to the heart. *Id.* It is akin to a wind tunnel but with water or similar fluid. In other words, hydrodynamic testing is concerned with how the prosthetic valve will operate *in vivo* from a fluid dynamics perspective. The valve must satisfy certain minimum performance requirements—delivering a minimum expectation of valve efficiency when

¹ The Fourth edition of ISO 5840 (2005) was in effect in 2009 (the priority date of the '935 Patent) and is referenced herein. Ex-1017.

operating at 70 bpm and a mean pressure of 100 mm Hg for an aortic valve position (i.e., a normal aortic blood pressure). *Id.* at 12. The guidelines for hydrodynamic testing include running tests at pressures of 80-160 mm Hg and cycle rates of 45-120 bpm. *Id.* at 56 (Section L.4.3). Because the goal of hydrodynamic testing is to characterize the performance of the prosthetic valve *in vivo*, the tester would like to mimic the heart and circulatory system to the extent possible within confines of the testing apparatus. *Id.* (Section L.4.2) Also, hydrodynamic testing is carried out at normal heart rates (referred to as “real-time testing”), usually around 70 bpm, even though normal heart rates in adults may reach 200 bpm for short periods of time. *Id.* Goldstein is an example of a “real-time” hydrodynamic performance assessment device.

The second type of testing set forth in ISO 5840 is structural performance assessment, of which one aspect is durability testing—the type of testing system at issue in the ’935 Patent. *Id.* at 13 (Section 7.2.4). Durability testing is performed to assess continued function of the prosthetic valve over a reasonable period of time (defined as 200 million cycles for a flexible heart valve and 400 million cycles for a rigid one). *Id.* Durability testing is performed at fluid pressures “consistent with normotensive conditions [i.e., normal blood pressure].” *Id.* While ISO 5840 allows for durability testing at normal heart rates, doing so would take over five years. Using accelerated rates, above normal physiological rates, could shorten testing time

considerably. *Id.* at 13. Most accelerated testers today are designed to run at 600-1200 bpm—roughly 8-17 times as fast as a normal heart rate. Girard Declaration (Ex-2003), ¶15.

One known problem with using accelerated testing is that it introduces pressures and resultant forces that are beyond those found *in vivo* (sometimes referred to as a water hammer effect) as a result of the valve repeatedly closing at a rapid rate. *See e.g.*, Exs. 1019, 1020. *See also* Ex-1005 (“At the instant of valve closing, the water hammer effect due to reversed fluid flow increases downstream pressure and decreases upstream pressure.”). In the Reul reference, the author compared forces under physiologic, real-time conditions (i.e., hydrodynamic testing) with those found above physiological or accelerated rates, concluding the back-pressures generated “during accelerated testing exceed the real-time loading forces by far.” Ex-1020 at 1. As noted in the Iwasaki article, “[a]ccurate estimation of durability in a timely manner [i.e., accelerated] is one of the most important unresolved issues.” Ex-1019 at 1. Iwasaki reports that using accelerated rates notably shortened valve life. *Id.* More particularly, the water hammer effect is caused by the rapid closing of the valve, which causes a pressure propagation when the fluid moving through the valve is forced to abruptly stop. *See* Ex-1005.

The concept of “compliance” is important in fluid dynamics as well as hydrodynamic and durability testers. The term “compliance” describes a general

category of mechanisms. Petitioner and its expert spend many pages addressing how the term “compliance” appears in descriptions of prior standards and the prior art, and erroneously conflate the genericized term “compliance” with the specific feature in the ’935 Patent—an excess volume area, which provides a unique type of compliance.

Testing systems—whether operating at real-time or accelerated rates—must manage multiple pressure differentials. A test system is designed to operate at a prescribed system pressure (**System Operating Pressure**). In an “open” testing system, the System Operating Pressure is atmospheric pressure. In a “closed” testing system, this system pressure may be above atmosphere for various reasons, such as to suppress cavitation. This System Operating Pressure is established prior to the system cycling and describes an operating state required for the system.

In addition, each system must manage the **Differential Pressure** across a closed valve (also called “back pressure”), which is the pressure applied across the closed valve to define the loading conditions in a durability test. This Differential Pressure must be controlled by the system such that there is sufficient Differential Pressure to be within the testing parameters required, while the system does not apply excess pressure that could cause the valve to fail during testing when it would not fail in *in vivo* conditions.

As described below, the ’935 Patented invention has another type of pressure

that did not exist in the prior systems, **Excess Volume Pressure**, which is generated by the fluid drive mechanism displacing fluid in the system through its motion and concurrently changing the volume of the overall test system. This change in volume consequently places the system test fluid under compression.

Accordingly, different mechanisms and solutions were developed to achieve different types of compliance in different contexts. For example, real-time pulse duplicator systems, which sought to replicate the conditions of the circulatory system, provided compliance that would mimic the distensibility of arteries. These systems used compliance to control and tune the arterial pulse pressure, which is necessary when the system uses a high volume of flow (only possible in real-time systems).

Some prior systems made use of compliance mechanisms to set, maintain and correct System Operating Pressure, which aids in suppressing cavitation. For example, the Dynatek system establishes and maintains systemic pressure through the capacitance tank. Ex-1006 at 15 (Step 41) (“Adjust the systemic pressure by pressurizing the capacitance tank to 2-3 psig as indicated on the pressure gauge.”); *id.* at 24 (“Cavitation is reduced, or inhibited, by the following operating conditions: ... (4) maximal system pressure.”). The ’935 Patented invention also allows the system pressure to be set and adjusted. ’935 Patent, 11:21-27 (“Once fluid has been filled to a desired level, in some scenarios, the fatigue testing system 100 may be

additionally pressurized with air or another gas via an air source 131 ...”).

In addition, the term “compliance” may be used in ways that are completely unrelated to fluid flow dynamics. For example, in the context of testing stentless valves, a tester must have *mechanical* compliance that would correspond to *in vivo* vessel diametric compliance at the implant location, as outlined in ISO 5840.²

In the context of the '935 Patent, however, the term “compliance” has a specific defined meaning. “As used herein, ‘compliance’ refers to the ability of the cavities forming the compliance chambers 135 to absorb some of the pressure placed upon the fluid in the test chamber 106 and further to control recoil toward the original volume dimensions upon removal of the compressive force.” '935 Patent, 9:11-16 (emphasis added).

In short, not all compliance mechanisms are the same. The *location* and *structure* of the compliance mechanism affects how it will operate and what types of pressures and volumes it can accommodate.

² The fact that Dr. Dasi cites this provision as evidence related to compliance of fluid dynamic pressures, Ex-1002 ¶25, illustrates that Dr. Dasi is improperly equating all different variations of compliance.

III. The '935 Patent

Around February 2008, BDC began researching and designing a new accelerated heart valve durability testing system. Ex-2005 ¶3. One of the primary problems to be solved was mitigating the excessive forces created by accelerated cycling. This research resulted in the issuance of multiple related patents (including the '935 Patent), as well as, the launch of a commercial product—the VDT-3600i, an accelerated testing system for prosthetic heart valves. *Id.* ¶5.

Before BDC's patents and product, commercial products which tested heart valves at an accelerated rate were unable to adequately control pressure rates. *Id.* ¶6. Consequently, these systems were susceptible to pressure spiking which prematurely deteriorated the materials used for the prosthetic heart valves being tested. *Id.* BDC's design departed drastically from prior designs. Rather than circulating fluid in a simple loop between stations, or oscillating the valve within the fluid, a reciprocating piston moves towards and away from a chamber upstream of the sample(s) to pressurize fluid within the test chamber and drive the pressurized fluid through the sample(s) being tested. '935 Patent, Abstract; *id.*, 13:28-32. Once the fluid flow exits from the samples, it flows into a return chamber before flowing back to the first chamber during the depressurization stroke of the test. *Id.*, 13:57-63. However, because the test fluid is incompressible and contained within a rigid structure, the test system includes an excess volume area which accepts the pressure increase by

providing temporary additional volume to store the liquid displaced during pressurization. *Id.*, 12:4-11. This unique utilization of an excess volume area on the outflow side of the valve permits the claimed invention to operate when the testing fluid is compressed, thereby providing a tester capable of operating at an accelerated rate while overcoming the disadvantages associated with swashplate and oscillating testers, such as Dynatek and Xi.

The '935 Patent also describes the use of compliance chambers “to act as a resilient spring force to dampen the effects of large, quickly changing pressure gradients within the test chamber.” '935 Patent, 9:11-28. While this is an additional benefit, it is secondary to the primary function of “provid[ing] excess volume area for fluid to move into when the piston 114 performs a compression stroke.” *Id.*, 12:4-6.

BDC revolutionized the market and within five years became the industry standard. Ex-2005 ¶¶9-14. By mid-2023, the BDC product accounted for about 70-75% of the worldwide market for heart valve durability testing systems. *Id.* at ¶16.

Petitioner launched a competing product, the ADC Heart Valve Durability Tester, which is the subject of an on-going lawsuit. *Id.* at ¶23. Petitioner then filed the present IPR.

A. Overview

The '935 Patent relates to a method for durability testing of prosthetic devices (such as heart valves) operating at an accelerated rate. Ex-1001, 1:19-23, 63-67.

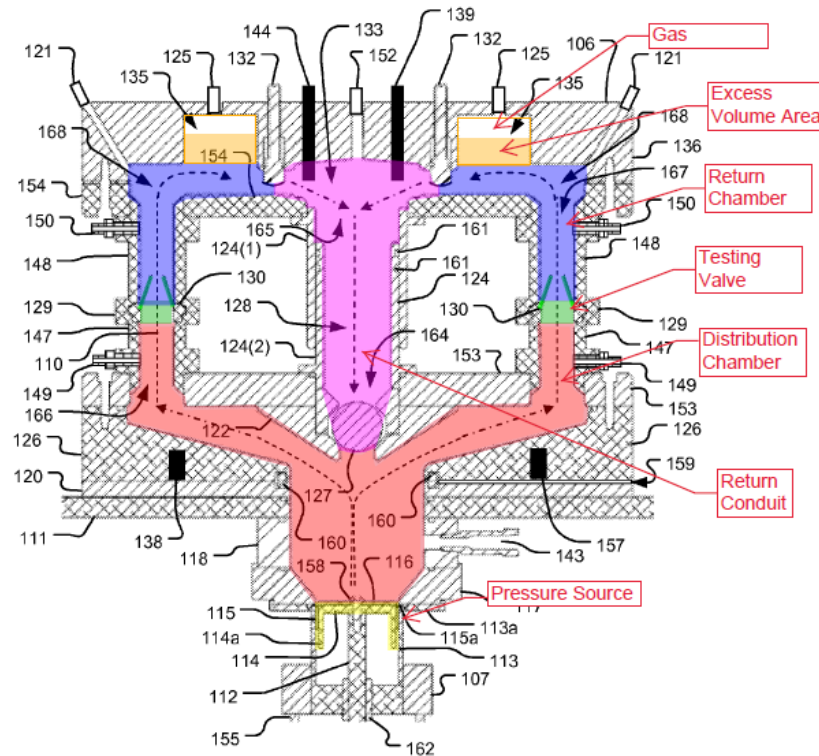


Fig. 3

The test fluid in the system is driven by a fluid drive member—the piston (yellow). The fluid drive member drives fluid upward and laterally into the fluid distribution chambers (red). The test fluid then passes through the prosthetic valve (green) being tested and into the fluid return chamber (blue). The excess volume area (orange), which is in fluid communication with the fluid return chamber, accepts excess

volume of test fluid during the drive stroke by compressing a gas previously occupying the excess volume area, and the test fluid then proceeds downward through the fluid return conduit (pink) during the return stroke of the fluid drive member.

The design of the '935 Patented invention is such that the volume of the test chamber changes depending on whether the system is in a drive stroke or a return stroke. During a drive stroke, the fluid drive member decreases the total volume of the test chamber; thereby, adding pressure to the test system as the fluid is under compression. During a return stroke, the total volume of the test chamber increases; thereby, reducing the pressure on the system.

Notably, the system would be incapable of operating without the excess volume area positioned on the opposite side of the heart valve from the pressure source. For instance, if the system lacked an excess volume area, when the drive mechanism moves and attempts to push more fluid into the already-full channel, the fluid would attempt to force itself through the weakest part of the system or render the pump inoperable. Ex-2003, ¶42. Similarly, if an area were placed solely upstream of the heart valve, the section downstream of the valve would fill with fluid and fluid displaced by the drive mechanism would flow in and out of the upstream area, thereby inhibiting flow through the valve. *Id.*, ¶60. Furthermore, the flow of fluid out of the upstream area would not provide back-pressure upon the heart valve,

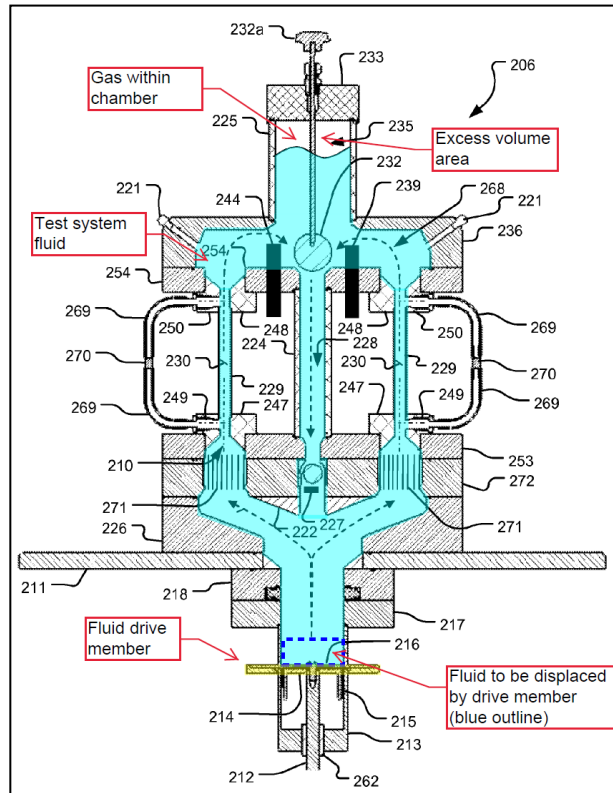
which would prevent the heart valve from closing. *Id.* When positioned downstream of the valve, the excess volume area also reduces/impacts the resistance and the forward flow pressure gradients across the valve, minimizing unnatural and undesirable pressure noise or spikes. *Id.*, ¶¶48-49. Accordingly, the existence of and the location of the excess volume area permits the system to operate at an accelerated rate while reducing damage to the heart valve being tested, thus, mitigating against a premature failure in the same.

An alternative embodiment is depicted in Figure 6 (annotated below). Similar to Figure 3, movement of the piston (yellow) displaces fluid (light blue) within the test system and places that system under a compressive state. When the piston is retracted on its backstroke, the displaced fluid can then flow back into the area previously occupied by the piston. Because fluid is incompressible, the displaced fluid cannot change its volume in response to the compressive state. Instead, gas³

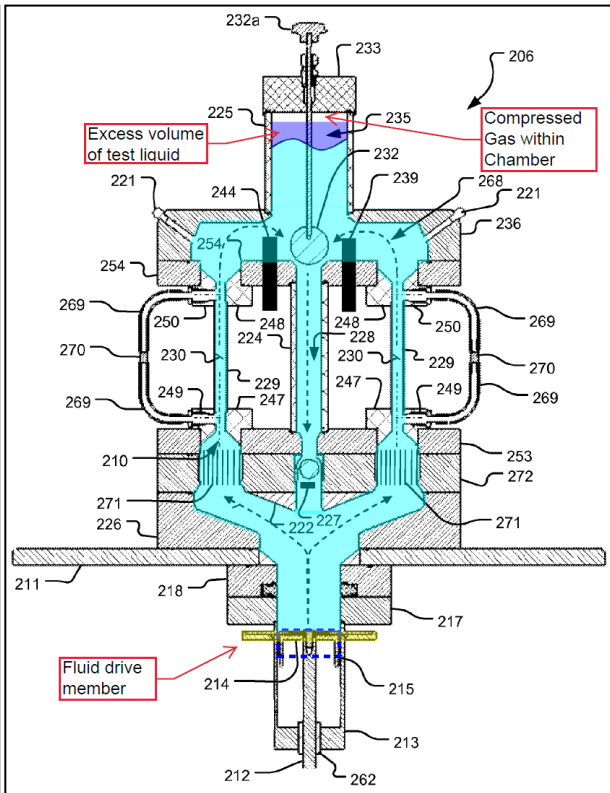
³ The '935 Patent discloses that the compliance chamber in the preferred embodiment may contain “air or another gas,” or may “house a porous material or an elastomeric material.” '935 Patent, 9:20-25. For ease of reference, this Preliminary Response refers to “gas” that provides an excess volume area, but this would also apply to porous or elastomeric material, or another material that provided excess volume area in the manner claimed by the '935 Patent.

located downstream from the valve is compressed to provide an excess volume area capable of temporarily storing the displaced fluid (dark blue).

Return stroke:



Drive stroke:



Accordingly, on the forward stroke of the piston, fluid is pushed through the valve, into the fluid return chamber, and into the excess volume area that is in fluid communication with the fluid return chamber on the downstream side of the valve. When the piston is retracted on its backstroke, the excess volume area returns to being occupied by the compressible gas. The space referred to as the excess volume area is in fluid communication with the fluid return chamber when the gas is displaced during system compression.

B. Prosecution History

Petitioner spends almost seven pages referring to prosecution of related patents before concluding that “compliance chambers plainly existed before the earliest claimed priority date.” Petition at 17. This misses the point. An excess volume area and a compliance chamber are not identical, and not all compliance chambers are capable of providing the claimed excess volume area at an accelerated rate. Ex-2003, ¶¶17, 65. Indeed, the file history shows that although compliance chambers may have been known in the art, compliance chambers that provide “an excess volume area capable of operating at the accelerated pulsed rate...” were not known. *See, e.g.* Petition at 12 (“Pickard’s compliance chamber had a different ‘purpose’”); Ex-1011 at 57 (arguing that the reservoirs of Lundell do not provide the function of the excess volume area), at 68 (Examiner’s Reasons For Allowance of ‘104 Patent stating that “The specific limitation of an accelerated cyclic test system for evaluating a valved prosthetic device ... when combined with the limitations of an excess volume area ... and its location also in independent claim 1 distinguish the present invention from the combined prior art.”).

Likewise, the specification of the ’935 Patent highlights the unique function of the excess volume area. *See* ’935 Patent, 3:14-16 (“A volume of test system fluid is stored in an excess volume area during a system driving stroke that opens the valved prosthetic device.”) and 12:4-6 (“The compliance chambers 135 provide

excess volume area for fluid to move into when the piston 114 performs a compression stroke.”). This is confirmed by the prosecution history.

During an interview with the Examiner, Patent Owner and the Examiner “discussed differences between accelerated and non-accelerated prosthetic device testers” and “also discussed the limits of non-accelerated compliance chambers as they relate to the claimed excess volume area.” Ex-1010 at 58. As a result of those discussions, the Examiner entered an Examiner’s Amendment that the “excess volume area [is] capable of operating at the accelerated pulsed rate” and noted that the specific limitation of an accelerated testing device with that excess volume area “distinguish the present invention from the combined prior art.” *Id.* at 56.

C. Procedural History

In summer 2022, Patent Owner learned that Petitioner was distributing marketing materials for a new tester that infringes the ’935 Patent. In August 2022, Patent Owner sent a letter notifying Petitioner of its infringement of the ’935 Patent. Petitioner responded, claiming that one of Patent Owner’s annotations pointed to the wrong feature but did not deny infringement. In spring 2023, Patent Owner filed a lawsuit in its home jurisdiction, the District of Colorado, only after trying unsuccessfully for months to persuade Petitioner to stop its commercialization of the Accused Product. After the Colorado District Court was persuaded that the Canadian Petitioner had attended and showed the Accused Product in Southern California, the

case was transferred to the Central District of California, and Patent Owner sought a preliminary injunction. In response, Petitioner asserted two invalidity defenses: arguing that the '935 Patent was anticipated by Dynatek (an argument not raised in this proceeding) and alternatively arguing that the '935 Patent was obvious based on combining the Xi air chamber with the Dynatek system (Ground B in this Petition). The District Court denied the preliminary injunction. Patent Owner appealed to the Federal Circuit. While the appeal was pending, Petitioner filed this Petition for *Inter Partes* Review.

The following month, in an unpublished opinion, the Federal Circuit affirmed the denial of the preliminary injunction, determining, based on the District Court record, that it was not clear error for the District Court to deny the injunction based on the low threshold required for arguing invalidity at that stage. *BDC v. Vivitro Labs, Inc.*, No. 2023-2393, 2024 U.S. App. LEXIS 7312 (Fed. Cir. Mar. 28, 2024). *See also Westminster Pharmaceuticals, LLC, v. LPRI France*, IPR2022-00677, Paper 7, Patent 8,183,227 B1, 2022 Pat. App. LEXIS 4312 (P.T.A.B. August 24, 2022) (noting in a footnote that a motion for preliminary injunction was denied but not further considering that fact in its decision denying institution of IPR). The Federal Circuit also expressed doubt as to the correctness of the District Court's preliminary interpretation of claim terms, but did not resolve the meaning of any claim term. *See BDC*, 2024 U.S. App. LEXIS 7312, at *17-18:

We need not consider the district court's claim construction because its determinations on invalidity are equally applicable to a broader construction of an "excess volume area" or the narrower one applied by the court. However, *we caution that claim terms are generally not limited to the preferred embodiments. See Laryngeal Mask Co. v. Ambu*, 618 F.3d 1367, 1372 (Fed. Cir. 2010).

IV. Person of Ordinary Skill in the Art

Patent Owner disagrees with Petitioner's proposed definition of a POSA, which requires experience with unspecified "cardiovascular devices." For instance, pacemakers and catheters may be considered "cardiovascular devices," but would not provide the requisite level of experience for this invention.

Instead, a POSA in this field would have had at least (i) a bachelor's degree in engineering, such as biomedical, mechanical, aerospace or civil engineering, and at least 4 years of experience with flow-based test systems for evaluating heart valves or valve repair devices; or (ii) an advanced degree in the same areas of academic study with at least 2 years of experience with the same systems.

V. Claim Construction

The claims at issue must be given their broadest reasonable interpretation consistent with the specification as it would be interpreted by one of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc). Thus, the focus of the inquiry regarding the meaning of a claim should be what

would be reasonable from the perspective of one of ordinary skill in the art. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010).

There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution. *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1580 (Fed. Cir. 1996); MPEP § 2111.01. To act as his own lexicographer, a patentee must “clearly set forth a definition of the disputed claim term” other than its plain and ordinary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002); *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008) (the patentee must “clearly express an intent” to redefine the term). Whether or not an explicit definition is provided, the specification remains “the single best guide to the meaning of a disputed term.” *Phillips*, 415 F.3d at 1315.⁴

⁴ In the underlying District Court litigation, Patent Owner argued that “in fluid communication,” “under compression” and “excess volume area” did not need specific constructions. While Patent Owner believed this plain and ordinary meaning was sufficient, the resulting dispute and confusion, including that noted by the Federal Circuit, make clear that an express construction would clarify the issues.

A. “in fluid communication” (Claim 1)

Petitioner’s proposed construction is that two elements must merely be in the same flow path in order to be in fluid communication. Petition at 23. Petitioner’s proposed construction is plainly wrong as it 1) is inconsistent with the plain and ordinary meaning of the term; 2) is inconsistent with the specification; and 3) would render the claim language superfluous. Petitioner’s proposed construction is, in essence, that “in fluid communication” has no meaning. More particularly, Petitioner’s interpretation is that two elements are “in fluid communication” regardless of their proximity, spatial relationship, or intervening structures so long as fluid eventually flows throughout the entire system. *Id.* at 19.

In contrast, the plain and ordinary meaning of “communicate” means “to cause to pass from one to another” and “to open into each other.” Ex-2003, ¶55 (quoting Ex-2004). In other words, fluid can move from one area to another unimpeded. Accordingly, the phrase “in fluid communication” denotes the relative position of two elements to permit fluid to pass unimpeded between the two elements; not that they are simply within the same larger fluid system, as alleged by Petitioner. As understood in the context of the specification, the portions “*in* fluid communication” are constantly in fluid communication with each other; the flow is not impeded at any time during the cycle.

Each use of the phrase “in fluid communication” in the specification supports

this understanding of the term. For instance, the specification describes fluid communication (i.e., unimpeded flow path) between the pressure source and the fluid distribution chamber. *See* '935 Patent, 2:44-46 (“The fluid distribution chamber also defines an aperture in a lower face in fluid communication with a pressure source.”), 2:13-16 (“The drive system is coupled to a lower opening in the test chamber and is in fluid communication with the fluid reservoir in the test chamber.”), 3:3-5 (“The fluid distribution chamber is positioned on a first side of the valved prosthetic device and is in fluid communication with a pressure source.”). *See also id.*, 4:20-27 (“The lower distribution chamber of the test chamber has a single fluid reservoir in fluid flow communication with each of the plurality of sample holders....”).⁵

⁵ Petitioner’s argument that “the distribution chamber and piston (i.e., pressure source) are separated by intermediate components including a plenum, base plate, and drive adapter,” and therefore would only indirectly provide fluid communication (Petition at 19), lacks merit. First, claims are generally not limited to a preferred embodiment. *Laryngeal Mask Co. v. Ambu*, 618 F.3d 1367, 1372 (Fed. Cir. 2010). Even still, as can be seen in FIG. 3, the plenum, base plate, and drive adapter simply serve to connect the pressure source to the test chamber and permit unimpeded flow throughout.

Likewise, the specification describes fluid communication from the test valve to the return conduits of the return chamber. *See* '935 Patent, Abstract (“a return flow conduit in fluid communication with each of the sample holders”), 9:29-32 (“separate return conduits 168 that are in fluid communication with respective pairs of the sample holders 129 and compliance chambers 135.”). The specification also describes fluid communication between the fluid return chamber and excess volume area. *See* '935 Patent, 3:9-12 (“the excess volume area is in fluid communication with the fluid return chamber”), 9:13-19 (“A volume of test system fluid is stored in an excess volume area during a system driving stroke that opens the valved prosthetic device. The stored volume of test system fluid is then released during a return stroke that closes the valved prosthetic device.”). Thus, the specification clearly describes “in fluid communication” to denote the relative position of two elements to permit fluid to pass unimpeded between the two elements.

Notably, the specification and claims do *not* describe the fluid distribution chamber and fluid return chamber as being “in fluid communication” with each other, and rightly so. Instead, it states the fluid distribution chamber is in fluid flow communication with the inflow openings of the test valve (*Id.*, 4:20-27) and the outflow openings of the test valve are in fluid communication with the return conduits of the fluid return chamber. *Id.*, 9:29-32. Likewise, claim 1 describes the location of these two chambers in relation to their position with respect to the valve:

“a fluid distribution chamber positioned *on a first side of the valved prosthetic device* and in fluid communication with the pressure source” and “a *fluid return chamber* positioned on *a second side of the valved prosthetic device*” and in fluid communication with the excess volume area. ’935 Patent, Claim 1 (emphasis added). Thus, the fluid distribution chamber is in fluid communication with the test valve, which is in fluid communication with the fluid return chamber. But fluid flows from the fluid distribution chamber to the fluid return chamber only when the valve is open.⁶

When the drive member is in a return stroke, the closed valve separates the fluid in the distribution and return chambers; the fluid cannot flow from the distribution chamber to the return chamber through the closed valve. This is yet another example of how two elements are “in fluid communication” only if fluid can pass unimpeded between the two elements throughout a cycle. Furthermore, fluid that has already passed through the valve is only communicated through the fluid

⁶ In the appeal, the Federal Circuit expressed uncertainty about the term “in fluid communication” and noted that Patent Owner “did not explain” how the valve could separate the fluid distribution and fluid return chambers. *BDC*, 2024 U.S. App. LEXIS 7312, at *8. Patent Owner has now provided this explanation.

return conduit, which structurally and fluidly connects the two chambers. *Id.*⁷

Finally, Petitioner’s proposed construction would render claim language superfluous and the driving of the test system fluid would become incoherent. Under Petitioner’s theory, “in fluid communication” is meaningless since fluid flows throughout the test chamber. But under the correct interpretation, “a fluid distribution chamber ... in fluid communication with the pressure source” denotes that fluid displaced by the compression stroke is unimpeded to pass into the fluid distribution chamber (on the first side of the valve) and, during the decompression stroke, fluid within the distribution chamber is unimpeded to pass back into the space previously unavailable during the compression stroke. Likewise, “the excess volume area is in fluid communication with the fluid return chamber” because fluid can pass unimpeded into the excess volume area from the return chamber (on the second side of the valve) during the compression stroke, and pass back into the return chamber from the excess volume area during the decompression stroke. Moreover, as

⁷ The specification does *not* describe the fluid return conduit as providing “fluid communication” between the distribution and return chambers; it uses the broader term, “fluidly connecting.” *See id.*, 2:51-53. This is because the one-way valve (127) of some embodiments impedes the flow of fluid during the drive stroke. *Id.*, 12:25-29; *see also id.*, 13:59-62.

discussed above, the system would be incapable of operating if fluid could not pass from the return chamber into the excess volume area after having passed through the valve.

Thus, the term “in fluid communication” denotes the relative position of two elements to permit fluid to pass unimpeded between the two elements at all times during the test cycle.

B. “excess volume area” (Claim 1)

An “excess volume area” is a space for storing pressurized fluid displaced by the driving of fluid by the pressure source that opens the valved prosthetic device. Petitioner contends that an “‘excess volume area’ is *just* a compliance chamber.” Petition at 23. This is false. While an excess volume area *may* provide compliance and may be part of a compliance chamber, not all compliance chambers provide an excess volume area (and not all excess volume areas require a compliance chamber). Instead, some compliance chambers merely provide damping of dynamic pressures and mimic mechanical distension of the circulatory system.

Aside from the impropriety of substituting “excess volume area” for “compliance chamber,” Petitioner needed to look no further than the specification of the ’935 Patent to see that the “compliance” of prior art systems is not the same type of compliance discussed in the ’935 Patent. Indeed, when compliance is referred to within the ’935 Patent it refers to the dual ability to 1) “absorb some of the pressure

placed upon the fluid in the test chamber” and 2) “control recoil *toward the original volume dimensions* upon removal of the compressive force.” ’935 Patent, 9:11-16. (emphasis added). It is the excess volume area that provides the second feature of controlling recoil towards the original system dimensions once the compressive force is removed. Thus, if a “compliance chamber,” as described in the prior art, is positioned within a system with unchanging volume dimensions, then it cannot provide the same type of compliance that is described in the ’935 Patent.

Contrary to Petitioner’s arguments, an “excess volume area” and a “compliance chamber” are *not* the same. As described above, test systems involve a number of different types of pressure, and compliance mechanisms may be used to mitigate these different pressures. Compliance mechanisms may mimic the mechanical distensibility of arteries, may buffer long-term changes in systemic pressure, may mitigate pressure spikes due to the water hammer effect, or may dampen noise in the system. In other words, compliance mechanisms may be used to manage System Operating Pressure and Differential Pressure, *see* Section II above, which existed in prior art systems. But the ’935 Patent disclosed a new and specific type of compliance mechanism (an excess volume area) designed to mitigate a certain type of pressure existing in the ’935 Patented invention (Excess Volume Pressure).

Petitioner acknowledges that the specification describes the function that the excess volume area serves. Petition at 23; *see also* '935 Patent, 12:4-9 (“The compliance chambers 135 provide excess volume area for fluid to move into when the piston 114 performs a compression stroke. As the pressure of the gas in the compliance chamber 135 increases, the volume occupied by the gas decreases to provide additional volume for displacement of the ... fluid within the test chamber.”); *see also id.*, 3:9-19 (“... A volume of test system fluid is stored in an excess volume area during a system driving stroke that opens the valved prosthetic device. The stored volume of test system fluid is then released during a return stroke that closes the valved prosthetic device.”). Thus, an “excess volume area” is a volume for storing pressurized fluid displaced by the driving of fluid by the pressure source that opens the valved prosthetic device. Accordingly, Petitioner’s attempts to encompass compliance chambers in systems (such as Dynatek and Xi) where the volume of fluid is not affected by a reduction in system volume, i.e. when not under compression, is not supported.

Petitioner’s attempted use of 112(f) to substitute “excess volume area” with “compliance chamber” fares no better. An “excess volume area” is an area (volume) that is capable of storing fluid affected by the driving of fluid by the pressure source that opens the valved prosthetic device. Petitioner’s construction also fails because it would render meaningless any distinction between the “compliance chamber” of

dependent claim 9 and the “excess volume area” of independent claim 1. *See* ’935 Patent, claim 9 (“The device of claim 1, wherein the *excess volume area comprises a compliance chamber* defining a cavity within the fluid return chamber.”) (emphasis added).

It is black-letter law that patent claims must be “interpreted [to] giv[e] effect to all terms in the claim.” *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006). These two terms—excess volume area and compliance chamber—are not the same thing. Further, in equating the two, Petitioner is improperly reading a limitation from the specification into the claims. The Federal Circuit specifically warned against that in the appeal in the related case. *See* Section III.C above, *quoting* *BDC*, 2024 U.S. App. LEXIS 7312, at *17-18 (“we caution that claim terms are generally not limited to the preferred embodiments.”). Providing a volume for excess fluid to flow into (the excess volume area) does not require the walls of a compliance chamber or any other specific structure. Thus, Petitioner’s inappropriately narrow definition—which imports a limitation from the specification into the claims and conflates two separate claim terms—should be rejected.

C. “under compression” (Claim 1)

“Under compression” means that the test system fluid is under compressive forces as a result of the driving of the pressure source, which reduces the system volume and forces fluid through the test valve. *See* ’935 Patent, 3:9-19 (“The excess

volume area is in fluid communication with the fluid return chamber and provides a volume for storing a volume of a test system fluid when the test system fluid is under compression. ... A volume of test system fluid is stored in an excess volume area during a system driving stroke that opens the valved prosthetic device. The stored volume of test system fluid is then released during a return stroke that closes the valved prosthetic device.”); *see also id.*, 12:4-9, 12:25-31.

Petitioner acknowledges that “[t]he *only* element of claim 1 that can place the test system fluid ‘under compression’ is the ‘*pressure source* configured to *drive* [the] test system fluid cyclically within the device.’” Petition at 26. However, Petitioner then wrongly argues that this would not require “overall force in the system” (i.e. “net neutral”). Undoubtedly, Petitioner’s positions on “in fluid communication” and “under compression” are attempts to shoehorn fundamentally different prior art references into the claims of the ’935 Patent.

Nevertheless, when read consistent with the specification, and as informed by the claim as a whole, it is clear that a net neutral configuration would not place the test system fluid under compression, as used in claim 1. “Under compression” must be read in the context of “pressurizable test chamber,” of which it is a sub-limitation. A pressurizable test chamber is one that can withstand compression caused by the drive mechanism to the overall system; not the ordinary variable pressures of different portions of fluid in an open system or in a non-pressurized system. As may

be appreciated from the specification and the claim language, the pressure source acts upon fluid on the first side of the valved prosthetic device to drive that fluid. *See* '935 Patent, 11:42-49. Thus, the pressure source thereby drives the fluid in one direction by reducing the system volume, which places the test fluid under compression and “drive[s] the pressurized fluid through the prosthetic devices being tested” where it can then be stored within the excess volume area while under compression. *Id.*, Abstract. The fluid is then released from compression as the pressure source withdraws, increasing the system volume.

Indeed, if not for the change in volume of the test system, the test fluid would not be placed under compression; it would simply be transported to another area within the system and would not need an excess volume area “for storing a volume of a test system fluid when the test system fluid is under compression.” *See* '935 Patent, 12:4-9. Thus, “under compression” means that the test system fluid is under compressive forces as a result of the driving of the pressure source, which reduces the system volume and forces fluid through the test valve.

VI. Petitioner Fails To Demonstrate a Reasonable Likelihood of Prevailing On Any of Its Asserted Grounds

Inter partes review cannot be instituted unless “the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.108(c). Petitioner asserts that

the challenged independent claim is unpatentable on three grounds, Xi, Dynatek in view of Xi, and Goldstein in view of Lu. But none of these references or combination teach or suggest each of the limitations in the challenged '935 Patent claim. Thus, Petitioner cannot show a reasonable likelihood that it would prevail on any of the challenged claims, on any proposed ground. Accordingly, its petition should be denied.

A. The Petition Fails To Show That Xi Anticipates Claim 1 (Ground A)

In proposed Ground A, Petitioner argues that Xi anticipates claim 1 and dependent claims 2-4, 8-9 and 12-13. Petition at 30-39. But Petitioner fails to present a *prima facie* case of anticipation or obviousness.⁸ Petitioner cannot show that Xi discloses the claimed system that requires “a pressurizable test chamber” or “an excess volume area capable of operating at the accelerated pulsed rate ... for storing a volume of a test system fluid when the test system fluid is under compression.”

1. Xi Teaches Oscillating the Test Valve; It Does Not Teach a Distribution Chamber on a First Side of the Valved Prosthetic Device

Xi discloses an accelerated tester using a drive motor. Ex-1004. The volume containing the system fluid within Xi is never compressed via a drive stroke and

⁸ Because Petitioner does not make a *prima facie* case of anticipation or obviousness of claim 1, its challenges to the dependent claims also fail.

does not experience the compressive forces associated with driving fluid through a valve. Instead, Xi attaches the heart valve to a rod, then moves the heart valve up and down through the test fluid. *Id.* at 7. On the upward stroke, the valve is open as the valve moves through the fluid. *Id.* On the downward stroke, the valve is closed and pushes test fluid through the system. *Id.* at 7-8. As the fluid is pushed through the system, it flows from the closed valve to an air chamber C₁ (11) (that contains both test fluid and air) and then into a liquid storage tank 17 before being redistributed to the valve (after traveling through a series of conduits and dampers). *Id.* at 8. As further explained by Lu, the compliance and resistance units within Xi “simulate the human systemic circulation for blood flow.” Ex-1005 at 191.⁹ More particularly, valve back pressure “is adjusted through the damper R₁ (13).” Ex-1004, at 8. The air chamber 11 positioned upstream of the damper prevents the valve from collapsing upon itself while the valve is used to push fluid through the system. Ex-2003, ¶85.

Petitioner alleges that the “distribution chamber” is the area above the valve. Petition at 35. In other words, the fluid pushed by the closed valve must pass through

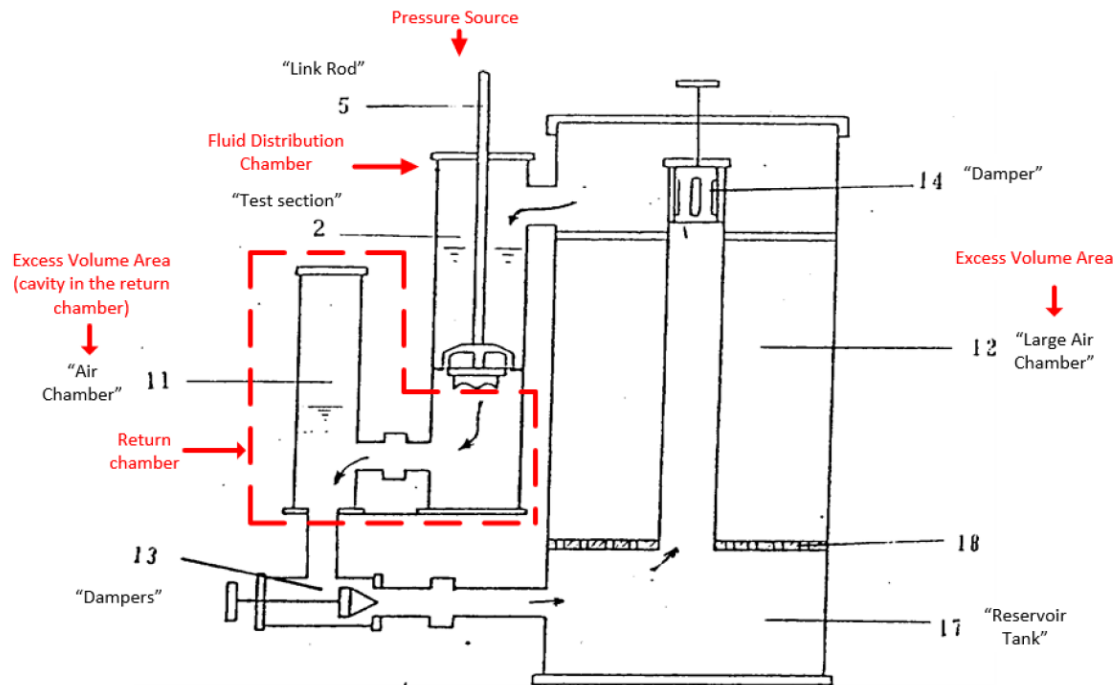
⁹ Petitioner’s position is that the TH220 described in Lu is “highly similar” to Xi. Ex-1002, ¶143. Notably, the TH220 is attributed to Tsinghua University, the Assignee of the Xi reference.

all the dampers and the entire system before reaching the alleged distribution chamber. As discussed above, this strained interpretation of “in fluid communication” is not supported by the specification or common sense.

Xi does not disclose “a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source.” Instead, Xi discloses using the valved prosthetic device as the pressure source. Ex-2003, ¶80. That is, the valve and the pressure source are the same structure in Xi, whereas they must be different structures in the ‘935 Patent. *See* Section VI.A.2, below. As described above, “a fluid distribution chamber ... in fluid communication with the pressure source” denotes that fluid displaced by the compression stroke can pass into the fluid distribution chamber on the first side of the valve and that during the decompression stroke, fluid within the distribution chamber is unimpeded to pass back into the space previously unavailable during the compression stroke. The distribution chamber is thus positioned between the pressure source and the valved prosthetic device. Xi does not disclose this since the tested valve is the pressure source.

Petitioner attempts to sidestep this deficiency of Xi by identifying the link rod and valve frame of Xi as the “pressure source.” Petition at 32-33 (annotated Fig. 4, reproduced below). However, the link rod and valve frame cannot drive the test fluid within the device without using the closed valve. Furthermore, the valve/frame

cannot simultaneously be the valved prosthetic device and the pressure source in fluid communication with the distribution chamber on a first side of the valved prosthetic device.¹⁰ Ex-2003, ¶80.



Thus, Xi does not teach or suggest “a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source.”

¹⁰ Petitioner’s argument that the valve “move[s] up and down ... [s]o *both sides* of [the] test section—the upstream distribution chamber *and* the downstream return chamber are ‘in fluid communication’ with the pressure source” (Petition at 37) suffers from the same deficiencies. Furthermore, to the extent this were true, the fluid distribution chamber would be both sides of the valve (contrary to the claims).

2. ViVistro Improperly Relies on the Test Valve to Satisfy Two Separate Elements of Claim 1

Claim 1 describes an “accelerated cyclic testing” device comprised of two elements: a pressure source (1a) and a pressurizable test chamber (1b). The pressurizable test chamber is comprised of several sub-components, including a fluid distribution chamber (1b1), fluid return chamber (1b2), fluid return conduit (1b3) and excess volume area (1b4). The fluid distribution chamber and fluid return chamber are part of the “test chamber” and on opposing sides of the test valve, which necessarily means that the test valve exists within the test chamber (1b).

ViVistro requires the test valve to satisfy two elements and be in two locations simultaneously (1a and 1b1/1b2).

1. A device for accelerated cyclic testing of a valved prosthetic device comprising
 - 1a a pressure source configured to drive a test system fluid cyclically within the device above a normal physiological rate, at an accelerated pulsed rate of greater than 200 beats per minute within the device; and
 - 1b a pressurizable test chamber for containing the test system fluid and further comprising
 - a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source;
 - a fluid return chamber positioned on a second side of the valved prosthetic device;
 - a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and
 - an excess volume area capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid communication with the fluid return chamber providing a volume for storing a volume of a test system fluid when the test system fluid is under compression.

In an effort to force the “square peg” (Xi) into the “round hole” (Claim 1), ViVitro requires the valve to be both the “pressure source” (1a) that is a separate element from the test chamber, and also the “valved prosthetic device” within the test chamber (1b1/1b2). Because the pressure source must be different than the valved prosthetic device, Xi cannot anticipate the ‘935 Patent.

3. Xi Teaches an Open System That Is Not a Pressurizable Test Chamber

Rather than showing that Xi discloses a closed system, Petitioner disagrees with Patent Owner’s explanation that Xi is an open system so it would not need to avoid excessive pressure. Petition at 33-34, n.10. To be clear, Petitioner bears the burden of showing that the prior art discloses all of the limitations found in the claims. *Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016). It is not Patent Owner’s burden to disprove what Petitioner fails to show. Petitioner has failed to show that Xi is a closed system. Petitioner argues that Xi must be a closed system because Xi discusses the water hammer effect and “good

sealing performance.”¹¹ Petition at 33-34, n.10. These arguments are unavailing.

First, the vague reference to “good sealing performance” in Xi does not suggest, much less demonstrate, that the system is closed. Both open systems and closed system can utilize seals, for example in connecting components of the system or in providing a seal around the test valve to ensure proper testing. Furthermore, Petitioner’s argument that the linear motor is positioned to “not create ... conflicts in sealing,” (*Id.*) is unpersuasive since Xi teaches that “[t]he linear motor (1) and main shaft (3) are located above the unit.” Ex-1004 at 6. Indeed, the lack of sealing would not create problems because the motor is above the fluid level in the system. *See, e.g.*, Ex-1005 at 186 (discussing oscillating TH220 tester that “placed the drive

¹¹ Petitioner also attempts to circumvent the word limits of an IPR petition by incorporating arguments by reference from Exhibit 1002. *See, e.g.* Petition at 34 (citing to declaration allegedly “explaining why Xi is ‘closed’”). “Arguments must not be incorporated by reference from one document into another document.” 37 CFR § 42.6(a)(3). *See Parus Holdings, Inc. v. Google LLC*, No. 2022-1269, 2023 WL 3939532, at *3 (Fed. Cir. June 12, 2023) (affirming Board’s decision not to consider arguments incorporated by reference). Petitioner’s improper incorporations by reference throughout its brief to support conclusory statements should be disregarded.

unit on the top ... thus ... avoid[ing] leaking problems.”). The water level can be seen in Fig. 4 presented by three lines of decreasing length.

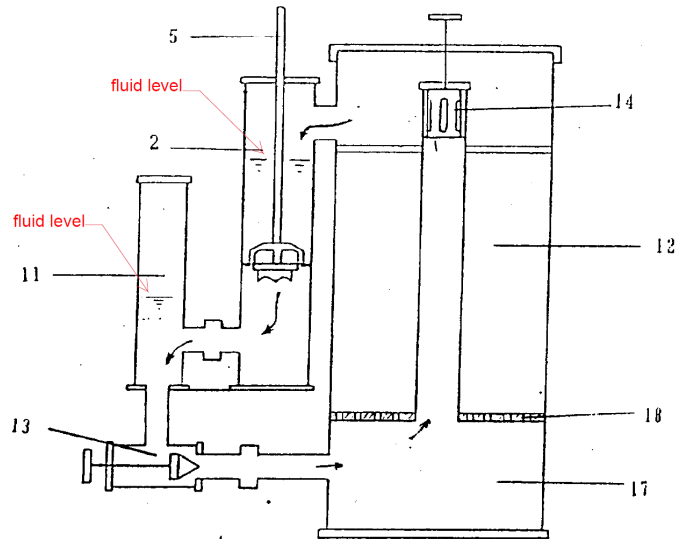


Fig. 4

Indeed, fluid levels are shown in the same manner in Fig. 5 of Reul (Ex-1020), which is open to atmosphere and also relied upon by Petitioner.

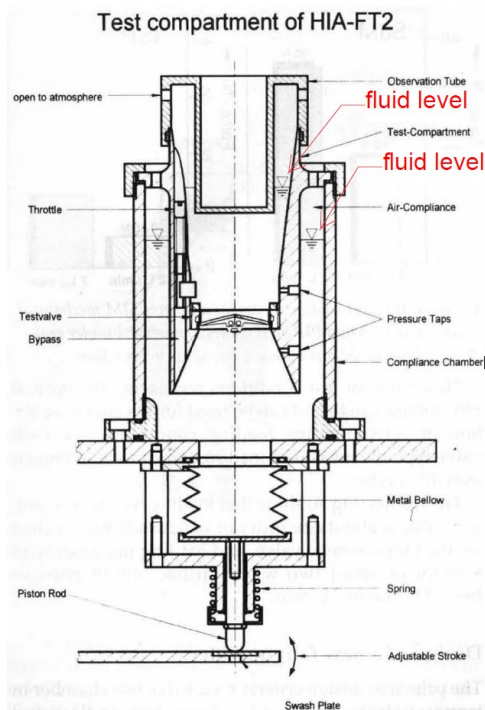


Figure 5: Schematic cross-section of newly developed test compartment for accelerated valve testing.

Second, the water hammer effect is not limited to closed systems because the water hammer effect is caused by the rapid closing of a valve, which causes a pressure propagation when the fluid moving through the valve is forced to abruptly stop. Ex-2003, ¶27. Notably, however, using an open system such as Xi can further mitigate the effects of water hammer because the energy from the momentum of the fluid can be more readily dissipated. *Id.*, ¶86. Thus, Petitioner has not shown that Xi is a closed system.

Moreover, the reference makes clear that the *Xi is open to atmosphere*. *Id.*, ¶82. As Figure 4 shows, the link rod moves up and down to open and close the valve. To create a pressurizable system, there would need to be a seal that prevents the air above the fluid from escaping around the link rod while permitting the link rod's movement. There is no description anywhere in Xi of such a seal. Likewise, Xi does not indicate that it accounts for friction between the unmentioned seal and link rod when measuring the valve load. Furthermore, Xi discusses monitoring that is comprised of "...a valve load measurement, a valve displacement measurement, and a valve back pressure measurement" and then further states "[t]he valve back pressure is measured using a blood pressure transducer (29)." Ex-1004 at 2. As discussed above, the valve back pressure is a measurement of the pressure difference across the closed valve (i.e., the difference of the upstream pressure from the downstream pressure on the closed valve). Inherent in this attribute are two pressure

measurements. Xi, however, states this parameter is determined by a single pressure transducer “(29)” that is located downstream of the valve. Therefore, the only manner to determine valve back pressure is if the test system is open to atmosphere on the upstream side of the valve (i.e., the valve back pressure is the difference between atmospheric pressure and the pressure measured downstream of the valve). Thus, Xi is an open system and the fluid reservoir on the inflow side of the valve is open to the atmosphere and is not pressurized. Ex-2003, ¶82.

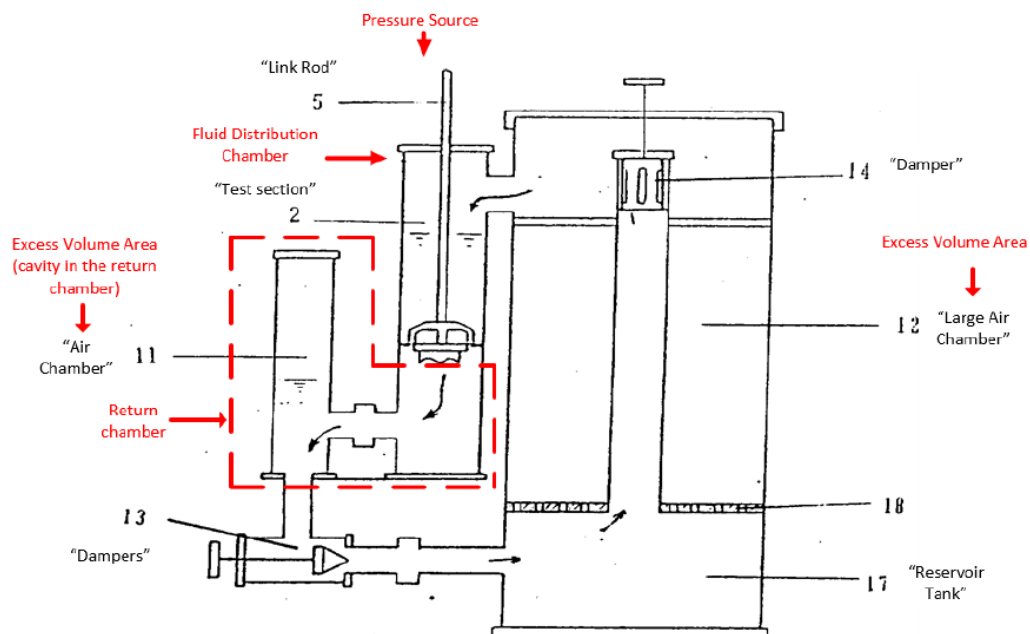
Because Xi has no pressurizable test chamber, it does not meet the limitations of claim 1. Claim 1 requires that the distribution chamber, return chamber, return conduit, and excess volume area are each part of the *pressurizable* test chamber. The Petition does not show that the Xi distribution chamber and return chamber are pressurizable; at most, Petitioner alleges that there is back pressure on the valve, which can be measured. Petition at 33. But, that back pressure is actively measured against atmosphere as an open system. This does not constitute a pressurizable chamber. Simply, an open chamber is not pressurizable.

Further, Xi is not subjected the rising pressures associated with a reduction in system volume during the driving stroke of the pressure source, because it uses the valve to push fluid through a loop, with the displaced fluid volume returning to above the valve during the same stroke. There is no reduction in volume that would place the test fluid under compression. Thus, Xi does not disclose a “pressurizable test

chamber” or an excess volume area.

4. Xi’s Compliance Chamber Does Not Include An Excess Volume Area That Provides A Volume For Storing A Volume Of A Test System Fluid When The Test System Fluid Is Under Compression

Petitioner strains reasonable interpretation in an effort to map the elements of claim 1 onto Xi’s system. Petition at 32 (annotated Fig. 4, reproduced below). As discussed above, Xi does not disclose a pressure source in fluid communication with a fluid distribution chamber on a first side of the valve. The pressure source and the valve are the same in Xi.



Furthermore, Xi does not disclose placing the test fluid under compression. As discussed above, “under compression” means that all of the test system fluid is under compressive forces as a result of the pressure source, which reduces the total system volume and forces fluid through the test valve. Xi is not capable of operating

in this manner. Instead, the available system volume within Xi remains constant, with the volume of fluid displaced below the valve during the downward stroke returning to above the valve during the same period by simply following the flow path. Thus, the fluid in Xi is not “under compression.”

Petitioner also alleges that air chamber C₁ (11) satisfies the “excess volume area” clause. Once again, rather than focus on the function described in the claims and the patent, Petition attempts to substitute “compliance chamber” for “excess volume area.” Petition at 39-40. Petitioner also misquotes the prosecution history (*id.*), and omits the remainder of the statement explaining that the use of compliance chambers was “known for the purpose of substituting for the arteries of the human circulatory system” in real-time, physiologically accurate systems. Ex-1011 at 54. Again, compliance has many meanings and the compliance being discussed in the ‘935 Patent relates to the change in system volume dimensions associated with the drive stroke.

Xi’s air chamber provides a type of compliance that is well known—to mitigate Differential Pressure. Indeed, Xi discloses that each test section has an air chamber C₁ (11) and damper R₁ (13) to control the valve back pressure, i.e., the trans-valve pressure differential, and “can be varied from 0 to 100 mg Hg, which can meet the physiological range.” Ex-1004, at 8. These are the minimum performance requirements permitted under ISO 5840 for hydrodynamic testing. *See* Ex-1017 at

12. That does not, however, mean that Xi is capable of providing the excess volume area that is necessary to absorb the stroke volume of a pump in a closed system.

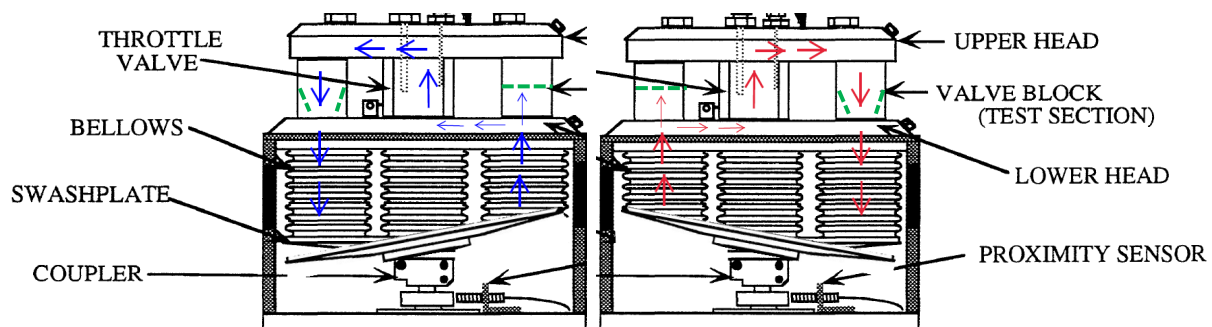
Petitioner appears to concede this fact. Rather than explain how Xi would store the volume of fluid under compression, Petitioner discusses compliance chambers in general and the water hammer effect. Petition at 39-40. In the concluding paragraph, Petitioner conclusorily states that a POSA would have understood that Xi's compliance chamber reduces water hammer by providing a volume to store "some" excess fluid. This is incorrect and unsupported. Ex-2003, ¶86. Xi has no need to store excess fluid because the volume within the system stays the same. As the valve of Xi is closed on the downward stroke, it causes fluid to flow counterclockwise (as shown in Fig. 4) through the system and return to above the valve during the same period. Thus, Xi does not disclose "an excess volume area capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid communication with the fluid return chamber providing a volume for storing a volume of a test system fluid when the test system fluid is under compression."

For each of these reasons, Petitioner fails to meet its burden of showing a reasonable likelihood that it would prevail with respect to the claims challenged in the Petition as anticipated by Xi. Accordingly, the Board should decline to institute review on Ground A.

B. The Petition Fails To Show That Claim 1 Is Obvious In View Of Dynatek & Xi (Ground B)

In proposed Ground B, Petitioner argues independent claim 1 and dependent claims 2-4, 8-9 and 12-13 are obvious over Dynatek in view of Xi. Petition at 45-58. But Petitioner fails to present a *prima facie* case of obviousness.¹²

The Dynatek system uses a swashplate, which is a circular disk mounted at an angle on a shaft, to drive the system. Ex-1006 at 5. As the swashplate rotates, fluid is drawn down into the extended bellows through the opened valve being tested. *Id.* As the swashplate rotates, the bellows then compresses, causing the fluid to reverse direction and close the valve and escape through a bypass port of the lower head into the central channel where it then moves to the upper head for another cycle. *Id.* The annotated figure below illustrates one cycle of the swashplate. In such a system, the associated bellows move fluid from one chamber to another, with flow moving through each “test section” and the central channel as it rotates.



¹² Because Petitioner does not make a *prima facie* case of obviousness of claim 1, its challenges to the dependent claims also fail.

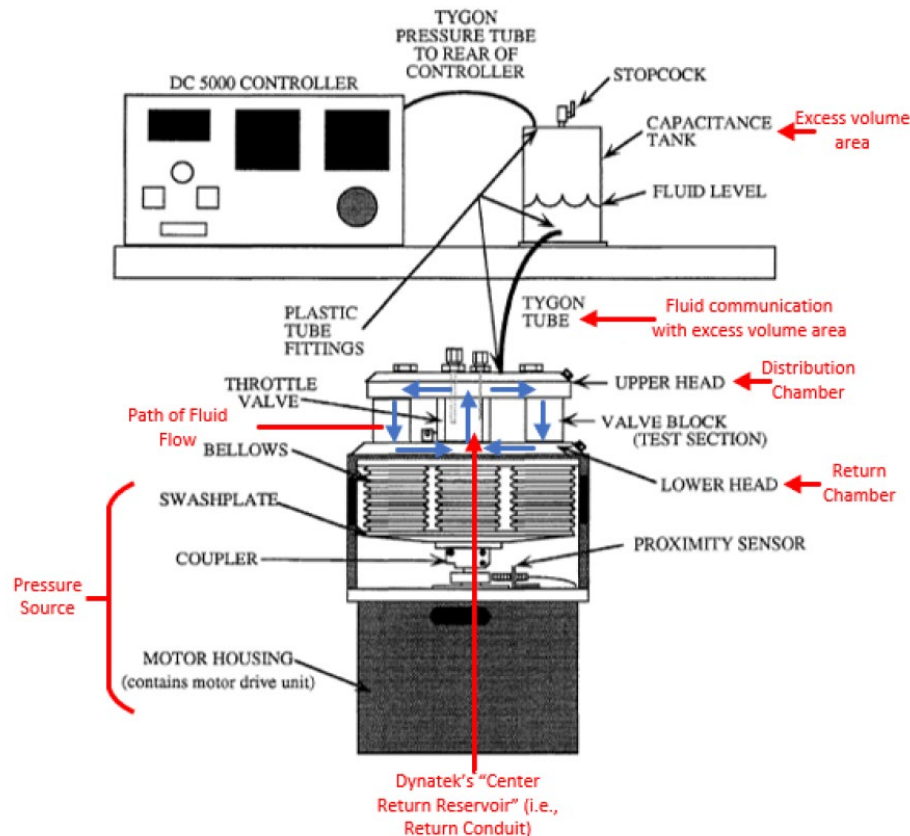
Dynatek uses a “capacitance tank” to “buffer *small variations* in the system pressure which arise *from transient small leakage and thermal effects.*” *Id.* at 19 (emphasis added). Air is added into the capacitance tank to adjust the systemic operating pressure. *Id.* at 15.

Petitioner cannot show that Dynatek in view of Xi discloses the arrangement of elements within the claimed system or “an excess volume area capable of operating at the accelerated pulsed rate ... for storing a volume of a test system fluid when the test system fluid is under compression.” Dynatek’s capacitance tank cannot meet this limitation. Furthermore, Petitioner’s proposed combination relies upon Xi’s air chamber to allegedly provide volume for storing the volume of the test system fluid when the test system fluid is under compression. *See* Petition at 54. As explained above, Xi does not disclose this feature. Even if it did, there would be no reason to combine it with Dynatek, because the Dynatek system has no change in system volume that would require a volume for storage of extra volume of test fluid. Ex-2003, ¶¶90-93. Institution can be denied for this reason alone.

1. Dynatek Does Not Teach a Pressure Source in Fluid Communication with a Fluid Distribution Chamber or an Excess Volume Area in Fluid Communication with the Fluid Return Chamber

Claim 1 requires “a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source.” It also requires “an excess volume area capable of operating at the accelerated pulsed

rate, wherein the excess volume area is in fluid communication with the fluid return chamber providing a volume for storing a volume of a test system fluid when the test system fluid is under compression.” Petitioner alleges that Dynatek’s swashplate is the pressure source, the upper head is the distribution chamber, the lower head is the return chamber, and the capacitance tank is the excess volume area. Petition at 45.



As can be seen from Petitioner’s own illustration of Dynatek, the alleged pressure source (swashplate) is not in fluid communication with the distribution chamber (upper head) because it is in fluid communication with the return chamber (lower head) and, at certain times in the cycle, the closed test valve impedes any

fluid flow from the fluid distribution chamber to the fluid return chamber. Indeed, fluid from the bellows must first flow through the return chamber (lower head), throttle valve, and fluid return conduit (center return reservoir) before reaching the distribution chamber (upper head). Importantly, Claim 1 requires that the fluid distribution chamber is positioned on a first side of the valved prosthetic device and the fluid return chamber is positioned on the second side of the valved prosthetic device. Thus, the pressure source cannot be in fluid communication with the chamber on the first side of the valve if the fluid displaced by the pressure source flows into the chamber on the opposing side of the valve.

Likewise, the “capacitance tank” that Petitioner alleges is an excess volume area is connected with the distribution chamber (upper head), not the return chamber (lower head). *See also*, Ex-1006 at 9 (“Connect ... capacitance tank fitting to top of upper head”).¹³ Indeed, fluid from the return chamber (lower head) must first flow through the throttle valve and the fluid return conduit (center return reservoir) before

¹³ Notably, Petitioner labels the figure “fluid communication with excess volume area”; rather than using the claim language “in fluid communication with the fluid return chamber.” If Petitioner had used the claim language, the error would have immediately been apparent: the labeled feature is clearly in fluid communication with the fluid distribution chamber instead of the fluid return chamber.

reaching the distribution chamber (upper head) to which capacitance tank is connected. This clearly impedes the flow between the lower head and the capacitance tank. Likewise, fluid would be impeded from flowing back to the lower head from the capacitance tank as fluid is constantly flowing from the lower head to the upper head due to the unsynchronized testing of Dynatek's valves.

Thus, Dynatek does not disclose an “excess volume area is in fluid communication with the fluid return chamber.”

2. Dynatek Lacks an Excess Volume Area

Nowhere in Petitioner's claim chart does Petitioner allege that Dynatek discloses an excess volume area capable of providing a volume for storing a volume of a test system fluid when the test system fluid is under compression. *See* Petition at 54-55. Instead, Petitioner argues that the capacitance tank is a type of compliance chamber. *Id.* Even so, this would not establish the claimed excess volume area for three reasons: (1) it does not provide a space for storing fluid under compression (displaced by the driving of fluid by the pressure source that opens the valved prosthetic device); (2) it is *incapable* of performing this function since the capacitance tank is on the inflow side of the valve; and (3) the connection of the capacitance tank—a single chamber for all valves separated from the test chamber by a long thin tube—prevents it from operating at an accelerated rate like the '935 Patent excess volume area located within the test chamber.

First, the Dynatek capacitance tank does not provide a volume for excess fluid to flow into, simply because there is no excess fluid in the system. In Dynatek, the associated bellows move fluid from one chamber to another, with flow moving through each “test section” and central channel as it rotates. As shown in the annotated figures above, as one section of bellow is compressing and pushing fluid through the bypass port of the lower head, the opposing bellows is extending and drawing fluid through the opened valve being tested. Thus, the fluid is not under compression (i.e. under pressure through a loss of volume in the system due to the drive stroke). *See* Ex-1006 at 5.

Second, the compliance chamber *cannot* provide an excess volume because it is on the wrong side of the valve. This illustrates the fundamentally different operation between the excess volume area and the capacitance tank in Dynatek. Because the claimed excess volume area is in fluid communication with the fluid return chamber, which is on the opposite side of the valve from the pressure source that displaces fluid to open the valve, it stores a volume of test fluid when the system is under compression. As the fluid is released during a return stroke, the valve remains closed due to the flow reversal. *See* '935 Patent, 14:39-47. In contrast, if fluid were temporarily stored within the capacitance tank, the fluid attempting to flow out of the capacitance tank would flow into the inlet side of the valve since the capacitance tank is connected to the distribution chamber (upper head). This would

frustrate the closing of valves as it opposes the flow of fluid from the compressed bellows on the other side of the valve, which is used to close the valve. Likewise, since Dynatek's design has multiple valves in various stages of opening and closing, a single capacitance tank, as used in Dynatek, would be insufficient to accommodate the cyclical storing and releasing of fluid from each test chamber simultaneously.

The Petition is completely devoid of any evidence that the capacitance tank of Dynatek provides a volume for storing a volume of a test system fluid when the test system fluid is under compression, or that it would be capable of doing so. Thus, claim 1 is not disclosed by Dynatek.

Third, the Dynatek system would not be “capable of operating at the accelerated pulsed rate,” as required in claim 1, while “storing a volume of a test system fluid when the test system fluid is under compression.” During prosecution, the Examiner's Amendment specifically added the underlined language: “an excess volume area capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid communication.” Ex-1010 at 56 (emphasis added). The Examiner remarked that this excess volume area capable of operating at the accelerated pulsed rate distinguished the invention from the prior art, including Pickard. *Id.* Like Pickard's compliance chamber, Dynatek's capacitance tank that is only designed to “buffer *small variations* in the system pressure which arise *from transient small leakage and thermal effects*” (Ex-1006 at 19) would not be capable

of operating at an accelerated rate to cyclically storing an entire stroke of the test system fluid when under compression. Ex-2003, ¶¶98-100.

The inability of the capacitance tank to handle cyclical compression is underscored by the size of the tubing: the capacitance tank is connected by 1/8 inch tubing that is 5 feet in length. *Id.*; Ex-1006 at pp. 12 ¶6. This tubing is approximately the same diameter as the charging cord for an iPhone; it is too narrow and too long to allow for effective passage of fluid during the accelerated cycles performed by the tester (>200 bpm, with typical operation of 600-1200bpm). Ex-2003, ¶¶98-99. The small tubing size would only exacerbate problems inherent with the placement of the capacitance tank on the upper head and operating at an accelerated rate, since fluid would be incapable of rapidly traversing from the lower head, through the throttle valve, through the central return reservoir, and into the upper head before reaching the capacitance tank. *Id.*, ¶100.

As discussed below in Section VI.B.4, Dynatek's capacitance tank does not operate in this manner since it is designed to control the System Operating Pressure; not to receive a volume of test system fluid when the test system fluid is under compression.

3. Xi Does Not Remedy the Deficiencies of Dynatek

Xi does not remedy the deficiencies of Dynatek. As discussed above in Section VI.B.2, just like Dynatek, Xi also does not disclose an excess volume area

for storing a volume of a test system fluid when the test system fluid is under compression. Furthermore, none of the examples of compliance cited by Petitioner allege to be capable of performing this function. In fact, one of the references relied upon to allegedly teach that a compliance chamber could be placed downstream of a heart valve is Pickard (Ex-1018). *See* Petition at 54.

Notably, Pickard was distinguished because its “compliance chamber had a different ‘purpose’” and would “mimic the circulatory system distensibility.” *Id.*, at 12. Xi’s air chamber similarly reduces high frequency pressure spikes across the valve. *See* Ex-2003, ¶72. In contrast, none of Xi, Dynatek, or Pickard store pressurized fluid displaced by the pressure source that opens the valved prosthetic device. Further, it is unclear how a POSA would combine Xi’s open system and Dyantek’s closed system, maintaining the capacitance tank that presumes a closed system, with the air chamber of Xi which exists in an open system. As described below, there is no plausible reason a POSA would combine these references, nor any obvious way to combine various elements of each system without destroying the overall operation of this new Frankenstein system.

4. A POSA Would Not Be Motivated To Combine Dynatek with Xi

Petitioner fails to provide adequate support to show that a person of ordinary skill in the art, in March 2009 (the priority date for the '935 Patent), would have been motivated to combine the Dynatek user manual with the Xi patent application.¹⁴

To invalidate on obviousness, a party must demonstrate “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, 1375 (Fed. Cir. 2016). In *Virtek Vision Int’l ULC v. Assembly Guidance Sys., Inc.*, the Federal Circuit provided clear guidance on evidence necessary to demonstrate a motivation to combine. 97 F.4th 882 (Fed. Cir. 2024). In reversing a PTAB decision because the Board “erred as a matter of law” in finding

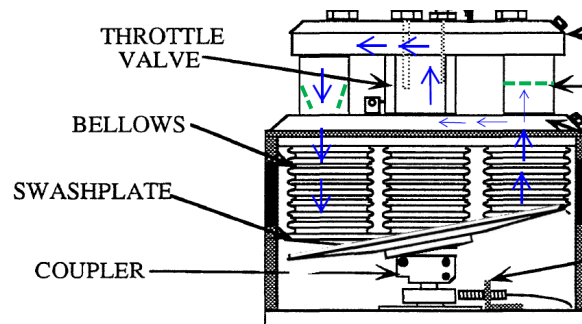
¹⁴ As of March 2009, Patent Owner’s expert had spent over 16 years working in product design, research & development and testing of cardiovascular medical devices, including as a Senior Director of Research & Development at St. Jude Medical. Ex-2003, ¶3. By contrast, Petitioner’s expert was still completing his post-doc and had not worked in the industry. Ex-1003. Petitioner’s expert is merely applying hindsight. By contrast, Patent Owner’s expert can persuasively speak to the level of skill and knowledge at the time.

a motivation to combine, the Federal Circuit made clear that a Petitioner must supply specific reasons for combining the individual references at issue. “It does not suffice to meet the motivation to combine requirement to recognize that two alternative arrangements... were both known in the art.” *Id.* at *6. “The mere fact that these possible arrangement existed in the prior art does not provide a reason that a skilled artisan would have substituted [feature 1] in [prior art 1] for the [feature 2] disclosed in [prior art 2].” *Id.* at *7. Yet, this is precisely what Petitioner does here.

As Patent Owner’s expert explains, a POSA would not have been motivated to combine Dynatek and Xi. Ex-2003, ¶¶114-117. There is no reason why one of ordinary skill would have combined the “air chamber” of Xi with the Dynatek M6 system, when the systems operate in fundamentally different ways. *Id.*, ¶114. As described above, Xi uses a motor to drive the valve through fluid, and Dynatek M6 uses a swashplate to move the test liquid around without changing the overall net volume of the system. And the two systems use compliance in two different ways: Dynatek using the capacitance tank to control System Operating Pressure and act as a reservoir to replace fluid due to system leakage and/or accommodate changes in volume due to expansion/contraction of system structure due to long-term thermal effects (*Id.*, ¶72) and Xi uses the air chamber to mitigate Differential Pressure or back pressure on the valve in an open system. *Id.*, ¶85. Furthermore, Dynatek’s

capacitance tank functions globally (a single capacitance tank for all six valves), whereas Xi's air chamber is localized to a single valve.

There would be no need to combine the Xi air chamber with the Dynatek system. Dynatek does not push fluid through the system with a valve (and thus, does not necessitate the type of compliance required by Xi). Further, the Dynatek system needs flow to move the test fluid to the other side of the system to go through other valve; a Xi-type air chamber is not needed and would not be effective.



In fact, the Dynatek system *teaches away* from use of gas within the test chamber; the Dynatek user guide requires removing all air from the test chamber. Ex-1006 at p. 9 (“[B]ubble removal is one of the biggest challenges facing a valve tester.”). Dynatek then instructs operators to increase the global (systematic) pressure using the capacitance tank in order to further inhibit cavitation that could form in the system. *See, id.* at 15 (Step 41); *id.* at 23-24.

While Dynatek instructs users to add air to a remote reservoir (the capacitance tank) to help set and maintain overall System Operating Pressure and act as a reservoir to replace fluid due to system leakage and/or accommodate changes in

volume due to expansion/contraction of system structure due to long-term thermal effects, the function of the capacitance tank is entirely different from placement of gas in the test chamber, which Dynatek warns against. Thus, a POSA would not have a motivation to combine these two, and would not have a reasonable expectation of success in doing so.

Petitioner’s reliance on other references to supply a motivation to combine Xi with Dynatek similarly fails. Petitioner describes Iwasaki (Ex-1019) and Dynatek (Ex-1006) as disclosing accelerated testers with compliance, but neither disclose the type of compliance relevant to the ’935 Patent. Iwasaki describes the HIA, Rowan Ash (no compliance) and a Tsinghua tester that is based on Xi. These testers are not closed systems and only utilize a compliance chamber to dampen dynamic pressure spikes—not to accommodate the full stroke volume with an “excess volume area.”

C. The Petition Fails To Show That Claim 1 Is Obvious In View Of Goldstein and Lu (Ground C)¹⁵

In proposed Ground C, Petitioner argues independent claim 1 and dependent

¹⁵ Because Grounds D & E address only dependent claims, they are not addressed in this Preliminary Response. Because Ground C fails, for the reasons described herein, Grounds D and E, which involve dependent claims and rely upon the same prior art references—Goldstein and Lu—also fail.

claims 2-4, 7-9 and 12-13 are obvious in view of Goldstein and Lu. Petition at 59-70. But Petitioner fails to present a *prima facie* case of obviousness.¹⁶

**1. Goldstein Discloses A Real-Time Pulse Duplicator
Incapable Of Operating At Accelerated Rates**

The Goldstein reference cited by ViVistro (Ex-1007) is a real-time pulse duplicator device that operates in a fundamentally different way from the '935 Patented invention. The Goldstein system is intended to study valve function and as a bioreactor for cell seeding of biological valves. In particular, Goldstein operates at a “variable frequency from 60-120 bpm and a cardiac output of 2-7.5 L/min.” Goldstein, 10:3-4. Thus, it is not an accelerated pulsed rate. It includes a mechanical mitral valve to keep flow going in a loop and a compliance element to simulate circulatory resistance. *Id.*, 10:25-41. In addition, the compliance tank is raised above the rest of the loop to provide a pressure head against which the fluid must flow and provide back pressure on the aortic valve. *Id.*, 10:38-47. Thus, this system is a large volume system and would not be able to function at accelerated rates with appropriate flows and pressures across the aortic valve. This is because of inertial mass of the large flow loop volume not being able to maintain the conditions at typical durability test speeds. Ex-2003, ¶103. Similar to the compliance module of

¹⁶ Because Petitioner does not make a *prima facie* case of obviousness of claim 1, its challenges to the dependent claims also fail.

other prior art references, which are used to shape the systemic pressure waveform to mimic the circulatory system distensibility (*e.g.*, capillaries), the compliance element of Goldstein is likewise incapable of minimizing the kinetic energy of fluid flow from translating into high static fluid pressure in the test system during the accelerated frequency testing.

As further explained by Patent Owner's expert:

Some real-time testers, such as Pickard (1987), had a system that essentially imitated the circulatory system.... However, it is not possible to convert a real-time tester such as Pickard into an accelerated tester simply by speeding up the rate; it cannot maintain the pressures conditions needed (*i.e.* the back pressure necessary to test the valve). As the system is operated faster, the fluid flow and fluid momentum will prevent the system from creating adequate back pressure at the test valve.... [Other] issues may include drive system difficulties, flow rates and/or pressures that are required for achieving conditions required for performing accelerated durability testing.

...

If it were possible to turn a real-time pulse duplicator tester into an accelerated durability tester by simply speeding it up, everyone would have done this decades ago.

Ex-2003, ¶¶19, 110.

In early 2009, the operational limitations of pulse duplicator systems

prevented them from being effective when sped up to accelerated rates. *Id.*, ¶¶110-112. Further, it was not obvious to a POSA that operational characteristics of pulse duplicators could be adapted or were capable of running at high speeds for durability testing. *Id.*, ¶104. This is why durability testers like those described by Iwasaki (Ex-1019) and Dynatek (Ex-1006) were configured quite differently to achieve high speeds while generating acceptable pressure conditions. *Id.*

The '935 Patent claimed the first durability system with characteristics of pulse duplicators that could function as an accelerated tester. During prosecution of a related patent, the Examiner pointed to a real-time pulse duplicator system, Pickard, that the Examiner initially contended disclosed all elements of claim 1. Ex-1009 at 63, 71. After further communications with Patent Owner, the Examiner recognized the fundamental distinction between the operations of real-time versus accelerated testers, and allowed the claims. *Id.* at 88; *see also* Ex-1010 at 56 (“an accelerated cyclic testing device with an excess volume area capable of operating at the accelerated pulsed rate... distinguish the present invention from the combined prior art,” including Pickard), at 58 (noting that the Examiner and Patent Owner discussed “differences between accelerated and non-accelerated prosthetic device testers” and “the limits of non-accelerated compliance chambers as they relate to the claimed excess volume area.”).

Petitioner, likely realizing its heavy burden to overcome validity if it cites a

prior art reference that was already distinguished by the Examiner during prosecution, does not cite Pickard. Instead, Petitioner cites a different reference—Goldstein—that has the very same features the Examiner identified in Pickard. For the same reasons, Goldstein does not render obvious the '935 Patented invention.

2. It Is Not Obvious To Operate Goldstein's Real-Time Pulse Duplicator At Accelerated Rates

Petitioner relies on the conclusory statement from its expert that a POSA that knew of the Goldstein reference “would be motivated by...the benefits of accelerated testing” and therefore “would have been able to, and would not be deterred from, accelerating Goldstein above the expressly disclosed rates.” Petition at 61. But closed system pulse duplicators with compliance chambers have been around much longer than the Goldstein patent. The fact that more than 20 years lapsed between publication of the Pickard patent for a real-time tester (1987) and development of the '935 Patented accelerated tester (2009) is compelling evidence that it was *not* an “obvious” modification of simply adjusting the settings. Ex-2003, ¶112. Simply because two different testers for different purposes existed in the prior art does not show a motivation to combine. *Virtek Vision Int'l*, 97 F.4th 882 at *9 (“an assertion that because two coordinate systems were disclosed in a prior art reference and were therefore ‘known,’” fails to show motivation to combine as a matter of law).

In fact, the Krynauw thesis (Ex-1015)—which ViVitro relies upon even

though it *post-dates* the '935 Patent priority date¹⁷—demonstrates that it was *not* possible to create an accelerated tester by simply changing the settings. Krynauw describes a closed system similar to the pulse duplicators intended to run at physiological conditions and not accelerated conditions required for durability testing. *Id.* at 73. In Section 5.2, Krynauw summarizes his conclusions including that the system could only run at speeds up to 230 bpm—just barely above the high end of the normal range 30-200bpm, and far lower than the typical accelerated testing rates of 600-1200 bpm. Ex-2003, ¶113. Based on the Krynauw thesis describing the attempted development of a workable high speed durability test system (after the '935 Patent priority date), Krynauw's failed efforts demonstrate that it was *not* obvious, even to a sophisticated POSA in 2009, to successfully design an accelerated durability tester as described in the '935 patent.

Nor does the addition of the Lu reference change the analysis. The Lu publication (Ex-1005) describes the mathematical relationships between the dynamic inertial loads and the relationship of compliance in helping to control the pressures in accelerated testers like Xi. Lu suggests a compliance that would allow testing at both physiological and accelerated rates to control loads on the valve

¹⁷ See Ex-1016, ¶5 (averring that thesis was submitted in May 2009, not May 2008 as erroneously stated on cover page).

(Differential Pressure or back pressure) of the amplitude or displacement of the valve in the Xi system. Ex-2003, ¶87. Although these mathematical relationships certainly apply to setting the compliance in a closed system, neither Lu or Xi suggested or attempted to drive the pressures and use a compliance chamber to provide an “excess volume area” for the entire stroke volume. *Id.* This was not done in an accelerated tester until BDC developed its system. *Id.* For these reasons, claim 1 of the '935 Patent is not rendered obvious by a combination of Goldstein and Lu.

In addition, a POSA would understand that modifying Goldstein to operate at an accelerated rate would frustrate the purpose of Goldstein. In particular, Goldstein “is directed to the problem of providing a flow system to assist in transforming a heart valve that is based on a xenograft [donor tissue, such as animal] into an autograft [recipient tissue].” Ex-1007, 1:6-9. It therefore provides a system to “optimiz[e] recellularization” and maintain “flow under tissue culture conditions” (*Id.*, 1:44-48) to “physically precondition[] a living heart valve prior to implantation.” *Id.*, 4:51-54. Petitioner suggests no reason, and Goldstein and Lu provide no motivation, to operate the system of Goldstein at an accelerated rate (even if it were possible) and prematurely wear down a heart valve being transformed in preparation for implantation. Thus, a POSA would not be motivated to combine Goldstein and Lu.

VII. Conclusion

Institution must be denied because Petitioner fails to meet its burden of showing a reasonable likelihood that it would prevail with respect to claims challenged in the Petition. First, none of the cited references, or their combination, disclose the claimed “excess volume area capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid communication with the fluid return chamber providing a volume for storing a volume of a test system fluid when the test system fluid is under compression” within a pressurizable test chamber. Second, Petitioner fails to provide any reasonable rationale for combining Xi with Dynatek or for combining Goldstein with Lu. Accordingly, the Board should conclude that the information presented in the Petition and accompanying evidence do not establish a reasonable likelihood that Petitioner will prevail, and deny institution of all grounds asserted in the Petition.

Date: May 8, 2024

/s/ Jordan L. Stott

Jordan L. Stott (Reg. No. 71,867)
Dorsey & Whitney LLP
101 S. Capitol Boulevard, Suite 1701
Boise, ID 83702

Gregory S. Tamkin (*pro hac vice*)
Dorsey & Whitney LLP
1400 Wewatta Street, Suite 400
Denver, CO 80202

Shannon Bjorklund (*pro hac vice*)
Dorsey & Whitney LLP
50 South Sixth Street, Suite 1500
Minneapolis, MN 55402

Attorneys for Patent Owner

CERTIFICATE OF WORD COUNT

The undersigned hereby certifies that the foregoing Patent Owner Preliminary Response complies with the type-volume limitations of 37 C.F.R. § 42.24(b). Excluding the items listed in 37 C.F.R. § 42.24(a) as not included in the word count, and using the word count of the word-processing system used to prepare the paper (Microsoft Word), the Patent Owner Preliminary Response contains 13,844 words.

Date: May 8, 2024

/s/ Jordan L. Stott

Jordan L. Stott (Reg. No. 71,867)

CERTIFICATE OF SERVICE

The undersigned certifies that on May 8, 2024, the foregoing Patent Owner Preliminary Response and Exhibits 2003–2005 were served via email, upon the following:

Warren J. Thomas

wthomas@mcciplaw.com

John W. Harbin

jharbin@mcciplaw.com

Lee Hamilton

lhamilton@mcciplaw.com

Meunier Carlin & Curfman LLC

999 Peachtree Street NE, Suite 1300

Atlanta, GA 30309

Date: May 8, 2024

/s/ Jordan L. Stott

Jordan L. Stott (Reg. No. 71,867)