

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

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,237,935

TABLE OF CONTENTS

PETITIONER’S EXHIBIT LIST.....	IV
I. INTRODUCTION	1
II. BACKGROUND OF ARTIFICIAL HEART VALVE TESTING.....	2
III. THE CHALLENGED PATENT	7
A. Overview of the patent disclosure	7
B. Prosecution history of ’935 patent and family members.....	10
IV. LEVEL OF ORDINARY SKILL IN THE ART	17
V. CLAIM CONSTRUCTION	18
A. <i>fluid communication</i>	18
B. <i>excess volume area</i>	23
C. <i>under compression</i>	26
VI. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104	27
A. Standing	27
B. Identification of challenge	27
VII. GROUND A: CLAIMS 1-4, 8-9, AND 12-13 ARE ANTICIPATED OR OBVIOUS IN VIEW OF XI.....	30
A. Overview of Xi	30
B. Detailed claim analysis	32
1. Claim 1	32
a. [1pre] “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”.....	32
b. [1b] “a pressurizable test chamber for containing the test system fluid”	33
c. [1c] “further comprising a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication	

with the pressure source;” [1d] a fluid return chamber positioned on a second side of the valved prosthetic device;	34
d. [1e] a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and	37
e. [1f] The “excess volume area” clause	38
(i) “capable of operating at the accelerated pulsed rate”	38
(ii) wherein the excess volume area is in fluid communication with the fluid return chamber	39
(iii) providing a volume for storing a volume of a test system fluid when the test system fluid is under compression	39
2. Claims 2, 4	41
3. Claims 8-9, 12	41
4. Claim 3	42
5. Claim 13	43
VIII. GROUND B: CLAIMS 1-4, 8-9, AND 12-13 ARE OBVIOUS OVER DYNATEK AND XI	45
A. Overview of Dynatek	45
B. Motivation to Combine	46
C. Detailed claim analysis	50
1. Claim 1	50
2. Claims 2-4, 8-9, 12-13	55
IX. GROUND C: CLAIMS 1-4, 7-9, AND 12-13 ARE OBVIOUS OVER GOLDSTEIN AND LU	59
A. Overview of Goldstein	59
B. Overview of Lu	60
C. Motivation to Combine	60
D. Chart of all challenged claims	62
X. GROUND D AND E: CLAIMS 7 AND 10 ARE OBVIOUS IN FURTHER VIEW OF GOLDSTEIN	70
XI. THERE ARE NO OBJECTIVE INDICIA OF NONOBVIOUSNESS	71
XII. DISCRETIONARY DENIAL IS NOT WARRANTED	72

A. Denial is not warranted under § 314(a)	72
B. Denial is not warranted under § 325(d)	75
XIII. CONCLUSION	75
XIV. MANDATORY NOTICES	76
A. Real parties-in-interest	76
B. Related matters	76
C. Counsel and service information	76
XV. CLAIMS LISTING	78

PETITIONER'S EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 9,237,935 to McCloskey et al. (issued Jan. 19, 2016) (the '935 patent or the challenged patent)
1002	Declaration of Lakshmi Dasi, Ph.D. (Jan. 24, 2024)
1003	CV of Lakshmi Dasi, Ph.D.
1004	Chinese Patent CN 1035153C to Baoshu Xi, Zhaohong Pei, Peizhen Zu & Shouyan Li (June 18, 1997) with certified translation (Xi)
1005	Po-Chien Lu, Jia-shing Liu, Baoshu Xi, Shawyan Li, Jia Wu & Ned H.C. Hwang, <i>On Accelerated Fatigue Testing of Prosthetic Heart Valves</i> , in FRONTIERS IN BIOMEDICAL ENGINEERING 185-196 (Ned H.C. Hwang & Savio L-Y. Woo eds., 2003), <i>available at</i> https://doi.org/10.1007/978-1-4419-8967-3 (Lu)
1006	Operating Instructions for M6 Six-Position Heart Valve Durability Testing Device, Dynatek Dalta Scientific Instruments (1993) (Dynatek) [Attachment B to Garitey Declaration, Ex-1029]
1007	U.S. Patent 5,899,937 to Goldstein et al. (issued May 4, 1999) (Goldstein)
1008	Excerpts from U.S. Provisional App. No. 61/158,185 (filed Mar. 6, 2009) (priority document for challenged patent)
1009	Excerpts from File History of the '708 patent, U.S. Patent App. No. 12/718,316 (filed Mar. 5, 2010) (the '316 application)
1010	Excerpts from File History of the '935 patent, U.S. Patent App. No. 14/137,313 (filed Dec. 20, 2013)
1011	Excerpts from File History of U.S. Patent App. No. 14/523,104 (filed Oct. 24, 2014) (continuation of the '935 patent)
1012	U.S. Patent No. 8,627,708 to McCloskey et al. (issued Jan. 14, 2014) (parent of the '935 patent) (the '708 patent)
1013	Redline comparison of '708 patent Abstract and Specification to '935 patent Abstract and Specification
1014	Patent Owner's Preliminary Response, <i>Waters Technologies Corp. v. Biomedical Device Consultants & Labs.</i> , IPR2018-00498 (Apr. 27, 2018), Paper 5

Exhibit No.	Description
1015	Hugo Krynauw, <i>Design and implementation of an apparatus for hydrodynamic and fatigue testing of prosthetic aortic valves</i> , (MSc thesis, University of Cape Town, 2009), available at https://open.uct.ac.za/items/ca487bfd-e0b3-4e22-bb72-6be7c8d8d8a6
1016	Declaration of Hugo Krynauw (Dec. 10, 2023)
1017	International Standard ISO 5840:2005, Cardiovascular implants – Cardiac valve prostheses, Fourth Edition, (March 2005)
1018	U.S. Patent 4,682,491 to Pickard (issued July 28, 1987) (Pickard)
1019	Kiyotaka Iwasaki et al., <i>Implications for the establishment of accelerated fatigue test protocols for prosthetic heart valves</i> , Artificial Organs, Vol. 26, Issue 5, 420-429 (2002)
1020	Helmut Reul & Klaus Potthast, <i>Durability/Wear Testing of Heart Valve Substitutes</i> , Journal of Heart Valve Disease, Vol. 7, Issue 2, 151-157 (1998)
1021	U.S. Patent 696,277 to Sponseller et al. (issued Mar. 25, 1902)
1022	Appellant BDC's Opening Brief, <i>Biomedical Device Consultants & Laboratories of Colorado, LLC v. ViVitro Labs Inc.</i> , No. 23-2393 (Oct. 24, 2023), ECF No. 20
1023	Declaration of Craig Weinberg, Ph.D., <i>Biomedical Device Consultants & Laboratories of Colorado, LLC v. ViVitro Labs Inc.</i> , No. 2:23-cv-04291 (June 25, 2023), ECF No. 61
1024	Declaration of Michael Girard, <i>Biomedical Device Consultants & Laboratories of Colorado, LLC v. ViVitro Labs Inc.</i> , No. 2:23-cv-04291 (June 25, 2023), ECF No. 62
1025	Order to Stay Litigation Pending Appeal, <i>Biomedical Device Consultants & Laboratories of Colorado, LLC v. ViVitro Labs Inc.</i> , No. 2:23-cv-04291 (Sept. 22, 2023), ECF No. 97
1026	Appellant BDC's Reply Brief, <i>Biomedical Device Consultants & Laboratories of Colorado, LLC v. ViVitro Labs Inc.</i> , No. 23-2393 (Dec. 4, 2023), ECF No. 26
1027	U.S. Patent 5,916,800 to Elizondo et al. (issued June 29, 1999) (Elizondo)

Exhibit No.	Description
1028	BDC Test Equipment product brochure, <i>available at</i> https://web.archive.org/web/20210831235703/https://www.bdcclabs.com/wp-content/uploads/2021/08/BDC-Labs-Test-Equipment.pdf
1029	Declaration of Vincent Garitey (Jan. 18, 2024)
1030	[RESERVED]
1031	Operating Instructions for M6 Valve Durability Testing Machine, Dynatek Dalta Scientific Instruments (1991) [Attachment A Garitey Declaration, Ex-1029]
1032	Photograph of Dynatek M6 serial number plate [Attachment C to Garitey Declaration, Ex-1029]
1033	ProtomedLabs Test equipment identification form (EE-VV-DYN-01_SGM) [Attachment D to Garitey Declaration, Ex-1029]
1034	Operating Instructions for M6 Six-Position Heart Valve Durability Testing Device, Dynatek Dalta Scientific Instruments (1993) [Attachment E to Garitey Declaration, Ex-1029]
1035	E.P.M Rousseau et al., <i>Design of a System for the Accelerated Loading of Heart Valve Prostheses</i> , Journal of Biomechanics, Vol. 17, Issue 2, 145-153 (1984)
1036	U.S. Patent 5,176,153 to Eberhardt (issued Jan. 5, 1993) (Eberhardt)
1037	Transcript of Aug. 17, 2023, Preliminary Injunction Hearing, <i>Biomedical Device Consultants & Laboratories of Colorado, LLC v. ViVitro Labs Inc.</i> , No. 2:23-cv-04291 (Sept. 6, 2023), ECF No. 92
1038	VDT-3600i User Guide, Revision 2.3 (Jan. 2015)
1039	Declaration of John Harbin (Jan. 24, 2024)

I. INTRODUCTION

Artificial heart valves must be highly reliable and thus must be tested extensively, according to international standards, before implanting in a human patient. Specialized systems that roughly simulate the cardiovascular system have been developed to meet these standards. One type of testing assesses the “durability” of prosthetic heart valves to ensure they will last for a reasonable time after implantation. Durability tests are often performed at “accelerated” speeds to simulate hundreds or thousands of heartbeats every minute. But at high speeds, the test fluid can exhibit pressure spikes that cause the valve to fail in a test when it would not fail in a human. These pressure spikes in fluid systems are sometimes known as “water hammer.”

US Patent 9,237,935 (the ’935 patent) is directed to an “accelerated” test system for evaluating a valved prosthetic device. Patent Owner BDC claims that its system solved the water hammer problem by using an air-filled “compliance chamber,” which the claims recite as an “excess volume area,” to dampen the pressure spikes in an accelerated tester. BDC has argued to the Office during prosecution that this configuration was “entirely new,” despite conceding compliance chambers were “well known” in lower-speed testing devices. Ex-1011, 54. And in recent litigation, BDC has argued the feature was “the novel aspect” of the patent. Ex-1022, 10-11.

However, multiple prior art references that were *not considered* by the Office teach both the problem and solution supposedly recognized by BDC. In one example, a 2003 publication taught that “all” of the most common accelerated testers included “adjustable ... compliance” and that a “compliance component can reduce the effects of the water hammer.” Ex-1005, 186-188. Other references also teach the compliance chamber in an accelerated tester.

Petitioner ViVitro Labs Inc. (ViVitro or Petitioner) requests *inter partes* review (IPR) of claims 1-4, 7-10, and 12-13 (the Challenged Claims) of the '935 patent and cancelation of those claims as unpatentable for the reasons explained below.

II. BACKGROUND OF ARTIFICIAL HEART VALVE TESTING

With every expansion and contraction of a beating heart, valves in the heart open and close to direct the blood to the lungs, through the body, and back to the heart. Ex-1002 ¶ 20. Artificial or prosthetic valves have been developed to provide a lifesaving solution for patients whose valves no longer function properly. Ex-1002 ¶ 20. These prosthetic valves must be incredibly reliable and safe, while also lasting for years. Ex-1002 ¶ 21. At the same time, they must minimize the risk to patients. Ex-1002 ¶ 21.

Motivated by these problems, designers created “accelerated testers” that move fluid through the valve repeatedly at an “accelerated” rate—above the

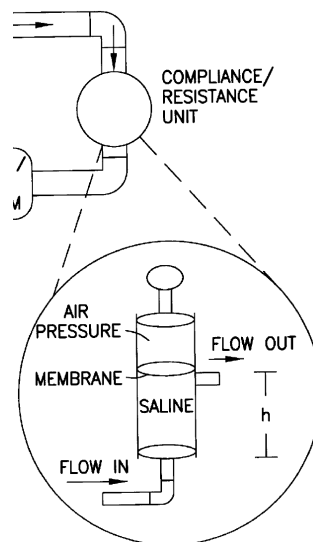
physiological rate of a human heart. Ex-1002 ¶ 22. These accelerated testers inflict years of stress on a valve in only months, allowing designers to validate their designs before implanting them into patients. Ex-1002 ¶ 22. Such testers commonly include a pump, fixtures to attach one or more valves to, and a closed loop for fluid to flow through. Ex-1002 ¶ 22.

The stresses on the test valve from the fast-moving fluid are different than those in the human body. Ex-1002 ¶ 23; Ex-1005, 186-87. Designers of accelerated testers use ordinary fluid mechanics principles like flow rate, pressure, and volume to apply standardized forces to the valves being tested. Ex-1002 ¶ 23.

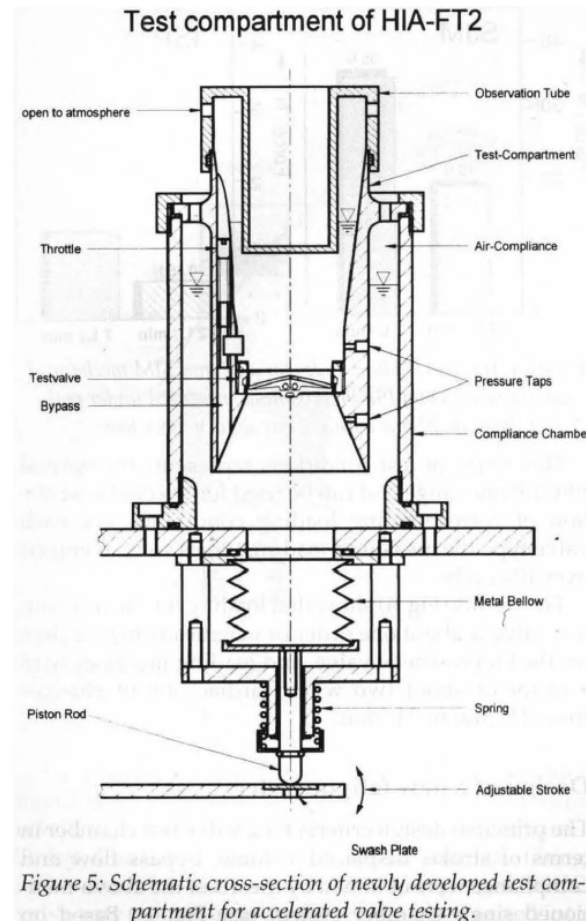
One such parameter is compliance. The “compliance” of the tester is a key design parameter for an accelerated tester. Ex-1002 ¶¶ 24-25. In a human body, compliance is the ability of the circulatory system to expand and absorb increases in blood pressure caused each time the heart pumps. Ex-1002 ¶ 24 (explaining elasticity of blood vessels provides compliance). In the same way, a tester can be designed with “compliance” to absorb pressure increases caused by the pump or motor in the tester. Ex-1002 ¶¶ 24-26. Indeed, the 2005 ISO/ANSI standard for testing heart valves recommends compliance chambers and certain specifications for them in both hydrodynamic and durability testing. Ex-1002 ¶ 25 (citing ISO standards). By 2003, “all” of the “most common” accelerated testers had “adjustable compliance.” Ex-1005, 186.

A common way to provide compliance in the tester was to use an air-filled compliance chamber. Ex-1002 ¶ 26. Compliance chambers in general are well known in the field of fluid engineering; such structures date back to at least 1901. Ex-1002 ¶ 26 (describing general “water hammer” effect and known simple solutions); Ex-1011, 54. To mimic compliance of elastic blood vessels or absorb pressure spikes, an air compliance chamber provides extra space in the tester for fluid to flow. Ex-1002 ¶¶ 26, 28. In this way, a “compliance component can reduce the effects of the water hammer.” Ex-1005, 188; Ex-1002 ¶ 26.

Several examples of air compliance chambers are shown in the art. Goldstein discloses an “adjustable resistance and compliance element ... placed downstream” of the valve. Ex-1007, 10:25-35, FIG. 3 (below).



Reul describes an accelerated tester with an adjustable, air-filled compliance chamber that provides “additional control of loading forces.” Ex-1020, 153-154 (Fig. 5).



And Iwasaki modified a Rowan Ash accelerated tester to include “an air compliance chamber,” as shown below containing both fluid and air, like the Xi air chamber. Ex-1019, 422-423 (Fig. 5, below).

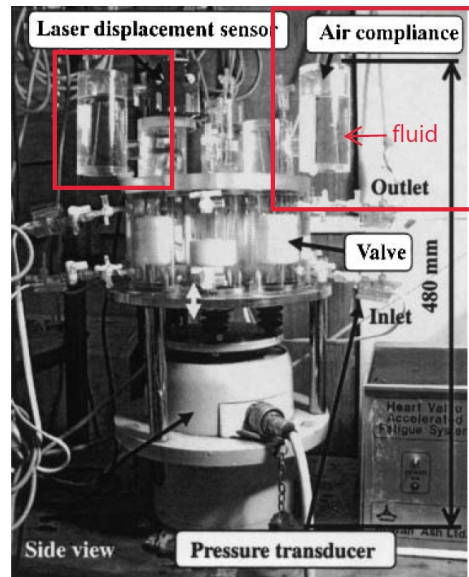


FIG. 5. A modified version of the Rowan Ash accelerated fatigue tester for prosthetic heart valves is shown. A compliance element was added to the original system.

Xi shows “air chambers” C_1 for each of six independent “valve test sections” and one “large air chamber C_2 ” in an accelerated tester. Ex-1004, 7-8. Lu illustrates a “TH2200 (Tsinghua University)” accelerated tester that is plainly some iteration of the Xi design. Compare Ex-1005, 186, 190-191 (Figs. 1-2), with Ex-1004, 11-13 (Figs. 2-4). See also Ex-1002 ¶¶ 44 n.8, 131. Lu’s (abbreviated) description of the structure and operation likewise matches Xi. Ex-1005, 191 (last two paragraphs of Section 4.1). Lu even labels the elements “C1” and “C2”—corresponding to the same identifiers in Xi— as “small compliance” and “large common compliance” chambers, respectively. Ex-1005, 191. Xi Fig. 4 and Lu Fig. 2 are shown below. Ex-1004, 13; Ex-1005, 191.

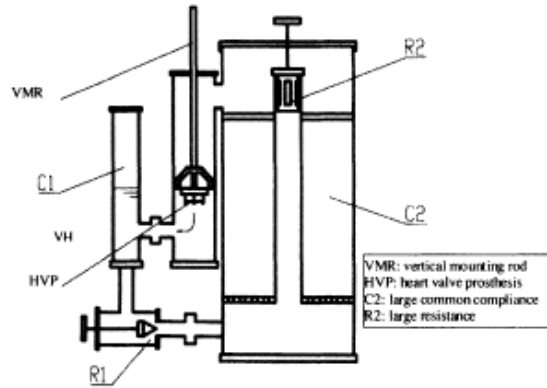
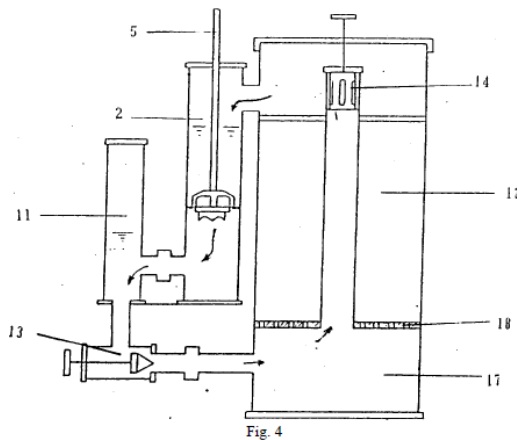


Fig.2 Schematics of Individual Circulatory Flow Loop

Thus, air compliance chambers were well known in the art.

III. THE CHALLENGED PATENT

A. Overview of the patent disclosure

The '935 patent discloses a system and method for accelerated fatigue/durability testing of prosthetic devices, including heart valves. Ex-1001, 1:19-22, 63-67. As described and annotated by BDC,¹ the system includes a drive mechanism (pink) that moves a piston and diaphragm up and down to pump fluid through the system. *See, e.g.*, Ex-1001, 11:43-59.

¹ This annotated figure and most of the description of the patent in this section are adapted from BDC's Preliminary Response in an IPR of a continuation of the '935 patent. *See generally* Ex-1014, 9-13.

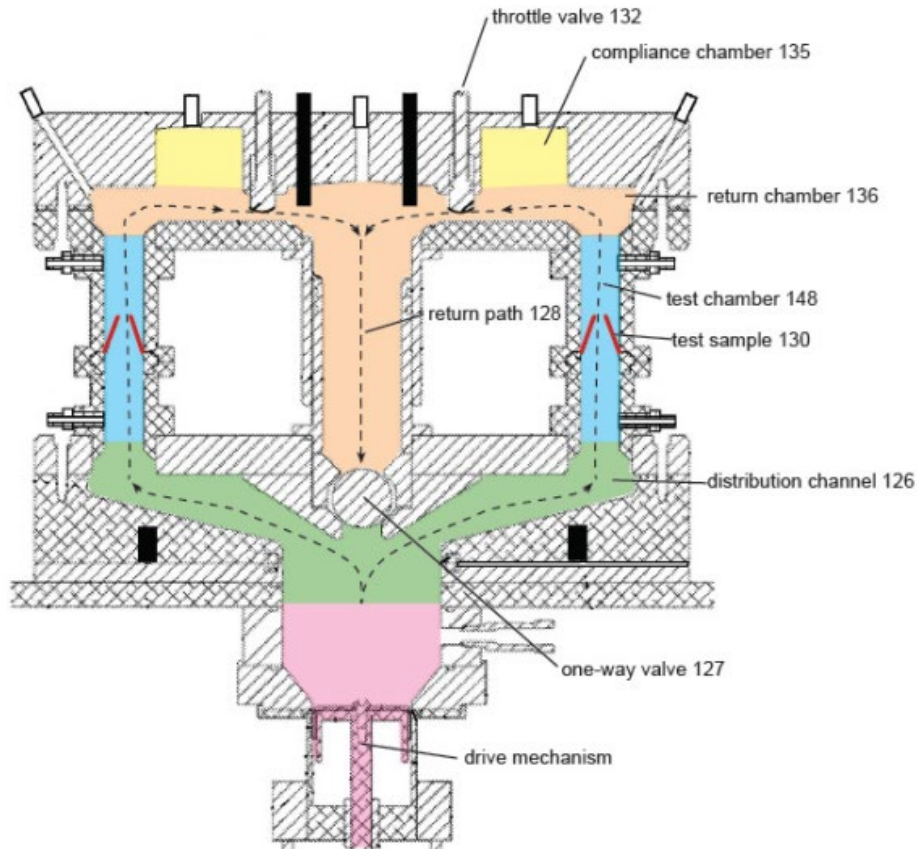


Figure 3 of the '224 Patent
(colorized and labeled with reference numerals removed)

Fluid enters distribution chamber 126 (green, labeled “channel”) and moves up to the left and right of a central one-way valve 127. Ex-1001, 11:60-12:3. The fluid continues through the test samples (heart valves) 130 (red) mounted in test chambers 148 (blue) and then enters return chamber 136 (orange). *Id.* Since the channel (green, blue, and orange sections combined) is full of fluid at the start, the drive mechanism increases pressure when it pumps fluid into the system. Ex-1001, 11:43-59. Some volume of “excess fluid” is displaced into the compliance chamber structures 135 (yellow). Ex-1001, 12:4-9; *see also* Ex-1014, 11.

Next, the piston and diaphragm move down, closing the one-way heart valve. Ex. 1001, 12:25-33. The “excess fluid” leaves the compliance chambers and exits through return conduit 168, central return chamber 133, and return path 128 through valve 164. Ex-1001, 11:60-64. The cycle is then repeated. *Cf.* Ex-1024 ¶¶ 13-14.

The compliance chambers thus provide a “spring force to dampen” pressure spikes on the test samples. Ex-1001, 9:25-29. And their “spring factor” can be adjusted using pressurized air to mitigate and tune the pressure. Ex-1001, 12:12-18, 52-58.

An alternative embodiment is shown in the annotated Figure 6 below using like colors. In this embodiment, one, common compliance chamber 235 provides a compliance volume for all the sample holders 230. Ex-1001, 14:8-15.

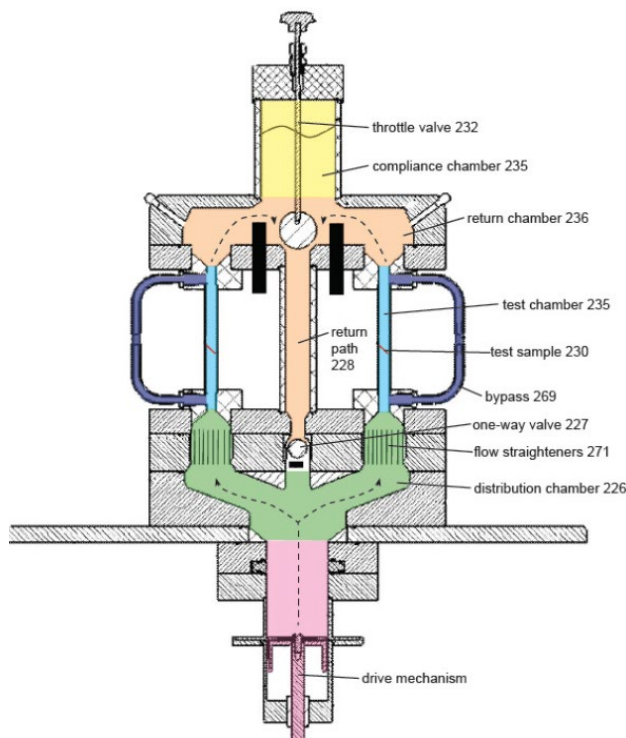


Figure 6 of the '224 Patent
(colorized and labeled with reference numerals removed)

B. Prosecution history of '935 patent and family members

Despite the art summarized above, during prosecution of the patent and its family members, BDC emphasized the novelty of the compliance chambers in an accelerated tester. This argument persuaded the Office to allow the claims.

The '935 patent issued in January 2016 from Patent Application No. 14/137,313 filed in 2013, claiming the benefit of earlier provisional and nonprovisional applications. A child continuation application No. 14/523,104 was also filed February 12, 2015.

The 2009 provisional application disclosed one embodiment with figures and description corresponding to the embodiment in Figure 6 of the '935 patent.

Compare Ex-1001, Fig. 6, *with* Ex-1008, 21 (Figure 2). It disclosed a compliance chamber 35 allows “damping of the system” and admitted that “[t]hose who are skilled in the art *will appreciate* that the dynamics of the system can be controlled through the stroke volume of the piston 14, throttle valve 32 and compliance chamber 35.” Ex-1008, 15 ¶ [035].² There is no mention of an “excess volume area.”

The first nonprovisional application added a new embodiment and additional written description that generally correspond to the first five figures (and their description) in the '935 patent. *Compare* Ex-1001, Figs. 1-5, *with* Ex-1009, 40-44. That disclosure, however, contains only one instance of the phrase “excess volume area,” and used “excess volume” once more in the following paragraph: “The compliance chambers 135 provide *excess volume area* for fluid to move into [O]n the downward stroke, ... *excess volume* returns to the compliance chambers 135.” Ex-1009, 25 ¶¶ [0059]-[0060]. Independent claims 1 and 17 recited “a compliance chamber providing a volume for holding a gas or elastomeric material that compresses under a pressure placed upon fluid in the test chamber” that “allows fluid in the test chamber to occupy a portion of the volume.” Ex-1009, 33, 36; *see also* Ex-1012, 17:23-27, 19:23-27 (claims as issued). The abstract likewise

² All emphasis in quotations in this Petition is added unless otherwise indicated.

called out the compliance chambers' role in regulating pressure. Ex-1009, 28. *See also* Ex-1002 ¶¶ 72-73.

During prosecution, the examiner rejected the claims as obvious, citing “Pickard” as disclosing the compliance chamber features. Ex-1009, 52-53. BDC did not dispute that Pickard included a compliance chamber. *See generally* Ex-1009, 60-78.³

Instead, BDC argued (during an April 2013 interview and the subsequently filed remarks) that Pickard's compliance chamber had a different “purpose” because Pickard is a “real-time” test system, not an *accelerated* system. Ex-1009, 63, 71. According to BDC, the “compliance” in Pickard “shape[s] the systemic pressure waveform to mimic the circulatory system distensibility,” while BDC's compliance chambers “prevent or minimize the kinetic energy of fluid flow from

³ Nor could BDC dispute it. Pickard labels FIG. 8 a “compliance chamber.” And “air chamber 530” absorbs some of the pressure from the fluid and applies a spring force onto it. Ex-1018, 6:67-68, 12:57-13:9; *see also id.* at 1018, 3:46-55; *see also* Ex-1018, 5:58-62 (teaching compliance chamber wall “expands *to receive excess fluid*” and “fluid pressure is compensated by means of air pressure on an opposite side of the diaphragm”).

translating into high static fluid pressure in the test system during the accelerated frequency testing.” Ex-1009, 71.

The examiner’s Notice of Allowance (after the single, non-final rejection) did not mention the compliance chamber feature. *See* Ex-1009, 88. Instead, the examiner appeared persuaded by BDC’s arguments distinguishing its claims as directed to “accelerated” rather than real-time testing. Ex-1009, 60-63, 65, 71 (summarizing interview and adding “accelerated” to preamble). That application issued as Patent 8,627,708 (the ’708 patent).

In December 2013, BDC filed the continuation application that eventually issued as the ’935 patent, Application 14/137,313 (the ’313 application). This time, BDC added two paragraphs of new description in the “Summary” section that discussed “exemplary implementations” including “an excess volume area.” Ex-1010, 12 ¶¶ [0011]-[0012]; *see also* Ex-1013, 3 (illustrating added text in redline comparison between ’708 and ’935 patents).⁴ The originally filed claims also recited the “excess volume area” limitation. Ex-1010, 31-32.

Before any substantive action was taken on the ’313 application, BDC filed *another* continuation application in October 2014, Application 14/523,104 (the ’104 application), claiming priority to the earlier filed applications. Ex-1011, 5, 10.

⁴ As shown in Ex-1013, the disclosure was otherwise generally the same.

This application included a “Track One” request, Ex-1011, 35, so it received substantive actions *before* its still-pending parent.

In March 2015, the examiner rejected the claims of the ’104 application as anticipated by Pickard and obvious over Pickard and Lundell. Ex-1011, 39-42. BDC’s representative and one of the inventors (Dr. Weinberg) held an interview in May 2015 that, according to the examiner, “centered around the term ‘accelerated’ in the preamble of claim 1.” Ex-1011, 45.

A few weeks in June, BDC responded to the office action. BDC’s interview summary described the “purpose” of the now-claimed “excess volume area” in nearly identical terms as the “compliance chamber” of the (grandparent) ’313 application: “to prevent or minimize the kinetic energy of fluid flow generated by the system driver from translating into high static fluid pressure in the test system during the accelerated frequency testing.” *Compare* Ex-1011, 51, *with* Ex-1009, 71 (differing only in “generated by the system driver”).

The (alleged) differences between “accelerated” and “real-time” systems were a focus of BDC’s Response; it did not dispute that Pickard discloses a compliance chamber or the recited “excess volume area.” BDC again characterized Pickard as a “real-time” test system and “not ... an accelerated system as claimed for the purposes of evaluating leaflet wear and implant durability.” Ex-1011, 52 (emphasis in original). BDC further asserted that “real-time and accelerated testing

have *completely different* requirements and use *completely different* methodologies.” Ex-1011, 52-53.

BDC then argued the cited art’s compliance chamber features did not disclose the “excess volume area” limitation in an accelerated tester. First, BDC admitted that “using a compliance chamber to store excess volume of test fluid in a *real-time, physiologically accurate*, cardiac valve test system is well known.” Ex-1011, 54. BDC stated, “in fact, compliance is *required* by ISO 5840 in Annex L and detailed guidelines for compliance chambers are provided in Annex F.” *Id.* This statement was misleading, however. In truth, “Annex L” is only “informative” and provides “guidance”—not requirements—for hydrodynamic (aka “real-time”) testing, Ex-1017, 53; *id.* at 37-38 (providing that “Wear/durability” testing “should be tested in [a] low *compliance chamber*”).

BDC then characterized prior art *accelerated* durability test systems as lacking any “specific design elements or system features to address [the] phenomenon of pressure spikes”—or as BDC previously described it, the “kinetic energy of fluid flow” causing “high static fluid pressure”—in the test system. Ex-1011, 51, 55. And it argued that the claimed *excess volume area*, which it again used interchangeably with *compliance chamber*, solved that problem:

The purpose of the excess volume areas (*i.e.*, *compliance chamber(s)*) as claimed ... is “to act as a resilient spring force to dampen the effects of large, quickly changing pressure gradients

within the test chamber” in the test system during the accelerated frequency testing.

Ex-1011, 57 (quoting Specification). In BDC’s view, the prior art “fails to teach the claimed method *in the context of an accelerated cyclic test system*” and failed to “contemplate[] or recognize[]” the “concerns, goals, or solutions” of the invention. Ex-1011, 55. Thus, BDC stated that “a method *in an accelerated cyclic test system* that uses an excess volume area is *entirely new*.” Ex-1011, 54.

A few months later, the examiner issued a Notice of Allowance in the ’104 application. The examiner was persuaded that the combination of an “accelerated cyclic test system” including an “excess volume area ... and its location” distinguished the claims over the cited art. Ex-1011, 68-69 (citing “applicant’s reasoning” in the June 17 response). That application issued as Patent 9,186,224 (the ’224 patent).

Finally, BDC returned its attention to the pending ’313 application. A month after receiving the notice of allowance in the ’104 application, BDC filed a preliminary amendment “to place [the ’313 application claims] in better condition for allowance” in view of the continuation. Ex-1010, 48. After another interview two weeks later, focusing once more on the difference between accelerated and non-accelerated testers, the examiner issued a first-action allowance in the ’313 application. Ex-1011, 55-58. The ’935 patent issued in January 2016.

But BDC’s characterizations of the prior art were false. Accelerated testers with compliance chambers plainly existed before the earliest claimed priority date, as shown above. And the ISO standard *specifically recommends* a “compliance chamber” for both hydrodynamic *and* durability testing, Ex-1017, 37-38 (Annex F); Ex-1002 ¶ 25. None of these facts were presented to the Office.

IV. LEVEL OF ORDINARY SKILL IN THE ART

The ’935 patent identifies its technical field as relating to “systems and methods for fatigue testing of prosthetic devices,” such as “prosthetic vascular and heart valves, under simulated physiological loading conditions and high-cycle applications.” Ex-1001, 1:19-23. A POSA in this field would have had at least (i) a bachelor’s degree in biomedical engineering, or a related field, such as mechanical engineering, biomechanical engineering, or bioengineering, who also has at least 3 years of experience with cardiovascular devices; or (ii) an advanced degree in the same areas of academic study with at least 1 years of experience with cardiovascular devices. Ex-1002 ¶¶ 90-91; *see also Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (“[T]he prior art itself reflects an appropriate level [of skill]”).⁵

⁵ The 2009 master’s thesis of Hugo Krynauw, “Design and implementation of an *apparatus for hydrodynamic and fatigue testing of prosthetic aortic valves*,”

V. CLAIM CONSTRUCTION

ViVitro does not believe that any terms require explicit construction.

However, based on arguments in the related litigation, ViVitro anticipates that BDC will raise specific interpretations to avoid the cited art that are contrary to both the plain meaning of those terms and the way those terms are used in the patent.

A. *fluid communication*

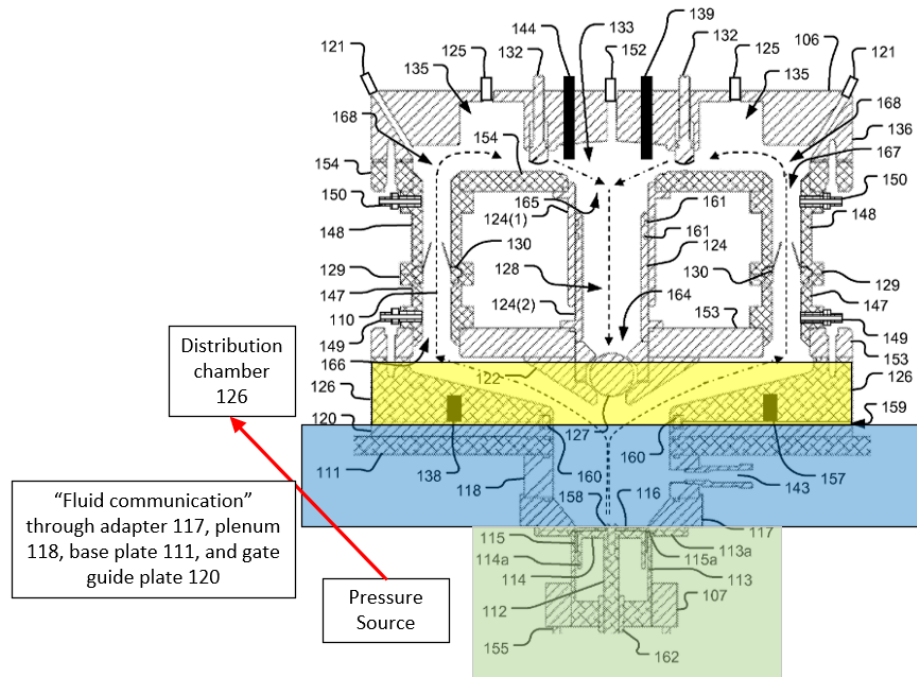
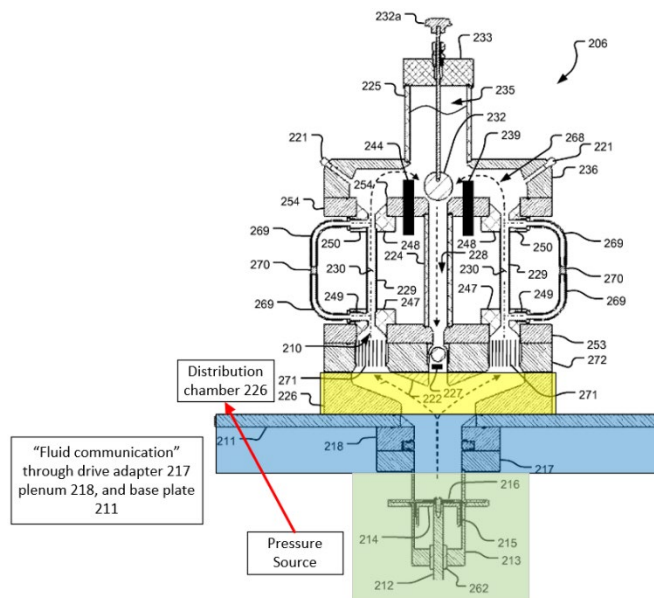
Claim 1 recites “a fluid distribution chamber positioned on a first side of the valved prosthetic device and *in fluid communication* with the pressure source,” and “an excess volume area ... *in fluid communication* with the fluid return chamber.” This term should be given its ordinary meaning, which simply means that fluid can flow from one referenced element to another. Ex-1002 ¶¶ 94-95. In the litigation, BDC appears to agree the term “connotes the flow path of fluid, *its plain meaning*” although it nevertheless has (wrongly) contended that elements that are within the same “flow path” are nevertheless not “in fluid communication. *See* Ex-1026, 18-19 (arguing meaning), 24 (distinguishing reference as “in fluid communication”

provides additional evidence of the level of skill. *See generally* Ex-1015; Ex-1002 ¶ 164. It reflects his research and development work between 2007-2009, before and around the claimed priority date. Ex-1016 ¶¶ 3-4.

with wrong “chamber”). Put simply, the term does *not* require any direct connection or specific spatial relationship between elements.

First, the patent itself uses the term “fluid communication” to refer to indirect relationships between elements that are not directly connected, and to refer to fluid flow from one point to another. Ex-1002 ¶¶ 95, 97-99. The patent describes (and claims) that the “pressure source” and “distribution chamber” are “in fluid communication” with one another. Ex-1001, 17:31-39. But the embodiments of FIGS. 3 and 6 (below) illustrate the distribution chamber and piston (i.e., pressure source) are separated by intermediate components including a plenum, base plate, and drive adapter. Ex-1002 ¶¶ 95-97; *see also, generally*, Ex-1001, 7:12-8:5.⁶ Additionally, the patent describes how “fluid passes around a throttle valve 232 and a return fluid flow *is communicated through* return conduit 224,” in Fig. 6. Ex-1001, 13:59-60.

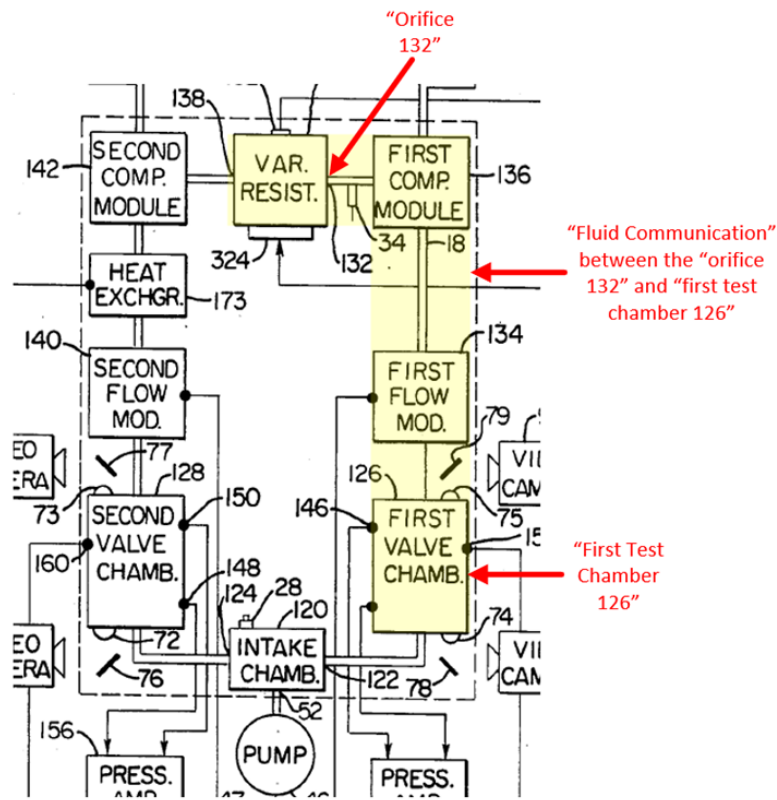
⁶ Regardless of whether the piston, cylinder, and/or drive adapter correspond to the claimed “pressure source,” they are not touching the distribution chamber.

Annotated FIG. 3**Annotated FIG. 6**

Ex-1002 ¶ 96. Last, the patent disclaims any particular type of “position, orientation, or use” for “directional references” and disclaims any direct

connection or relationship for “[c]onnection references” in the patent. Ex-1001, 16:63-17:9. So the looser “fluid communication” term should not be limited in those ways, either. Ex-1002 ¶ 100.

Other art in the field show POSAs used “fluid communication” similarly to refer to fluid flow—including through intermediate components. Ex-1002 ¶ 101. Fluid in Pickard’s “piston reservoir 50 ... *communicates with* circulatory loop 18 *through* an intake opening 52 extending between” those elements. Ex-1018, 7:42-53, Fig. 1. And its restriction chamber 130 has an orifice 132 is “*in fluid communication with* first test chamber 126 *by conduit means formed by*” flow module 134 and compliance module 136.” Ex-1018, 8:24-32, Fig. 2 (below).



Likewise, Fig. 3 of Elizondo shows a “pneumatic pump 64 ... *in fluid communication* with chamber 11 *through* conduit 62.” Ex-1027, 4:65-5:2. The sterility of its “fluid communication path” is not “affected by the *passage of the fluid through* the assembly.” Ex-1027, 8:1-6. And it describes the similar term “adapted for communication” (which it does not actually use, though *fluid communication* appears frequently) as referring “to any means or methods for establishing *fluid flow through* the system.” Ex-1027, 9:3-5. See also Ex-1002 ¶¶ 102-103.

These references merely illustrate the known sense of the term as broadly encompassing a fluid flow path through other components. *See* Ex-1002 ¶¶ 101-104; *cf. also In re Liquid Dispensing Sys. Patent Litig.*, No. 1:18-MD-02832-KMM, 2019 WL 12023099, at *6 (S.D. Fla. Dec. 16, 2019) (plain meaning of “being in fluid communication” was “connected in a way that allows fluid to flow from one location to another location”).

No usage of “in fluid communication” requires any particular spatial relationship or direct connection, although BDC has argued that ViVistro’s position would render the term “meaningless” (without proposing an alternative). *See* Ex-1026, 18. While BDC argues that “each recitation of ‘fluid communication’” is followed by a “different component,” the term does not imply any spatial relationship. Ex-1026, 18-19. Instead, *other* claim language requires specific

relationships: orienting chambers on the “first” and “second side” of the valve (claim 1); reciting the fluid return conduit “structurally and fluidly connect[s]” the return chamber to the distribution chamber; and reciting a “cavity within” the return chamber (claim 9). In the parent of the ’935 patent, BDC similarly recited these chambers having ports that “fluidically couple with a first” and “second end” of a sample holder (claim 1) and a compliance chamber “positioned substantially above ... [a] second plurality of ports and between” those “ports and the fluid return conduit” (claim 3). Ex-1012, 17:8-19, 47-50. When BDC wanted to recite specific locations or orientations of claim elements, it did. For the challenged claims, BDC chose the broader “in fluid communication” language. It cannot undo that choice.

Accordingly, “fluid communication” between elements of the claims merely requires a fluid flow path between them, or that fluid is *communicated* (by some force or pressure) from one point to another. *See also* Ex-1002 ¶ 104.

B. *excess volume area*

Claim 1 recites 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.” The phrase *excess volume area* was made up long after the priority date to refer to the “compliance

chambers” described above. *See* Section III.B; Ex-1002 ¶ 106. It is undisputed that, at minimum, the term “excess volume area” *encompasses* a compliance chamber. Ex-1022, 8, 31 (BDC arguing a compliance chamber is “one way to provide an excess volume area”); Ex-1023 ¶ 7 (Inventor declaring: “One type of ‘excess volume area’ is a ‘compliance chamber.’”).

Petitioner contends, consistent with its arguments in the litigation, that an “excess volume area” *is just* a compliance chamber. But that specific question does not need to be resolved here because the art cited in the Grounds all disclose compliance chambers, which BDC concedes are excess volume areas. Nevertheless, an abbreviated discussion of why the term is limited is included for completeness.

The patent describes compliance chamber structures that perform the same “compliance function” that BDC concedes is “described in” the claims. Ex-1022, 15, 43. “The compliance chambers 135 *provide excess volume area* for fluid to move into when the piston 114 performs a compression stroke,” and they “provide additional volume for displacement of the ... fluid within the test chamber.” Ex-1001, 12:4-9.

While BDC added additional “summary” to the Specification using the phrase “excess volume area,” the intrinsic (and extrinsic) evidence lacks *any example* of a prior use or disclosure of something else named an “excess volume

area.” That is because there is *nothing* BDC can point to as an “excess volume area” that a POSA would not also recognize as a well-known “compliance chamber.” BDC itself signaled these terms are synonymous in its 2015 Office Action Response. Ex-1011, 57 (discussing claimed “excess volume areas (**i.e.**, compliance chamber(s))” (bold emphasis added)); *TF3 Ltd. v. Tre Milano, LLC*, 894 F.3d 1366, 1372 (Fed. Cir. 2018) (“i.e.” “signals an intent to define the word to which it relates); *Rembrandt Wireless Techs., LP v. Samsung Elecs. Co.*, 853 F.3d 1370, 1376 (Fed. Cir. 2017). Defining “excess volume area” for the examiner was useful because nothing suggests there was any established meaning in the art of the term “excess volume area.” Ex-1002 ¶¶ 106, 108. So it is appropriate to construe the term as it was disclosed in the patent. *Indacon, Inc. v. Facebook, Inc.*, 824 F.3d 1352, 1357 (Fed. Cir. 2016).

Moreover, “excess volume area” acts as “nonce” word to substitute for “means” so that § 112(f) applies. The claim does not “recite sufficiently definite structure or else [it] recites function without reciting sufficient structure for performing that function.” *Williamson v. Citrix Online, LLC*, 792 F.3d 1339 (Fed. Cir. 2015) (en banc in relevant part) (cleaned up). BDC *argued* that “[n]owhere does the specification require the excess volume area to have structure.” Ex-1022, 32-33; *see also* Ex-1022, 29 (“[A]n area is not a separate structural chamber.”). Thus, *as posited by BDC*, the claim circularly describes *only what it does*: an

“excess volume area” is merely an “area” where “excess volume” is stored. Ex-1022, 30. So “excess volume area” is also a means-plus-function term. *See also* Ex-1002 ¶ 107.

C. *under compression*

Claim 1 recites the excess volume area performs its function “when the test system fluid is *under compression*.” The parties agree the fluid is incompressible. Ex-1026, 20 n.9; Ex-1002 ¶ 110. So a POSA would understand the term to mean the fluid is “under pressure”—or, as BDC’s expert opined, that “compressive forces are being placed on” the fluid—from the recited “pressure source.” *See* Ex-1024 ¶ 22; *see also* Ex-1002 ¶¶ 110-111.

The *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.” Ex-1002 ¶ 111. So the claim only requires a “pressure source” that “drive[s]” the fluid through the device to place it “under compression.” Ex-1002 ¶¶ 111-12.

BDC has suggested in the litigation (to avoid prior art) that the claim requires an “overall force in the system” that is not “net neutral,” i.e., it requires a “net compression.” Ex-1022, 47-48, 54; *see also* Ex-1026, 19-20 (arguing “overall effect” in prior art reference is “a constant level of pressure”); Ex-1024 ¶¶ 42-44. Conspicuously, BDC cites no support in the specification or claims for this extra-

textual limitation. Nor could it, since the patent teaches the “compliance chamber ... provides a volume for holding a gas or an elastic material that compresses *under a pressure placed upon fluid* in the test chamber.” Ex-1001, 2:53-56; *see also* Ex-1001, 9:12-17, 12:4-7 (“The compliance chambers 135 provide excess volume area for fluid to move into when the *piston 114 performs a compression stroke.*”)

Accordingly, “under compression” merely means, as BDC’s expert agreed, that test system fluid is under pressure (or “compressive forces”) from a pressure source. Ex-1024 ¶ 22; Ex-1002 ¶ 112.

VI. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104

A. Standing

Petitioner certifies that the ’935 patent is available for IPR and that Petitioner is not barred or estopped from challenging the claims in this Petition.

B. Identification of challenge

The Challenged Claims are invalid under the following Grounds:

Ground	Claims	Statute	Prior Art
A	Claims 1-4, 8-9, 12-13	§ 102(a) § 103(a) ⁷	Xi
B	Claims 1-4, 8-9, 12-13	§ 103(a)	Xi and Dynatek
C	Claims 1-4, 7-10, 12-13	§ 103(a)	Goldstein and Lu

⁷ While grouped into one “Ground,” claim 13 is only challenged as obvious over Xi.

Ground	Claims	Statute	Prior Art
D	Claims 7 and 10	§ 103(a)	Xi and Goldstein
E	Claims 7 and 10	§ 103(a)	Dynatek, Xi and Goldstein

All asserted references were published more than one year before the 2009 claimed priority date, so they are prior art under § 102(b). Chinese patent publication CN 1035153C to Xi et al. (Ex-1004) published in 1997.⁸ U.S. Patent 5,899,937 to Goldstein et al. (Ex-1007) published in 1999. Lu (Ex-1005) is an chapter from Frontiers in Biomedical Engineering published in 2003.

“Dynatek” (Ex-1006) is a manual for the Dynatek M6, six-position heart valve durability testing device made publicly available in 1993. Its public accessibility before the priority date is supported by the testimony of Dr. Garitey, a French ViVitro employee, and ViVitro’s expert witness, Dr. Dasi.

Dr. Garitey previously worked for a company called “SICN” where he personally used two different M6 testers that SICN acquired in 1991 and 1993. Ex-1029 ¶¶ 3-7. Dynatek provided “operating instructions” (i.e., manuals) with those machines, and Dr. Garitey used the manuals provided by Dynatek to setup the machines and train others on how to use them. Ex-1029 ¶¶ 5-7. The machines and manuals remained under Dr. Garitey’s control as he moved to different

⁸ Ex-1004 contains both the certified English translation and original Chinese version of the Xi patent.

employers—including his company ProtomedLabs that ViVitro eventually acquired—until ViVitro gave the machines to a university laboratory in 2023. Ex-1029 ¶¶ 8-10. ViVitro still possesses multiple paper and electronic copies of these manuals. Ex-1029 ¶¶ 11-12, 17.

Ex-1006 is a copy of the 1993 revision of the M6 manual Dr. Garitey used (Attachment B to the declaration).⁹ Ex-1006 includes a packing list and shipping label with dates corresponding to when SICN purchased the M6 machine in 1993. Ex-1029 ¶¶ 16; Ex-1006, 42-43. The packing list itself shows that Dynatek provided a “Manual” with the machine. *Id.* And the serial number in the packing list, “9320-01A,” matches the serial number of (1) the actual device ViVitro used, shown in a photograph of the machine, (2) ProtomedLabs/ViVitro testing records identifying the machine used in 2013, and (3) handwriting on the cover of the document. Ex-1029 ¶¶ 13-16; Ex-1006, 42; Ex-1032. Dr. Garitey testifies that Ziegler France, the recipient shown on the packing list and shipping label, was the company SICN used for receiving machinery shipments at that time. Ex-1029 ¶ 16.

Additionally, both Dr. Garitey and Dr. Dasi (Petitioner’s expert witness) testify, based on their years of experience, that device manufacturers in this field

⁹ The manuals were originally provided in paper form and subsequently scanned.

The copy here is from ViVitro’s electronic files. Ex-1029 ¶¶ 10-12.

commonly provide manuals with their products. Ex-1029 ¶ 18; Ex-1002 ¶ 153.

These facts show that Ex-1006 was “disseminated or otherwise made available” to interested POSAs in 1993. *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1350 (Fed. Cir. 2008).

VII. GROUND A: CLAIMS 1-4, 8-9, AND 12-13 ARE ANTICIPATED OR OBVIOUS IN VIEW OF XI.

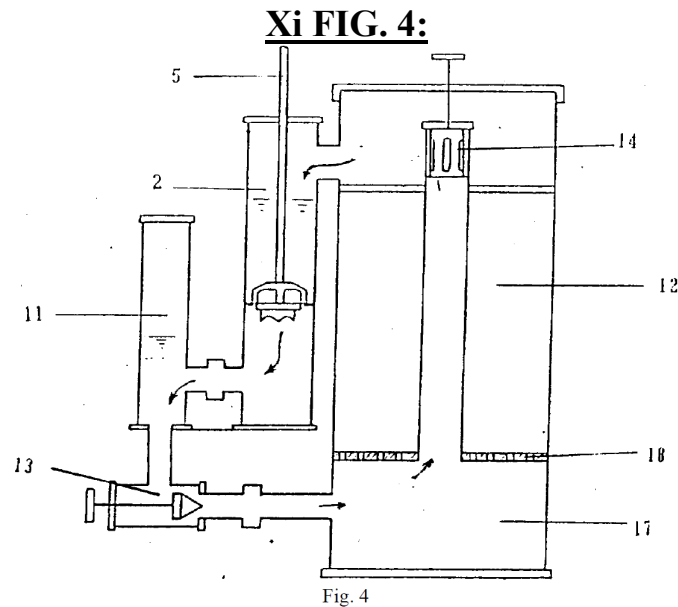
BDC argued in the related litigation that “the novel aspect of the ’935 patent” was its excess volume area (i.e., compliance chamber) in an accelerated test system. Ex-1022, 6, 10-11. As shown below, Xi discloses this feature—plus all others of the challenged claims.

A. Overview of Xi

Xi discloses an accelerated test system for heart valves that includes air-filled compliance chambers. Xi explains the known problem of increased “forces caused by the inertia and fluid inertia” during accelerated testing, “with the inertial forces and the trans-valve pressure differential together forming the total load on the valve.” Ex-1004, 7. Xi proposes solving this problem by, among other things, “adjust[ing] the compliance and impedance of the circulation loop system.” *Id.*

Xi provides adjustable compliance by “air chambers” C_1 for each of six independent “valve test sections” and one “large air chamber C_2 ” common to all test sections in its circulation loop. Ex-1004, 2, 7. During operation, the valve opens when the valve frame is moved up and closes when the frame is pushed

down. “[L]iquid flows from each test section (2) to its respective corresponding air chamber C_1 (11) and needle valve damper R_1 ,” before it flows into the “liquid storage tank (17)” with the “large air chamber C_2 (12).” Ex-1004, 8. Liquid is then “divided and diverted back to each test section through the adjustable damper R_2 .” Ex-1004, 7-8.

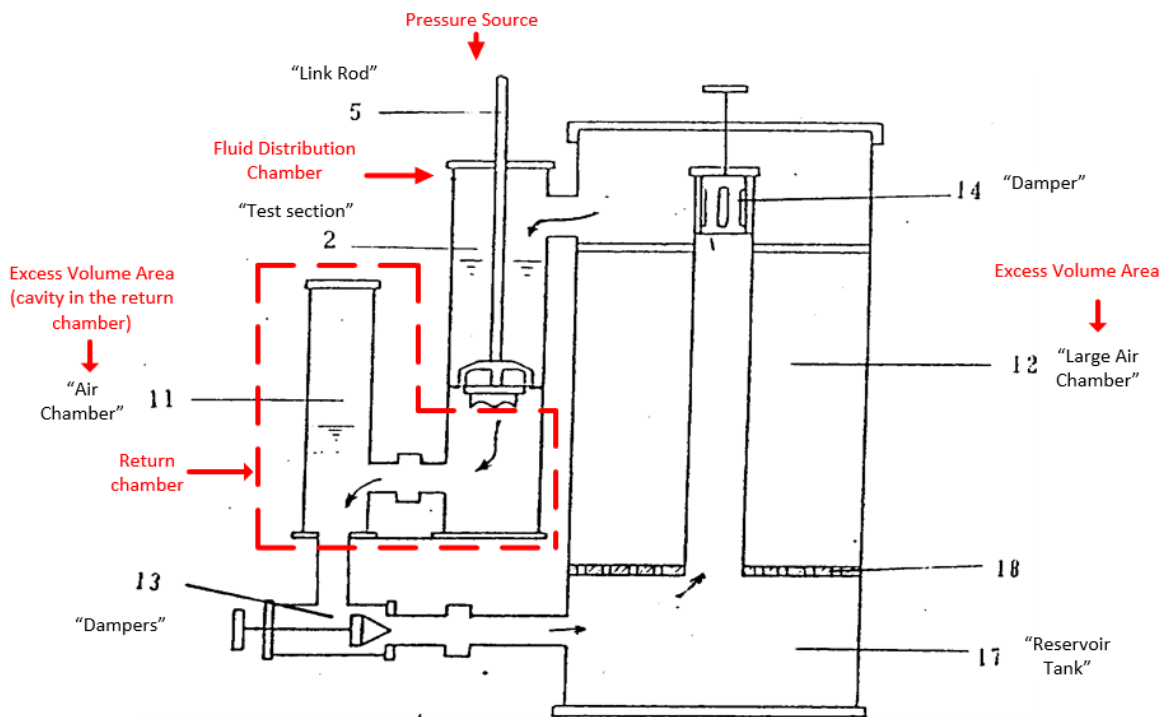


A POSA would have recognized these air chambers as “compliance chambers.” Ex-1002 ¶ 35. Xi’s design provides “a good balance of inertia and compliance.” Ex-1004, 7. It teaches that its system results in improved “valve back pressure” and “no water strike is produced when the valve is opened and closed.” *Id.* The device consequently “reduce[s] the occurrence of *the water hammer effect*” experienced in accelerated testing. Ex-1004, 6. Thus, a POSA would understand

that Xi's "air chambers" and "dampers" provide the desired compliance and impedance Xi's system. Ex-1002 ¶ 35.

B. Detailed claim analysis

An annotated version of Xi's FIG. 4 is provided to illustrate the primary elements of claim 1. See Ex-1002 ¶ 113.



1. Claim 1

- a. [1pre] "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"

Xi discloses a "prosthetic heart valve fatigue ... test device" where the "circulation frequency can reach 2,000 beats/min." Ex-1004, 6.

Xi's "linear motor (1) ... drive[s] the reciprocating motion of the link rod (5) and valve frame (6) in the test section (2) to open and close the test valve." Ex-1004, 5. When the rod is pushed down, the valve closes and "pushes the liquid down," and eventually liquid is "diverted back to each test section." Ex-1004, 7-8; Ex-1002 ¶ 116. Thus, Xi's valve frame and rod teach a pressure source to drive fluid cyclically through the device. Ex-1002 ¶¶ 115-117.

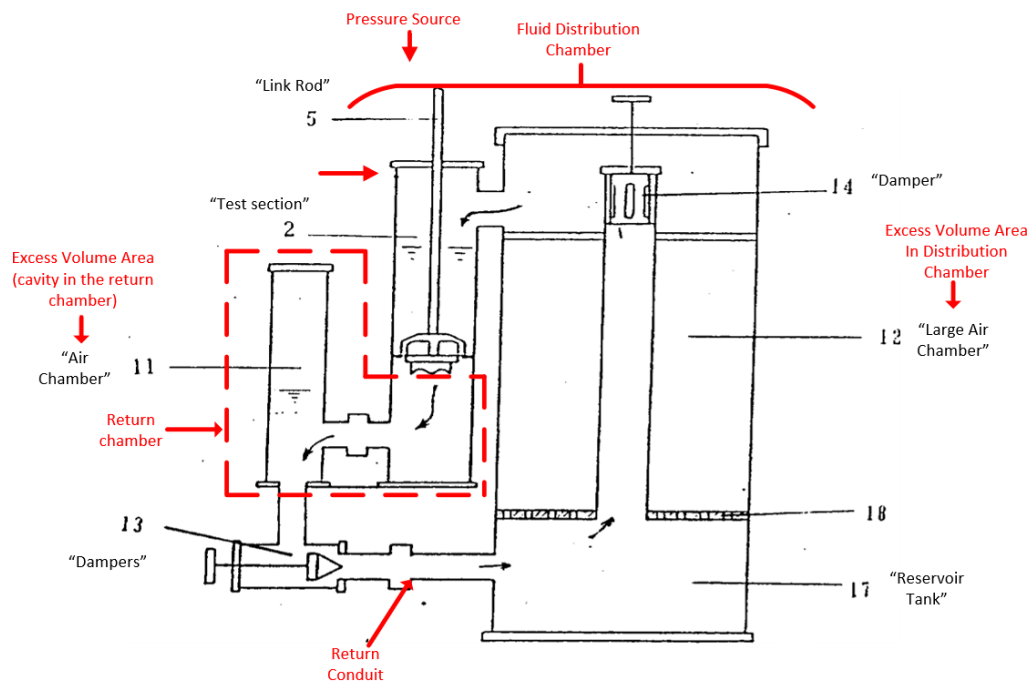
b. [1b] "*a pressurizable test chamber for containing the test system fluid*"

Xi's "circulation loop (30) and the test section (2) can simulate the compliance and impedance of the arterial system" and "greatly reduce ... the water hammer effect" while having "good sealing performance," and the linear motor is positioned to "not create ... conflicts in sealing." Ex-1004, 6. Valve back pressure is measured through a "pressure measurement hole ... on the side wall of the test section When pressure is *not being measured*, it is opened to atmosphere and zeroed." Ex-1004, 9. A POSA would understand that the test section (at minimum the portion on the back side of the valve) must be pressurized when pressure *is* being measured. Ex-1002 ¶ 119.¹⁰

¹⁰ BDC and its expert contend that Xi is an "open" system, not "closed," so that it does not need "to avoid excessive pressure" during operation. Ex-1024 ¶ 53. But

- c. [1c] “further comprising a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source;”
 [1d] a fluid return chamber positioned on a second side of the valved prosthetic device;

The “distribution chamber” is the area of Xi above the valve (the “first side”), and the “return chamber” is the area below and downstream of the valve (the “second side”), as illustrated below. *See also* Ex-1002 ¶ 120.



that BDC’s position is contradicted by Xi’s express teaching that its device addresses excessive inertial forces due to the water hammer effect, as well as Xi’s teachings about “good sealing performance.” Ex-1004, 6-7; Ex-1002 ¶ 119 (explaining why Xi is “closed”).

When “reciprocating motion” of the link rod and valve frame pulls the valve frame upward, “fluid inertial action” opens the valve leaflets (downward). Ex-1004, 5, 7. The valve frame then is pushed downward, closing the valve leaflets and “push[ing] the liquid down.” Ex-1004, 7-8. Fluid then moves through the device, in the direction of the arrows in Fig. 4, returning to the top of test section through the tank (17) and damper (14). Ex-1004, 7-8; Ex-1002 ¶ 121.

Consequently, the “distribution chamber” and “return chamber” of Xi are simply the areas upstream and downstream of the valve, respectively. Ex-1002 ¶ 122. They are where the fluid (a) is *distributed* to the valve and (b) *returns* from after passing through the valve. Ex-1002 ¶ 122. This identification is consistent with the ’935 patent’s description of the distribution and return chambers in the flow path from upstream to downstream of the valve. *E.g.*, Ex-1001, 10:44-49 (describing the “flow path through each of the sample holders 129 between the distribution chamber 126 and the return chamber 136”), 4:31-35 (describing “*return* flow ... from the *outflow* section of the sample holders,” through the return chamber, through “central return flow channel,” back to the distribution chamber).¹¹

¹¹ Nothing in the claims requires any specific structure or function of the “distribution” or “return” chambers aside from their relationship to other elements,

BDC’s witnesses and counsel have similarly described the return chamber as “downstream” of the valve. Ex-1023 ¶¶ 7, 9 (Weinberg describing design’s compliance chamber “in a return chamber, downstream of the valve”); Ex-1024 ¶¶ 13-14 (annotating FIG. 3 and describing how excess volume area helps “return the downstream volume to the pump”); Ex-1022, 6-7 (describing allegedly “novel accelerated test system ... placed an ‘excess volume area’ on the *outflow* side” of the valve that “releas[es] fluid *downstream* of the valve during the *return* phase”).

Xi’s distribution chamber is also “in fluid communication with”—i.e., in the flow path of, *see* Section V.A—with the “pressure source” for two reasons. Valve frame (6) occupies a cross-section of the test section, so that when the link rod moves the frame up and down, it applies a force or pressure against (and through) the fluid in each direction. Ex-1002 ¶ 126; Ex 1004, 7-8. The valve frame thus applies pressure on the fluid in the distribution chamber when moving up, and it applies pressure on the fluid in the return chamber when moving down. Ex-1002

such as being “in fluid communication” with the pressure source or excess volume area, discussed below. *See also* Ex-1002 ¶¶ 122-123.

¶ 126.¹² The distribution chamber is therefore both above and in fluid communication with the valve frame. Ex-1002 ¶¶ 125-26.

Second, the link rod, valve frame, and valve move up and down *through* the identified distribution chamber to cause the fluid flow from one side of the valve to the other. Ex-1002 ¶ 126; *see also* Section V.A above (claim construction of *fluid communication*). So *both sides* of test section—the upstream distribution chamber *and* downstream return chamber are “in fluid communication” with the pressure source. Notably, the same holds true for the ’935 patent: The distribution and return chambers are both “in fluid communication with” the pressure source. *See* Ex-1002 ¶¶ 122, 125-126.

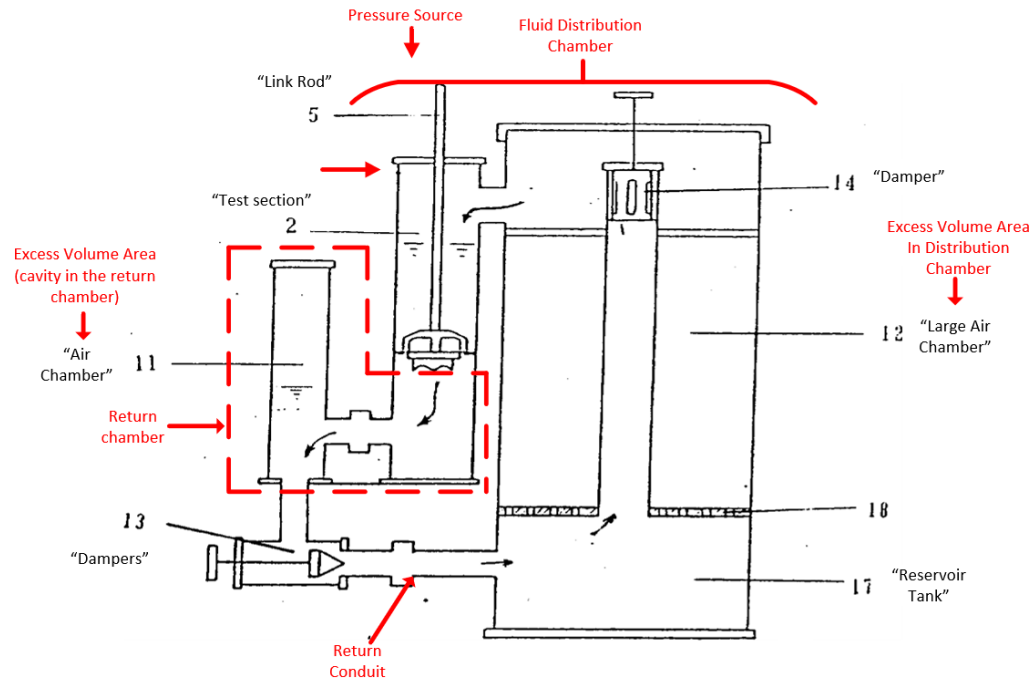
d. *[1e] a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and*

Xi discloses that fluid “flows from each test section (2) to its respective corresponding air chamber C₁ (11) and needle valve damper R₁ (13),” then “into the liquid storage tank (17),” before it is “divided and diverted back to each test section.” Ex-1004, 7-8. So fluid in Xi flows through the valve and “exit[s] through the return conduit” before flowing through other elements and back to the

¹² During the downstroke, the closed valve applies additional pressure to the fluid.

Ex-1004, 7-8; Ex-1002 ¶ 126.

distribution chamber, just as in the '935 patent. *Cf.* Ex-1001, 11:60-64 (describing fluid flow 110"). Xi therefore discloses a return conduit that "structurally and fluidly connect[s]" the distribution chamber to the return chamber. Ex-1002 ¶ 127.



e. [1f] The "excess volume area" clause

Xi's air chamber meets all the limitations of the recited excess volume area as detailed below.

- (i) "capable of operating at the accelerated pulsed rate"

First, the air chamber is part of an accelerated tester that operates at an accelerated rate. *See generally* Ex-1004; *see also* Section VII.B.1.a above.

- (ii) wherein the excess volume area is in fluid communication with the fluid return chamber

Second, fluid the air chamber is “in fluid communication” with the return chamber identified in [1d] above because “flows from each test section (2) to its ... air chamber C₁ (11).” Ex-1004, 8; Ex-1002 ¶ 130.

- (iii) providing a volume for storing a volume of a test system fluid when the test system fluid is under compression

Third, a POSA would have recognized Xi’s air chamber as an example of the “well known” *compliance chamber*. Ex-1002 ¶ 131; Ex-1011, 54 (BDC admitting these were well known). BDC’s counsel *conceded* that “Xi does have some sort of compliance chamber.” Ex-1037, 127:11-15. And as explained in the construction of “excess volume area,” a compliance chamber *discloses* and performs the same function as an excess volume area. *See also* Ex-1023 ¶ 7 (inventor Weinberg declaring that a compliance chamber is a “type of ‘excess volume area’”). *See* Ex-1002 ¶ 131; Section III.B above (illustrating several air compliance chambers).

BDC has also effectively conceded these compliance chambers “store a volume of fluid when the ... fluid is under compression.” During prosecution of the continuation, BDC admitted it was well known to “us[e] a compliance chamber *to store excess volume of test fluid*” in *real-time* systems. Ex-1011, 54. BDC also argued the “purpose” of the claimed “excess volume area (*i.e., compliance*

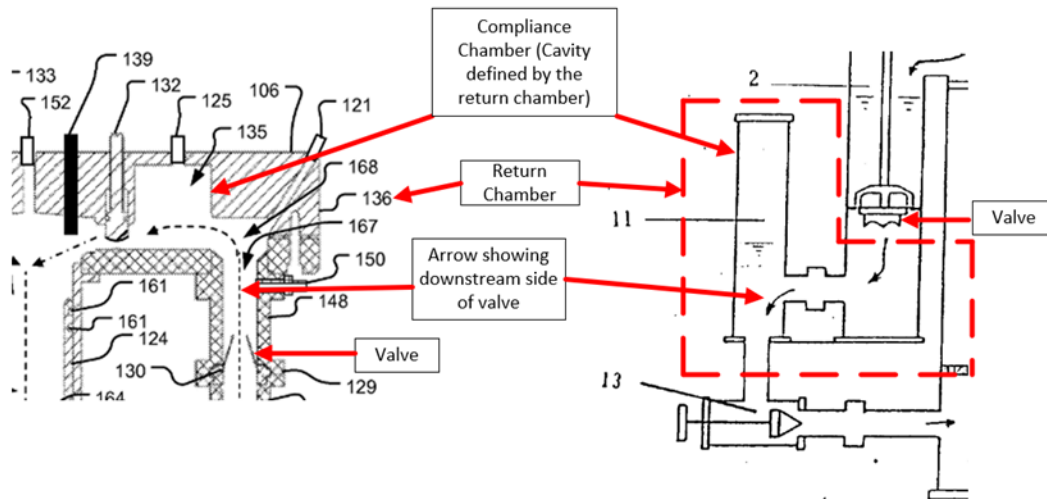
chamber(s)” was “to prevent or minimize the kinetic energy of fluid flow generated” and “to act as a resilient spring force to dampen the effects” of the pressure increases during accelerated testing. Ex-1011, 51, 57; *see also* Ex-1022, 6 (arguing the excess volume area “better manage[s] ... differential pressure spikes”).

A POSA would recognize Xi’s air compliance chamber performs these same functions. Ex-1002 ¶ 133. Xi described the same problem of increased “forces caused by the inertia and fluid inertia of the moving parts” on the valve. Ex-1004, 7. A POSA recognizes this problem as the “water hammer” effect and knows that compliance chambers mitigate it. *E.g.*, Ex-1005, 188 (teaching a “compliance component can reduce the effects of the water hammer” resulting from the “higher frequencies of accelerated testing”); *see also* Ex-1002 ¶¶ 27-29. Xi discloses that its air chamber compliance components also solve that problem. Ex-1004, 6; Ex-1002 ¶¶ 133-134.

A POSA would have understood—as BDC admitted during prosecution—that Xi’s compliance chambers “reduce ... water hammer” by providing (a) a volume to store some excess fluid and (b) a spring force to dampen the increased inertial forces when the fluid is “under compression”—i.e., when it is under pressure from the link rod (5) driving downward. Ex-1002 ¶¶ 133-34; *see also*, *e.g.*, Ex-1004, 7-8; *see also* Ex-1024 ¶ 22 (BDC’s expert opining that “under

compression” means “compressive forces are being places on the test system fluid, i.e., it is under pressure”). Xi accordingly discloses every limitation of claim 1. *See also* Ex-1002 ¶ 113.

Annotated '935 patent FIG. 3 (left) vs. Xi. FIG. 4 (right)



2. Claims 2, 4

Xi has a linear motor (claim 4) connected to and driving the link rod and valve frame, which exert pressure to displace the liquid in the test chamber (claim 2). Ex-1004, 5, 7-8; Ex-1002 ¶ 136.

3. Claims 8-9, 12

As explained above, Xi’s air chamber (11) discloses the claimed excess volume area. The air in that chamber provides compliance in the system, so that it is “compressed” and provides a “spring force” to mitigate the water hammer effect. *See* element [1f]; *see also* Ex-1002 ¶ 138. Xi therefore discloses **claim 8**. For the same reasons, Xi discloses “a volume for holding a gas ... that compresses under a

pressure placed on the fluid” as recited in **claim 12**. *Id.* Last, Xi’s air chamber (11) is “a cavity within the fluid return chamber” as recited in **claim 9**. *Id.*

4. Claim 3

Xi discloses an “arbitrary waveform generator” that “can provide an arbitrarily selected drive waveform” to move the motor and create the desired “valve back pressure waveform.” Ex-1004, 7-8. A POSA would understand that an “arbitrary” waveform means *any* waveform can be selected by the user—necessarily including cyclic, acyclic, and mixed fluid pressures—so that Xi anticipates claim 3. Ex-1002 ¶¶ 140, 144; *see also* Ex-1005, 190-191 (Lu describing Xi’s “*random wave* generator to create the driving waveform.”)¹³

Even if Xi did not expressly disclose cyclic and acyclic waveforms, it would have been obvious to a POSA that adjusting the input waveform to the drive motor would generate different fluid pressures in the test system. Ex-1002 ¶ 145. And a POSA would further understand that an arbitrary waveform could be adjusted to generate waveforms that are acyclic, cyclic, or a combination of both. *Id.*

¹³ The challenged patent similarly discloses that “arbitrary pressure waveform[s]” are possible with its driver. Ex-1001, 14:25-34.

5. Claim 13

Xi includes a “monitoring system” comprising “a valve load measurement, a valve displacement measurement, and a valve back pressure measurement.” Ex-1004, 8. Xi uses “strain-based force transducer[s] (24)” on the link rod to determine the “load received by the valve.” Ex-1004, 8. Xi measures valve back pressure using a “blood pressure transducer (29)” through a “pressure measurement hole ... on the side wall of the test section (2) on the back side of the valve (16).” Ex-1004, 2, 9. Fig. 2 below illustrates the transducers (24) and (29) above and below the valve.

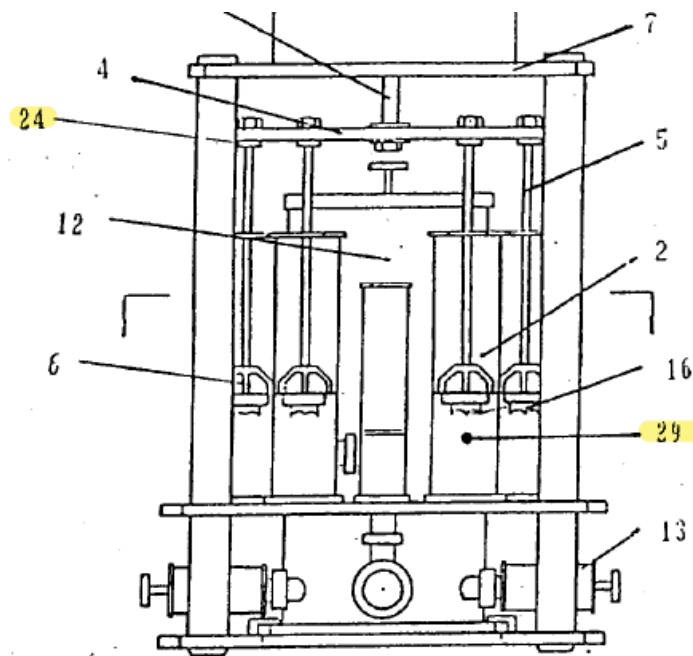


Fig. 2

Thus, Xi expressly discloses sensors on first and second sides of the valve. *Cf.* Ex-1001, 10:61-64 (identifying “pressure transducers” as example “sensors”); *see also*

Ex-1002 ¶ 148. And transducer (29) is received through a “hole,” which Petitioner identifies as the “second port” of claim 13. *See* Ex-1004, 5, 9; Ex-1002 ¶ 148.

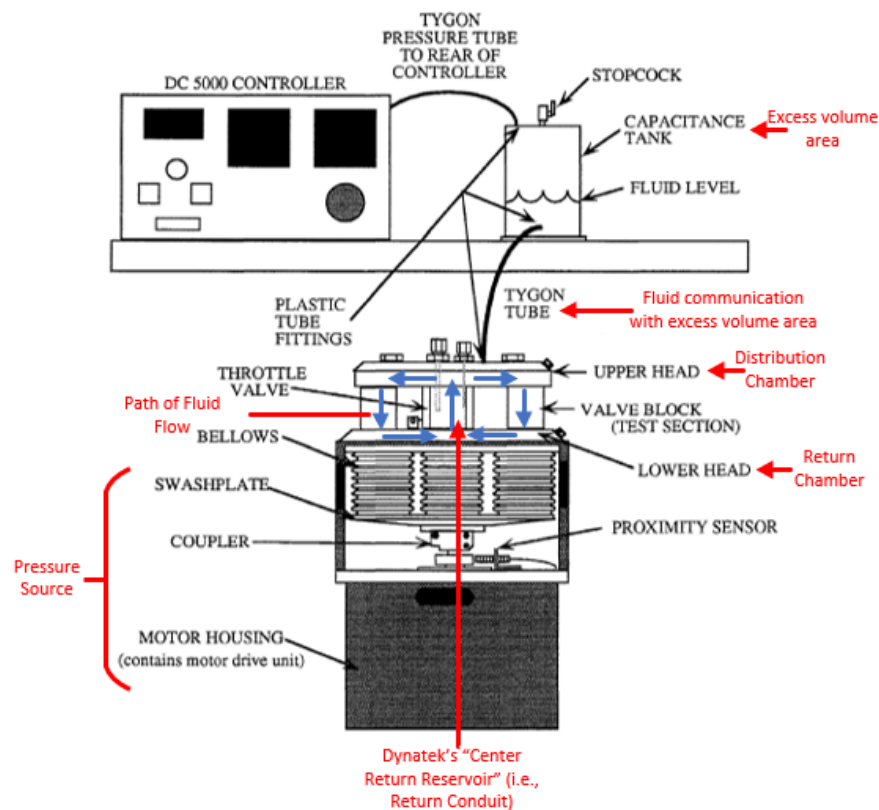
Xi does not expressly disclose whether transducer (24) is inserted through a “hole” or port in the device. Ex-1002 ¶ 149. It would have been obvious to a POSA, however, to add a second port/hole to the test section upstream of the valve to receive another sensor. A POSA would have been motivated by prior art teaching “measuring the pressure of the fluid *upstream and downstream* of the heart valve to generate channel pressure data” in both real-time and accelerated valve testing systems. Ex-1018, 21:33-35 (Pickard claim 33); *see also id.* at 6:7-15 (teaching such data is useful to “calculate the ... pressure waveform of the fluid through the flow channel”); Ex-1007, 11:34-37 (“Pressure transducers will be located *both upstream and downstream* of the valve”); Ex-1020, 152 (“[T]he pressure difference across the valve ... is *measured upstream and downstream* of the valve by two semiconductor pressure transducers”); Ex-1006, 15, 18 (“Pressure transducer *ports* are provided in the *top and bottom* manifolds,” on either side of the valve, “for [pressure] transducers”). And adding the second port, according to those same references, would have been an application of no more than ordinary skill and been a simple substitution for Xi’s transducer on the link rod. Ex-1002 ¶ 151. Accordingly, claim 13 is obvious over Xi.

VIII. GROUND B: CLAIMS 1-4, 8-9, AND 12-13 ARE OBVIOUS OVER DYNATEK AND XI

A. Overview of Dynatek

Dynatek discloses an accelerated heart valve testing device that recirculates fluid through valves using a motor to drive a set of bellows. *See* Ex-1006, 5.

Dynatek also discloses a “capacitance tank” that is partially filled with air and used to “buffer small variations in the systemic pressure” during operation. Ex-1006, 18-19. Dynatek FIG. 1, annotated below, illustrates the Dynatek M6.



Ex-1002 ¶ 169.

Petitioner contends that Dynatek’s “capacitance tank” is a “compliance chamber” that (like Xi’s) discloses the “excess volume area” limitation of the claims (discussed below). But even—or *especially*—if it is *not*, a POSA would have been motivated to combine the teachings Xi and Dynatek to arrive at the claimed invention.¹⁴ See Ex-1002 ¶¶ 158-59.

B. Motivation to Combine

As discussed in Section VII.B.1.e(iii), the art teaches that accelerated testers should include compliance chambers to help control loading forces and mitigate the water hammer effect. See also Ex-1002 ¶ 160 (summarizing teachings of Reul, Iwasaki, and Lu on controlling “loading forces” and “transvalvular pressure”). And Iwasaki specifically taught—7 years before the priority date—that if an accelerated test is originally “designed *without* a compliance element,” as BDC has argued Dynatek is, then it can and should be “modified to *incorporate an air compliance chamber*.” Ex-1019, 422.

¹⁴ In defeating BDC’s motion for preliminary injunction in the litigation, Petitioner argued that Dynatek anticipated several claims of the patent. BDC disagreed, arguing that Dynatek’s system “lacks three necessary elements.” Ex-1022, 17. To the extent these disagreements are relevant to this Ground, they are discussed below.

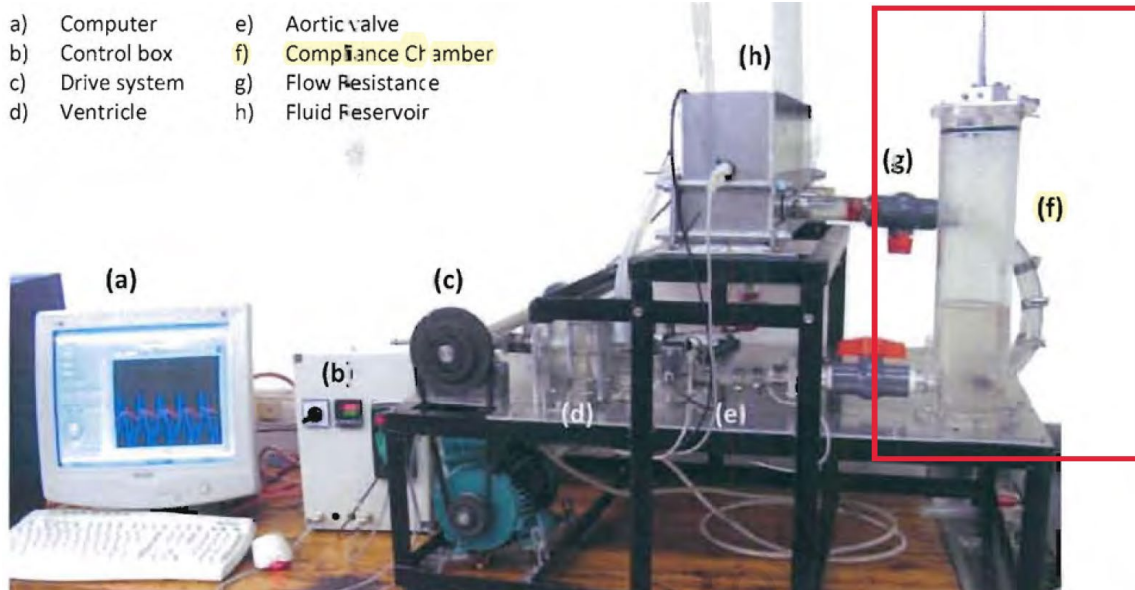
Likewise, both Dynatek and Xi note the importance of monitoring and controlling trans-valve pressure in accelerated testing. *See* Ex-1006, 23; Ex-1004, 4; Ex-1002 ¶ 161. So a POSA would have looked to Xi’s solution of an air compliance chamber downstream of the valve (not to mention the other art showing the same) to help control undesirable back-pressure and “reduce ... the water hammer effect.” Ex-1004, 6; Ex-1002 ¶ 161; *cf.* Ex-1001, 12:12-24. A POSA would therefore be motivated to combine Xi’s teachings with Dynatek.

BDC has argued that a POSA would not have been motivated to combine these references and would not have had a reasonable expectation of success in doing so because they “operate in fundamentally different ways.” Ex-1022, 18, 52-53. BDC has also argued that Dynatek “teaches away” from the combination. *Id.*; *see also id.* at 49. These positions are meritless.

First, it was well within the level of skill to combine these references. The prior art generally indicates POSAs incorporated compliance chambers into real-time and accelerated testers of diverse designs, as discussed above. Ex-1002 ¶ 163. And Iwasaki is evidence that a POSA would (and did) have the skill to *modify* a tester to add an air compliance chamber to a device lacking one. Ex-1019, 422-423.

The 2009 Krynauw thesis also shows that a POSA had the skill to design and build a combined real-time and accelerated test system—shortly before/around the

priority date—had a sophisticated understanding of issues and skill to address them. Ex-1002 ¶ 164; *see also generally*, Ex-1015. Krynauw was aware of the “effect of waterhammer on the valve” during accelerated testing *and* that adding compliance “reduced ... pressure spikes.” Ex-1015, 33, 68, 82; Ex-1002 ¶ 164. Krynauw’s design, unsurprisingly, used an air compliance chamber downstream of the valve—just like the ’935 patent. Ex-1015, 37-38 (Fig. 3.2, annotated below), 40-42 (describing design of chamber).



Thus, the design differences between Dynatek and Xi would have been no obstacle to a POSA, who knew how to include compliance chambers in many kinds of systems before the priority date. Ex-1002 ¶ 165.

Second, BDC contends Dynatek teaches away from including an air compliance chamber because *some* instructions direct users to remove air bubbles. Ex-1022, 49 (citing “**13 steps** devoted to ***removing*** all gas” (triple/double emphasis

in original)); *id.* at 53 (arguing Dynatek “repeatedly warns” to remove air). But BDC misrepresents the instructions on pages 5-12, which relate to “debubbling” the machine,¹⁵ and ignores *later* steps that instruct users to “add air” to pressurize the capacitance tank. Ex-1006, 14-16; Ex-1002 ¶ 167 (explaining debubbling and pressurization of compliance chambers). BDC’s user manual for the VDT-3600i (alleged to embody the patent) similarly tells users to remove or “*bleed* any residual air” from the system and to *fill* the compliance chamber with air. Ex-1038, 10, 16, 19. The Krynauw thesis does the same, Ex-1015, 61 (instructing to remove “trapped” air although it includes a compliance chamber). In any case, nothing within Dynatek criticizes, discredits, or otherwise discourages adding a compliance chamber with air, so there is insufficient evidence to find it teaches away from that feature. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

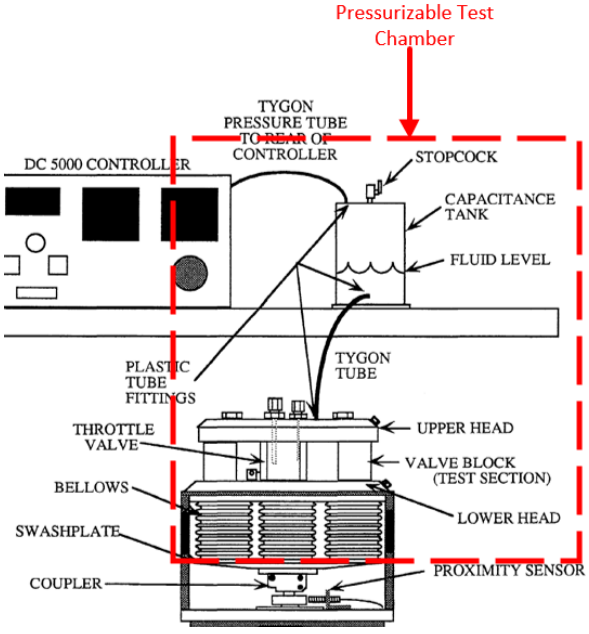
In sum, a compliance chamber was a known technique to address water hammer across a variety of devices, including in multiple accelerated test systems. A POSA would have therefore looked to Xi’s device to combine with Dynatek. *See also* Ex-1002 ¶ 168.

¹⁵ Dynatek explains, “bubble removal is one of the biggest challenges facing a valve tester.” Ex-1006, 9; *see also id.* at 12-14 (instructing how to “debubble”).

C. Detailed claim analysis**1. Claim 1**

As shown in the chart below, the combination of Dynatek and Xi renders claim 1 obvious.

Claim 1	Prior Art
[1pre] A device for accelerated cyclic testing of a valved prosthetic device comprising	Dynatek discloses a “heart valve durability/fatigue testing machine” that is “capable of speeds to 2000cpm” (cycles per minute). Ex-1006, 5, 23; Ex-1002 ¶ 170.
[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	Dynatek’s “swashplate drive is used to compress six bellows” to cycle fluid through the system. Ex-1006, 5; Ex-1002 ¶ 170. The “bellows compression increases pressure behind the valve, loading the leaflets” during each cycle. <i>Id.</i>

Claim 1	Prior Art
[1b] a pressurizable test chamber for containing the test system fluid and further comprising	Dynatek discloses a “Testing Chamber” comprised “upper and lower heads, throttle valve, valve blocks and capacitance tank.” Ex-1006, 5, 18, Fig. 1A (annotated below). Dynatek’s system has a “systemic operating pressure” that can be adjusted, in part, by “pressurizing the capacitance tank.” Ex-1006, 15 (Step 41); <i>see also</i> Ex-1006, 21 (describing the “pressure operating range” of the device), 23-25 (“Setting the Pressure and Flow Rate”), 26 (“Pressurize the system again.”). <i>See also</i> Ex-1002 ¶ 172. 

Claim 1	Prior Art
[1c] a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source;	Dynatek has an “upper head above the valves” that “contain[] the inlet flow passages.” Ex-1006, 5, 7 (Fig. 1A), 18. The upper head is in fluid communication with the pressure source (the drive and bellows). <i>See</i> Ex-1006, 5 (describing bellows compression causes fluid to flow to the upper head); Ex-1002 ¶ 173.
[1d] a fluid return chamber positioned on a second side of the valved prosthetic device;	Dynatek’s “lower head is ported from the valve discharge region into the center return reservoir.” Ex-1006, 7 (Fig. 1A), 18; Ex-1002 ¶ 174.
[1e] a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and	Dynatek’s “lower head is ported from the valve discharge region into the center return reservoir.” Ex-1006, 18. After passing through the valve, fluid “escapes through the bypass port, through the throttle valve and into the central reservoir where it is then available to the upper head above the valves for another cycle.” Ex-1006, 5; Ex-1002 ¶ 175.

Claim 1	Prior Art
[1f.1] an excess volume area capable of operating at the accelerated pulsed rate	Dynatek’s capacitance tank is filled with pressurized air and “is used to buffer small variations in the systemic pressure.” Ex-1006, 16 (Step 45), 19. A POSA would have therefore recognized the capacitance tank as a compliance chamber. Ex-1002 ¶ 176. And Dynatek teaches its capacitance tank is “capable of operating” at an accelerated rate because the <i>purpose</i> of the system is for accelerated fatigue testing. <i>See generally</i> Ex-1006; Ex-1002 ¶ 176. Even if Dynatek’s capacitance tank were not a compliance chamber, Xi also teaches using a compliance chamber. <i>See</i> Section VII.B.1.e(iii); Ex-1002 ¶ 177. A POSA would have therefore found it obvious to use either of Dynatek or Xi’s air chambers as a compliance chamber (i.e., excess volume area) in a combined system to provide additional control of loading forces and address the well-known water hammer effect. <i>See</i> Section VIII.B; Ex-1002 ¶ 178.

Claim 1	Prior Art
[1f.2] wherein the excess volume area is in fluid communication with the fluid return chamber	Xi and Lu expressly teach placing a compliance chamber immediately downstream of the valve. Ex-1004, 7-8, 13 (Fig. 4); Ex-1005, 190-91. And other evidence show that placing a compliance chamber downstream of the valve was a known or obvious configuration for many kinds of valve testing. Ex-1007, 10:25-35, FIG. 3; Ex-1018, 22:15-19 (teaching “a compensation chamber ... downstream of the heart valve”); Ex-1002 ¶¶ 179-181; <i>see also</i> Ex-1015, 37-38 (Fig. 3.2). Accordingly, a POSA would have found it obvious to include the compliance chamber of Dynatek or Xi downstream of the valve (e.g., to the lower head of Dynatek), within and in fluid communication with the return chamber. Ex-1002 ¶¶ 160-161, 182.¹⁶
[1f.3], providing a volume for storing a volume of a test system fluid when the test system fluid is under compression.	For the reasons described above with respect to Xi, an air compliance chamber connected to the lower head would provide a space to store excess volume of test fluid when the fluid is under compression. <i>See</i> Section VII.B.1.e(iii); <i>see also</i> Ex-1011, 54 (BDC admitting that a compliance chamber is used

¹⁶ Regardless of whether Dynatek’s capacitance tank is a compliance chamber, a POSA would have found multiple compliance chambers acceptable. Ex-1027, 10:15-34 (teaching accelerated testing device where “one or more ... compliant structures may be positioned *anywhere* in the system”); Ex-1004, 7-8 (air chambers C₁ and C₂); Ex-1005, 190 (same); Ex-1002 ¶¶ 181-182 (explaining benefit of including upstream *and* downstream compliance).

Claim 1	Prior Art
	“to store excess volume of test fluid”); Ex-1002 ¶ 183. Dynatek teaches, “<i>compressing</i> the bellows[] caus[es] the fluid to reverse direction and close the valve. Further bellows <i>compression</i> increases the <i>pressure</i> behind the valve, loading the leaflets or occluders.”). Ex-1006, 5. Thus, the system is “under compression” because it is “under pressure” as that term is properly construed. <i>See</i> Section V.C above; Ex-1024 ¶ 22 (BDC expert opining fluid is “under compression” when “compressive forces are ... placed on the test system fluid, i.e., it is under pressure”). Thus, obvious use of a compliance chamber in the combined system would meet the limitation of [1f.3] and perform the same function recited in the claim. <i>See, e.g.</i>, Ex-1004, 6-7 (discussing “reduc[ing] the water hammer effect” and preventing “water strike”); <i>see also</i> Ex-1002 ¶¶ 184-85.¹⁷

2. Claims 2-4, 8-9, 12-13

Each of the limitations are disclosed and rendered obvious by the combination of Dynatek and Xi. As discussed above, Xi discloses all these

¹⁷ BDC contends Dynatek is not “under compression” but that conflicts with its teaching about bellows compression increasing pressure. In any case, factual question like this are “best resolved at trial.” *Mylan Pharmaceuticals Inc. v. Biogen MA Inc.*, IPR2018-01403, Paper 12, 37-38 (Feb. 6, 2019).

limitations, so its disclosures are (generally) not repeated here. Dynatek provides additional disclosure of the elements as detailed below, which shows these claims are obvious.

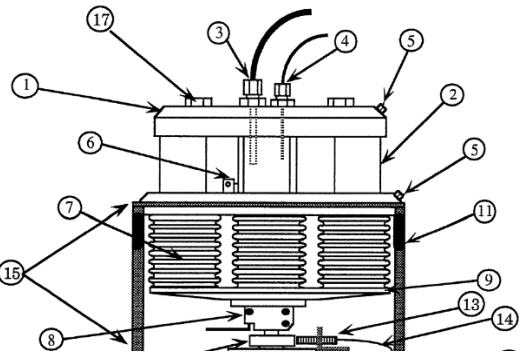
Claim 2	Prior Art
[2a] The device in claim 1 further comprising a drive motor; and	Dynatek has a “motor drive unit.” Ex-1006, 5, 7 (Fig. 1A); Ex-1002 ¶ 187.
[2b] a fluid displacement member connected with and driven by the drive motor to provide the pressure source that increases and decreases a pressure on the test system fluid in the test chamber.	“As the motor shaft turns, the adjustable tilting coupler rotates and pulls the swashplate down, extending the bellows. ... As the rotation continues, the swashplate is returned upward, compressing the bellows, causing the fluid to reverse direction and close the valve. Further <i>bellows compression increases the pressure</i> behind the valve” Ex-1006, 5, 7-8 (Figs. 1A and 1B). Dynatek’s bellows teaches the claimed fluid displacement member. Ex-1002 ¶ 187.

Claim 3	Prior Art
The device of claim 2, wherein the drive motor is configured to operate cyclically, acyclically, or a combination of both, to provide cyclic and acyclic fluid pressures within the test chamber.	Dynatek does not expressly disclose the limitation of claim 3. But Xi discloses an “arbitrary waveform generator” that “can provide an arbitrarily selected drive waveform” to move the motor and create the desired “valve back pressure waveform.” Ex-1004, 7-8. Accordingly, a POSA would have found it obvious to configure a drive motor to operate cyclically, acyclically, or a combination of both to provide those corresponding waveforms and pressures. Ex-1002 ¶ 194; <i>See also</i> Section VII.B.4 (discussing claim 3 unpatentable over Xi).

Claim 4	Prior Art
The device of claim 2, wherein the drive motor comprises a linear motor.	Dynatek’s swashplate and rotary motor drive fluid by moving bellows “upward” and “down,” i.e., a linear motion. Ex-1006, 5; Ex-1002 ¶ 188; <i>see also</i> Ex-1024 ¶ 41 (BDC’s expert illustrating up-and-down motion of the bellows). Xi discloses a “linear motor” driving the link rod and valve frame up and down. Ex-1004, 5; <i>see also</i> Section VII.B.2. It would have been obvious to use a known linear motor (like Xi) to provide linear motion in an accelerated tester. Ex-1002 ¶ 190-192. A POSA would be aware of a variety of pumps and motors in the art. Ex-1002 ¶ 60. So substituting among these known pump designs would have been no more than a simple substitution of known elements to achieve predictable results. Ex-1002 ¶ 191.

Claim 8, 9, 12	Prior Art
8. The device of claim 1, wherein the excess volume area further contains a volume of a compressible gas that is compressed by the volume of the test system fluid to provide a spring force when the volume of the test system fluid is stored in the excess volume area. 9. The device of claim 1, wherein the excess volume area comprises a compliance	As explained above, Xi’s air chamber and Dynatek’s capacitance tank teach compliance chambers and, consequently, the claimed excess volume area. The air in both chambers provides compliance in the system, so that it is “compressed” and provides a “spring force” to mitigate the water hammer effect. <i>See</i> element [1f]; Ex-1002 ¶ 195; <i>see also</i> Section VII.B.3 (explaining Xi teaches these claims). The combination of Dynatek and Xi therefore teaches the limitations of claim 8. For the same reasons, they disclose “a volume for holding a gas ... that compresses under a

Claim 8, 9, 12	Prior Art
chamber defining a cavity within the fluid return chamber. 12. The device of claim 9, wherein the compliance chamber provides a volume for holding a gas or elastomeric material that compresses under a pressure placed upon the test system fluid in the test chamber and allows the test system fluid in the test chamber to occupy a portion of the volume in the compliance chamber.	pressure placed on the fluid” as recited in claim 12. Last, it would have been obvious to locate the air compliance chamber downstream of the test valve to be “a cavity within the fluid return chamber” as recited in claim 9. <i>See also</i> Ex-1002 ¶¶ 195-197 (opining on claims 8-9, 12).

Claim 13	Prior Art
13. The device of claim 1, wherein the test chamber defines a first port on a first side of the valved prosthetic device and a second port on a second side of the valved prosthetic device; and the first port and the second port are configured to receive one or more sensor devices.	Dynatek provides “[p]ressure transducer ports ... in the <i>upper and lower heads</i> at each valve block position,” on either side of the valve. Ex-1006, 18, 8 (Fig. 1B, reference 5).  It would have therefore been obvious to include the same when combining Dynatek and Xi to arrive at claim 13. Ex-1002 ¶ 198; <i>see also</i> Section VII.B.5.

IX. GROUND C: CLAIMS 1-4, 7-9, AND 12-13 ARE OBVIOUS OVER GOLDSTEIN AND LU

A. Overview of Goldstein

Goldstein teaches a “closed, sterile pulsatile flow loop for studying tissue valves.” Ex-1007, Abstract. “[A]n adjustable resistance and compliance element (FIG. 3) is placed downstream to simulate the peripheral resistance of the circulation.” Ex-1007, 10:27-30. Goldstein further explains that compliance is “provided by allowing the fluid to collect in a Lexan tank and to push against a flexible membrane.” Ex-1007, 10:30-35. Goldstein’s “piston pump” pressurizes the system by “squeeze[ing]” a “flexible bladder” to “propel the ... fluid out through the aortic valve.” Ex-1007, 9:57-65.

Goldstein FIG. 3 illustrates the “in vitro flow loop for analyzing aortic valve function,” including the piston/pump chamber that cycles fluid through a conduit to the “aortic test section,” to a resistance and compliance unit, and from the resistance and compliance unit back to the pump chamber:

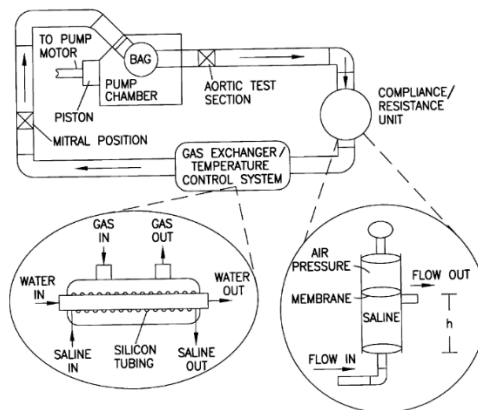


FIG. 3

Ex-1007, 5:5-6, FIG. 3.

B. Overview of Lu

Lu explains the benefits of accelerated testing of artificial heart valves—it “can significantly shorten the amount of time spent on research and development.” Ex-1005, 185. By 2003, accelerated tester design had “received much attention among industrial researchers and regulatory agencies.” Ex-1005, 185. Lu then identifies six state-of-the-art accelerated valve tester systems and notes that “*all* have adjustable resistance, compliance, amplitude, and cycle rate.” Ex-1005, 186.

Lu also explains how parameters of accelerated test systems are designed, including the relationships between flow velocities and forces on an accelerated test system (equation 1), as well as between pressure and compliance (equation 7, 8). Ex-1005, 189. Thus, Lu shows that designers as early as 2003 thoroughly understood how accelerated test systems operated and how to use compliance in the test systems. Ex-1002 ¶¶ 38-43.

C. Motivation to Combine

While Goldstein only expressly discloses using its system at cycle rates up to 120 beats per minute (bpm), Ex-1007, 9:67-10:4, a POSA would be motivated by (at least) Lu to speed up the rate to at least “an accelerated pulsed rate of greater than 200 [bpm]” as recited in claim 1, Ex-1002 ¶ 203. And in view of the teachings of Lu, Iwasaki, and Xi, a POSA would have recognized Goldstein’s air compliance chamber as the kind of “adjustable compliance” that Lu teaches is useful to

mitigate the water hammer that becomes more pronounced during accelerated testing. Ex-1002 ¶ 204. A POSA could have used Lu's formulae to model how Goldstein's compliance might affect its performance. Ex-1005, 189; Ex-1002 ¶ 204. And running the system at the accelerated rate would result in Goldstein's compliance chamber performing the same functions, and solving the same problems, as the claimed excess volume area. Ex-1002 ¶ 204.

Finally, a POSA would have been able to, and would not be deterred from, accelerating Goldstein above the expressly disclosed rates. Ex-1002 ¶ 205. A POSA would have been able select and configure a waveform generator and pump to achieve the desired accelerated rate—at minimum over 200 bpm recited by claim 1. Ex-1002 ¶¶ 205-206. And a POSA would have understood from Elizondo—a bioreactor capable of accelerated testing—that the benefits of accelerated testing could similarly be applied to a bioreactor like Goldstein with a reasonable expectation of success. Ex-1027, 1:1-10, 11:33-12:54; Ex-1007, 1:41-49; Ex-1002 ¶ 207. In other words, the benefits and likelihood of success of accelerating bioreactor-type testers were known to a POSA. Ex-1002 ¶¶ 207-208. The Krynauw thesis also demonstrates that, around the priority date, a POSA

would have contemplated a single device capable of both “hydrodynamic and [accelerated] fatigue testing.” Ex-1016 ¶ 3-4; Ex-1015, 1-2; Ex-1002 ¶ 208.¹⁸

D. Chart of all challenged claims

An annotated version of Goldstein’s FIG. 3 is provided to illustrate the primary elements of claim 1. *See* Ex-1002 ¶ 209.

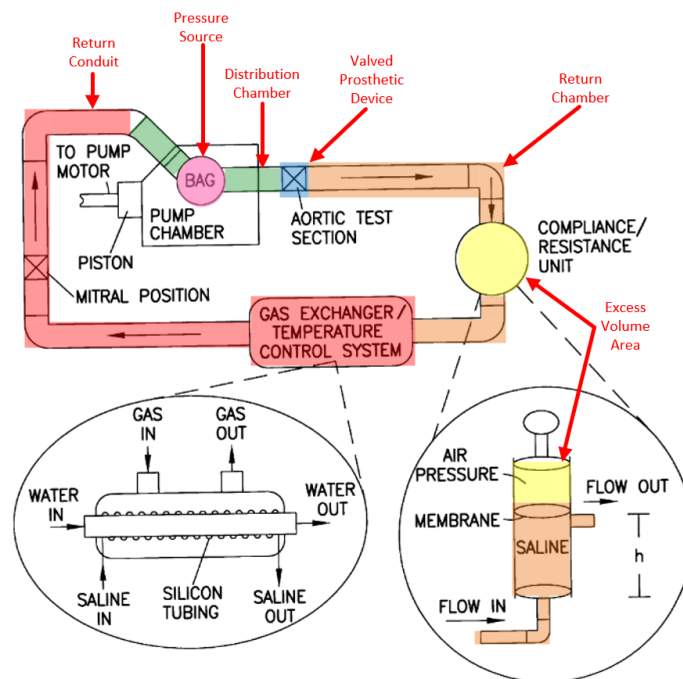


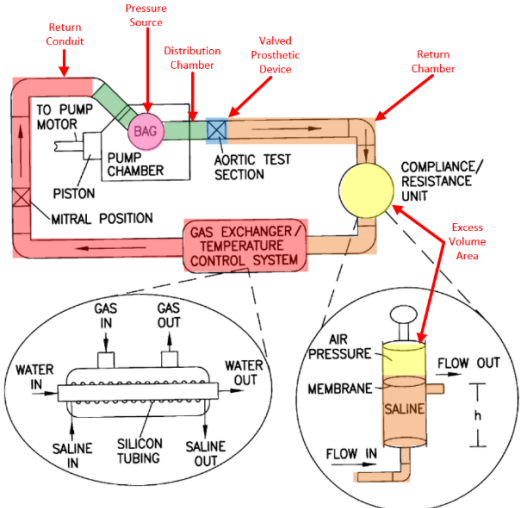
FIG. 3

¹⁸ BDC has argued that real-time and accelerated systems “have completely different requirements and use completely different methodologies,” such that they are “inherently at odds with one another.” Ex-1011, 52-53; Ex-1014, 1-2, 43. Those statements are belied by Krynauf’s thesis *and* by BDC’s own product marketing touting the “ability to operate both as a real-time wear and accelerated wear test system.” Ex-1028, 5.

As shown in the chart below, the combination of Goldstein and Lu renders the challenged claims obvious.

Claim 1	Prior Art
[1pre] A device for accelerated cyclic testing of a valved prosthetic device comprising	Goldstein teaches a “closed ... flow loop for studying tissue valves.” Ex-1007, Abstract. Lu teaches that accelerated testing of heart valves allows a POSA to speed up the development of heart valves. Ex-1005, 185. Thus, it would be obvious to use an accelerated cycle rate with Goldstein’s device for testing heart valves. Ex-1002 ¶¶ 210-212.
[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	Goldstein teaches, “A piston pump ... can be used to drive the pulsatile flow.” Ex-1007, 9:57-58. A “flexible rubber bladder” is “mounte[d] inside of a Lexan chamber filled with water.” Ex-1007, 9:61-62 “The piston can displace the water; this in turn will squeeze the flexible bladder and propel the blood analog fluid out through the aortic valve test section.” Ex-1007, 9:63-65. While Goldstein does not expressly teach operating “at an accelerated pulsed rate of greater than 200 [bpm],” it teaches the “waveform [and therefore rate] could be varied in frequency.” Ex-1007, 7:63-64. A POSA would be motivated by Lu (and Elizondo), and it would be obvious, to operate Goldstein at accelerated rates, using an appropriately programmed waveform generator. Ex-1002 ¶¶ 211-212; Ex-1007, 9:58-60 (teaching waveforms

Claim 1	Prior Art
	can “easily” be changed using off-the-shelf waveform generator).
[b] a pressurizable test chamber for containing the test system fluid and further comprising	Goldstein’s “closed ... flow loop” is a test chamber. Ex-1007, Abstract. Pressures are formed in the chamber by clamping the tubing or by raising the compliance tank. Ex-1007, 10:38-42. A POSA would have understood that Goldstein’s closed flow loop is pressurizable because Goldstein discloses creating pressures inside the closed loop. Ex-1002 ¶ 213.
[c] a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source;	Goldstein discloses “a fluid conduit leading from the bladder to a test section.” Ex-1007, 24:25-28 (claim 1). This conduit is in fluid communication with the pressure source. Ex-1002 ¶ 215.
[d] a fluid return chamber positioned on a second side of the valved prosthetic device;	Goldstein discloses another “fluid conduit leading from the test section to a downstream compliance and resistance element.” Ex-1007, 24:28-30 (claim 1).
[e] a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and	Goldstein discloses another “fluid conduit leading from the compliance and resistance element to the bladder.” Ex-1007, 24:29-37.

Claim 1	Prior Art
	 FIG. 3 As shown in Fig. 3, this portion of the “flow loop” structurally and fluidly connects the fluid return chamber back to the fluid distribution chamber. Ex-1002 ¶ 215.
[f] 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.	Goldstein discloses an “adjustable resistance and compliance element” that is “placed downstream to simulate the peripheral resistance of the circulation.” Ex-1007, 10:27-30. Goldstein teaches, “Compliance will be provided by allowing the fluid to collect in a Lexan tank and to push against a flexible membrane.” Ex-1007, 10:30-32. A POSA would recognize Goldstein’s “compliance” element as an air compliance chamber. Ex-1002 ¶ 217. And a POSA would have been able to use Lu’s teachings (in addition to background knowledge) of various formulae relating compliance to other parameters in such a test system to adapt Goldstein for

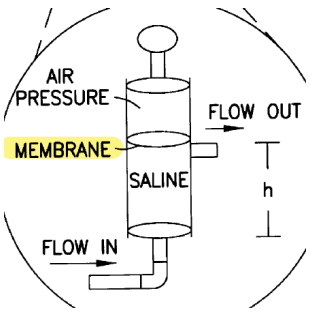
Claim 1	Prior Art
	accelerated speeds. Ex-1002 ¶ 217; Ex-1007, 2:8-14 (teaching POSAs could examine the effect of and optimize for many parameters). Thus, a POSA would understand that when Goldstein’s device is accelerated, the compliance chamber would be capable of mitigating the water hammer effect by “allowing the fluid to collect” in the chamber when the fluid is “under compression”—i.e., “under pressure” from the piston and bladder pressure source, even when operated at an “accelerated pulsed rate.” Ex-1002 ¶ 218; Ex-1007, 10:30-47.

Claim 2	Prior Art
2. The device in claim 1 further comprising a drive motor; and a fluid displacement member connected with and driven by the drive motor to provide the pressure source that increases and decreases a pressure on the test system fluid in the test chamber.	Goldstein FIG. 3 identifies a “pump motor” driving the piston, which increases and decreases the pressure by “squeeze[ing]” the “flexible bladder” to drive the fluid flow. Ex-1007, 9:57-65, FIG 3; Ex-1002 ¶ 220.

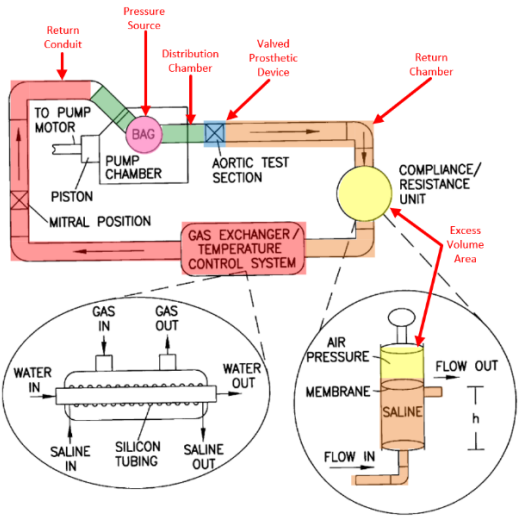
Claim 3	Prior Art
3. The device of claim 2, wherein the drive motor is configured to operate cyclically, acyclically, or a combination of both, to provide cyclic and acyclic fluid pressures within the test chamber.	Goldstein teaches the pump’s “motion can be programmed” with a commercially available “waveform generator ... allowing the flow waveform to be changed easily.” Ex-1007, 9:57-60.

	Lu illustrates transvalvular pressure measurements and forces including cyclic and acyclic components. Ex-1005, 193-94. And Lu teaches use of a “random wave generator to create the driving waveform” to affect the loading on the test valve.” Ex-1004, 190-91. While Goldstein does not expressly teach the identified waveform generator can operate “cyclically, acyclically,” or both, a POSA would have found it obvious to select and use such a waveform generator, including the one taught by Lu, to arrive at the limitation of claim 3. Ex-1002 ¶ 225 (explaining such selection would be within the level of skill of a POSA).
--	---

Claim 4	Prior Art
4. The device of claim 2, wherein the drive motor comprises a linear motor.	Goldstein does not expressly state whether its “pump motor” driving the “piston pump” is a linear motor. But Lu discloses an accelerated test system with “an electromagnetic linear actuator,” and that “pressure can be adjusted through the amplitude of the driving piston.” Ex-1005, 190, 192, 187; <i>see also</i> Ex-1019, 423 (identifying accelerated testers with linear motors). Further, the diversity of pumps and drive systems in the art demonstrate it was within a POSA’s skill to substitute a linear motor for Goldstein’s pump motor to drive Goldstein’s piston. Ex-1002 ¶¶ 222, 60.

Claim 7	Prior Art
7. The device of claim 1, further comprising an elastomeric material that forms at least a portion of a boundary of the excess volume area and that expands and contracts in response to changes in pressure on the test system fluid within the test chamber.	Goldstein's compliance chamber has a "flexible membrane" separating fluid from air, so that the fluid "push[es] against" the membrane. Ex-1007, 10:30-32. Elsewhere, Goldstein teaches using a "flexible <i>rubber</i> bladder" and claims a "flexible <i>elastomeric</i> bladder." Ex-1007, 9:61-67, 24:17. So it would have been obvious to use an "elastomeric" material for the membrane. Ex-1002 ¶ 229. 

Claim 8	Prior Art
8. The device of claim 1, wherein the excess volume area further contains a volume of a compressible gas that is compressed by the volume of the test system fluid to provide a spring force when the volume of the test system fluid is stored in the excess volume area.	Goldstein teaches, "[t]he pressure in the air space above the membrane can be varied to adjust the compliance." Ex-1007, 10:30-35. A POSA would have understood that when the fluid "push[es] against [the] flexible membrane," then the variable air pressure exerts a spring force back onto the membrane and fluid. Ex-1002 ¶ 226.

Claim 9	Prior Art
9. The device of claim 1, wherein the excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber.	Goldstein's "compliance" chamber is "downstream" of the valve, within the identified return chamber. Ex-1007, 9:52-57, FIG. 3; Ex-1002 ¶¶ 226-227.  FIG. 3

Claim 10	Prior Art
10. The device of claim 9, further comprising an elastomeric membrane separating at least a portion of the compliance chamber from fluid in the fluid return chamber.	See claim 7; Ex-1002 ¶ 229.
Claim 12	Prior Art
12. The device of claim 9, wherein the compliance chamber provides a volume for holding a gas or elastomeric material that compresses under a pressure placed upon the test system fluid in the test chamber and allows the test system	See claim 8; Ex-1002 ¶ 226.

fluid in the test chamber to occupy a portion of the volume in the compliance chamber.	
--	--

Claim 13	Prior Art
13. The device of claim 1, wherein the test chamber defines a first port on a first side of the valved prosthetic device and a second port on a second side of the valved prosthetic device; and the first port and the second port are configured to receive one or more sensor devices.	Goldstein teaches “two pressure taps” for “pressure transducers ... located both upstream and downstream of the valve being tested.” Ex-1007, 11:31-37. <i>See also</i> Ex-1002 ¶ 230.

X. GROUND D AND E: CLAIMS 7 AND 10 ARE OBVIOUS IN FURTHER VIEW OF GOLDSTEIN

Goldstein’s flexible membrane separating the air and fluid in its compliance chamber could also be added to Xi (Ground D) or the combination of Dynatek and Xi (Ground E) to arrive at claims 7 and 10.

Claims 7 and 10 depend from claims 1 and 9, respectively. They add a limitation of an elastomeric membrane separating the excess volume area/compliance chamber from the fluid.

Dynatek expressly teaches that “[m]achine sterility should be maintained throughout testing.” Ex-1006, 31. Dr. Dasi explains that POSAs desired to maintain sterility of the operating fluid to minimize contamination (e.g., by

bacteria or mold) during the long-running durability tests. Ex-1002 ¶ 233.

Goldstein teaches a “flexible membrane” to “separate[] the sterile fluid from the unfiltered air.” Ex-1007, 10:30-33.

So a POSA would have been motivated to preserve sterility in both Xi and a device according to the combination of Dynatek and Xi to keep the fluid cleaner for longer. Ex-1001 ¶¶ 233-234. This would reduce the number of times the testing would need to be stopped to drain, clean, and refill the device. Ex-1002 ¶ 234. The air compliance chambers in Goldstein and Xi are similar structures that operate in the same way. *Id.*; *see also* Section III.B. So using the flexible, elastomeric membrane taught or suggested by Goldstein would improve the similar accelerated testers of Grounds A and B in the same way. Ex-1002 ¶ 234; *see also id.* ¶ 229 (explaining obviousness use of “elastomeric” material for the membrane). Claims 7 and 10 are therefore obvious in view of the combination of either of those two testers in further view of Goldstein.

XI. THERE ARE NO OBJECTIVE INDICIA OF NONOBVIOUSNESS

In the related litigation, BDC has vaguely argued that various secondary considerations of nonobviousness are relevant to the patentability of the claims. *See* Ex-1022, 54-55. But BDC has never presented any objective indicia of nonobviousness with a provable nexus to the claims that would impact any of the Grounds in this Petition. At most, it is generally undisputed that BDC sells an

accelerated tester that would generally be considered commercially successful.

ViVitro is unaware of any evidence that BDC's product is coextensive with any claim or that any other alleged "evidence of secondary considerations is the 'direct result of the unique characteristics of the claimed invention.'" *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373-74 (Fed. Cir. 2019).

In any case, where a strong *prima facie* case of obviousness exists, as it does here, secondary considerations may not disturb the final conclusion of obviousness. *See, e.g., Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007). BDC bears the burden to prove a nexus between any asserted secondary consideration and the claimed invention. *Prometheus Lab 'ys, Inc. v. Roxane Lab 'ys, Inc.*, 805 F.3d 1092, 1101 (Fed. Cir. 2015). So Petitioner reserves the right to respond to any evidence of secondary considerations that BDC may later proffer.

XII. DISCRETIONARY DENIAL IS NOT WARRANTED

A. Denial is not warranted under § 314(a)

Fintiv and the Office's interim guidelines dated June 21, 2022 ("Interim Procedures") favor institution. **Factor 1** is at worst neutral because no request for a stay pending IPR has been filed yet. *Sand Revolution II LLC v. Continental Intermodal Group - Trucking LLC*, IPR2019-01393, Paper 24, 7 (June 16, 2020) (informative).

Factors 2 and 3 favor institution because the litigation is in its earliest stages. No trial date has been set; no scheduling order has even been entered. The only proceedings before the district court so far relate to BDC's motion for preliminary injunction, which the district court denied because it found no likelihood of success on the merits. BDC appealed that order and stipulated to a stay of the litigation until the appeal terminates, after which the parties will provide a *new* proposed discovery plan and case schedule for the district court's consideration. Ex-1025. While the parties exchanged preliminary infringement and invalidity contentions before the stay, fact discovery has not even *started*, much less have an end date in sight.

Finally, to the extent BDC contends Petitioner should have filed this Petition earlier, BDC's actions—aggressively pursuing its motion for preliminary injunction, filing in the wrong court and forcing ViVistro to move to dismiss or transfer, and seeking expedited consideration of its appeal of the denial of that motion—impacted ViVistro's preparation of this Petition. And, in any case, this Petition is still being filed early in the litigation and several months before the statutory bar. *See Supercell Oy v. Gree, Inc.*, PGR2020-00038, Paper 14, 15 (Sept. 3, 2020) (finding petition filed late within the statutory window did not favor denying institution where only minimal investments had been made in the parallel proceeding).

Factors 4 and 5 are at worst neutral because, while the parties are the same and there is some overlap with the invalidity issues in the district court, the Board would likely enter a final written decision (approximately 18-months from filing) before the district court reaches the invalidity issues at trial, given the nascent stage of the litigation and the median time to trial in Central District of California of 28.4 months.¹⁹ That median suggests trial may not occur until May 2026, months after a final written decision would likely issue here. The Board has found that these factors favor institution where the final written decision precedes a trial in the district court. *See, e.g., Huawei Tech. Co. v. WSOU Inv., LLC*, IPR2021-00225, Paper 11, 14 (June 14, 2021); *MED-EL Elektromedizinische Geräte GmbH v. Sonova AG*, IPR2020-00176, Paper 13, 15 (June 3, 2020). Additionally, challenged claims 7 and 10 were not asserted in the district court, so this Petition addresses some issues that will not be litigated there.

The Board only addresses **Factor 6** if Factors 1-5 support discretionary denial, which they do not. *CommScope Techs. LLC v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23 (Feb. 27, 2023) (precedential). This Petition presents a compelling unpatentability challenge. The cited prior art, none of which was cited

¹⁹ https://www.uscourts.gov/sites/default/files/fcms_na_distprofile0930.2023.pdf

(page 68).

by the examiner, rebuts BDC's arguments during prosecution that persuaded the examiner to allow the claims. Accordingly, the Board should not deny institution under *Fintiv* and the Interim Procedures.

Last, this is the first petition filed against this patent, so the *General Plastic* analysis does not apply.

B. Denial is not warranted under § 325(d)

The Petition presents new grounds of unpatentability relying on new references not cited considered during prosecution. Accordingly, part one of the *Advanced Bionics* framework is not met. Petitioner need not address part two.

XIII. CONCLUSION

For at least the foregoing reasons, Petitioner requests that the Board institute an *Inter Partes* Review and cancel claims 1-4, 7-10, and 12-13 of the '935 patent.

Respectfully submitted,

/Warren Thomas/

Warren J. Thomas (Reg. No. 70,581)

XIV. MANDATORY NOTICES

Petitioner ViVitro Labs Inc. submits the following mandatory notices pursuant to 37 C.F.R. § 42.8(a)(2).

A. Real parties-in-interest

ViVitro contends the sole real “party-in-interest” in this Petition is ViVitro Labs Inc. However, for the avoidance of doubt, ViVitro further states that it is wholly owned by a parent company, Starfish Holdings Inc., of Canada.

B. Related matters

BDC asserted the challenged patent against ViVitro in *Biomedical Device Consultants & Laboratories of Colorado, LLC v. ViVitro Labs, Inc.*, 1:23-cv-867 (D. Colo. filed Apr. 7, 2023), subsequently transferred to the Central District of California as No. 2:23-CV-04291-HDV (C.D. Cal.). An appeal of the district court’s denial of BDC’s motion for preliminary injunction is pending, as of the filing of this Petition, at the Court of Appeals for the Federal Circuit, No. 2023-2393.

C. Counsel and service information

Under 37 C.F.R. §§ 42.8(b)(3) and 42.10(a), Petitioner identifies Warren J. Thomas (Reg. No. 70,581) as lead counsel and the following back-up counsel: Lee Hamilton (Reg. No. 80,413) and John W. Harbin (pro hac pending). All counsel can be reached by mail at Meunier Carlin & Curfman LLC, 999 Peachtree St, NE,

Suite 1300, Atlanta, GA 30309; and by phone at 404-645-7700. Petitioner consents to electronic service by email to the counsel above.

XV. CLAIMS LISTING

Claim Element	Challenged Claims
[1pre]	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
[1c]	a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source;
[1d]	a fluid return chamber positioned on a second side of the valved prosthetic device;
[1e]	a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and
[1f]	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.
[2a]	The device in claim 1 further comprising a drive motor; and
[2b]	a fluid displacement member connected with and driven by the drive motor to provide the pressure source that increases and decreases a pressure on the test system fluid in the test chamber.

Claim Element	Challenged Claims
[3]	The device of claim 2, wherein the drive motor is configured to operate cyclically, acyclically, or a combination of both, to provide cyclic and acyclic fluid pressures within the test chamber.
[4]	The device of claim 2, wherein the drive motor comprises a linear motor.
[7]	The device of claim 1 further comprising an elastomeric material that forms at least a portion of a boundary of the excess volume area and that expands and contracts in response to changes in pressure on the test system fluid within the test chamber.
[8]	The device of claim 1, wherein the excess volume area further contains a volume of a compressible gas that is compressed by the volume of the test system fluid to provide a spring force when the volume of the test system fluid is stored in the excess volume area.
[9]	The device of claim 1, wherein the excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber.
[10]	The device of claim 9 further comprising an elastomeric membrane separating at least a portion of the compliance chamber from fluid in the fluid return chamber..
[12]	The device of claim 9, wherein the compliance chamber provides a volume for holding a gas or elastomeric material that compresses under a pressure placed upon the test system fluid in the test chamber and allows the test system fluid in the test chamber to occupy a portion of the volume in the compliance chamber.
[13]	The device of claim 1, wherein the test chamber defines a first port on a first side of the valved prosthetic device and a

Claim Element	Challenged Claims
	second port on a second side of the valved prosthetic device; and the first port and the second port are configured to receive one or more sensor devices.

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b) and agreement of the parties, I certify that on January 25, 2024, a copy of this Petition and all accompanying exhibits were served on counsel for the Patent Owner by email to:

schmidt.kent@dorsey.com
shoaei.maral@dorsey.com
bjorklund.shannon@dorsey.com
tamkin.greg@dorsey.com

/Felice M. Ernst/
Felice M. Ernst, Paralegal
Meunier Carlin & Curfman LLC
999 Peachtree St, NE
Suite 1300
Atlanta, GA 30309

CERTIFICATION OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), Petitioner certifies that the foregoing Petition for *Inter Partes* Review contains 13,952 words, excluding the portions as permitted by § 42.24(a).

/Warren Thomas/
Warren J. Thomas (Reg. No. 70,581)