

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

DECLARATION OF DR. LAKSHMI DAS

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I. INTRODUCTION

A. Experience

1. My name is Lakshmi Dasi. I have been retained by Counsel for ViVitro Labs Inc. (ViVitro) as an expert in this matter. I am a tenured professor in the Wallace H. Coulter Department of Biomedical Engineering at Georgia Institute of Technology. I am the director of the Cardiovascular Fluid Mechanics Laboratory at Georgia Tech. In this position, I direct a research program in heart valve engineering, particularly related to emerging transcatheter technologies for both pediatric and adult structural heart diseases. I have over 15 years of research experience and over 100 peer-reviewed publications.

2. As part of my formal education and early engineering background, I focused initially on the study of fluid mechanics principles which underlie the cardiovascular system, before further focusing my specialization on cardiovascular research, including with respect to complex congenital heart defects and prosthetic heart valves. I have experience in designing and testing cardiac devices starting in 2004. From that point, cardiovascular flow and artificial valves became an ever-increasing part of my professional study and research focus. In 2009, I established a research laboratory called the “Cardiovascular & Biofluid Mechanics Laboratory” (CBFL) at Colorado State University. In 2015, I relocated this laboratory to The Ohio State University. This laboratory has a strong emphasis on

cardiovascular bioengineering across a broad class of problems in my field focusing on flow physics and physiology.

3. I have been a principal investigator or co-principal investigator on projects that have received over \$6.4 million in funding to develop next-generation surgical and transcatheter heart valve technologies, including a \$2.9 million National Institutes of Health (NIH) project that was awarded in August 2017. We also received funding from NIH/NCAI as well as Ohio I-Corps towards developing new transcatheter heart valve technologies. In addition, we received over \$6 million in pending NIH funding on transcatheter heart valve technologies.

4. I am a Fellow of the American College of Cardiology. The American College of Cardiology includes clinical and nonclinical cardiovascular professionals and promotes the latest knowledge and innovations to improve heart health. The American College of Cardiology publishes scientific journals, accredits hospitals and institutions, and advocates for health policy and standards relating to cardiology. I am also a Fellow of the American Institute of Medical and Biological Engineers.

5. I understand that a copy of my curriculum vitae is being filed as Exhibit 1003.

B. Materials considered

6. In forming my opinions expressed in this declaration, I have reviewed and considered the documents identified in the list of exhibits below, each of which were provided to me by counsel at Meunier Carlin & Curfman LLC. To the extent I am provided with additional documents and information in this proceeding, including any expert declarations, I may offer further opinions. In forming my opinions, I have also relied on my education and experience.

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)
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)
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)

Exhibit No.	Description
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
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). ISO 5840:2005 Standard
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

Exhibit No.	Description
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
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)
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
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)

C. Legal Principles

7. I have been informed by counsel for ViVitro that the following legal principles apply to an assessment of patentability. I have applied these legal principles throughout my analysis in this declaration.

1. Priority date

8. I have been instructed to assume that claims of the '935 patent are entitled to claim priority to the March 6, 2009 day of filing BDC's first provisional application (the "Priority Date"). I understand that the language of a patent and the content of the prior art are analyzed from the perspective of a person of ordinary skill in the art (POSA) at the time of the patent's priority date. Accordingly, I have

been asked to opine on issues related to the patentability of the patent's claims in view of the prior art (including patents and printed publications) publicly available as of March 2009 and in view of the knowledge possessed by a person of ordinary skill in the art ("POSA") around March 2009.

2. Claim construction

9. I have been instructed that, to assess the patentability or unpatentability of a claim, one must first ascertain the scope of the claimed invention, which requires understanding the terms in the claim. In particular, I have been informed that the claims of the patent should be given their ordinary and customary meaning as they would be understood by one of ordinary skill in the art in view of the '935 patent's specification and prosecution history.

3. Anticipation

10. I have been told that for a claim to be anticipated, and therefore unpatentable, every limitation of the claimed invention must be found in a single prior art reference, either expressly or required through inherency, as arranged in the claim. The understanding that a POSA would have after reviewing the prior art reference is the standard for determining what the reference discloses.

4. Obviousness

11. I have been informed that a claim may be rendered obvious, and therefore unpatentable, even though the claimed invention is not identically disclosed in a single prior art reference, if the differences between the claimed

invention and the prior art are such that the claimed invention as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

12. When considering obviousness, I was asked to (i) determine the scope and content of the prior art; (ii) ascertain the differences between the prior art and the claims at issue; (iii) resolve the level of ordinary skill in the pertinent art; and (iv) consider evidence of objective indicia (or “secondary considerations”) of nonobviousness (if available). I note that I am not presently aware of any evidence of secondary considerations for the ’935 patent that affects my opinions presented in this declaration.

13. I have been instructed that a reference may be modified or combined with other references or with the person of ordinary skill’s own knowledge if the person would have found the modification or combination obvious. I have also been instructed that the obviousness analysis may take into account the inferences and creative steps that a person of ordinary skill in the art would employ.

14. In determining whether a prior art reference could have been combined with another prior-art reference or other information known to a POSA, I have been instructed that the following principles may be considered: (i) a combination of familiar elements according to known methods is likely to be obvious if it yields predictable results; (ii) the substitution of one known element

for another is likely to be obvious if it yields predictable results; (iii) the use of a known technique to improve similar items or methods in the same way is likely to be obvious if it yields predictable results; (iv) the application of a known technique to a prior art reference that is ready for improvement is likely obvious if it yields predictable results; (v) any need or problem known in the field and addressed by the reference can provide a reason for combining the elements in the manner claimed; (vi) a person of ordinary skill may be able to fit the teachings of multiple references together like a puzzle.

15. I have also been instructed that, while there is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention, a suggestion to combine known elements to achieve the claimed invention may come from the prior art as a whole or individually, as understood with the knowledge of one skilled in the art. In addition, I have been instructed that the inferences and creative steps a person of ordinary skill in the art would employ are also relevant to the determination of obviousness.

16. I have been instructed that, when a work is available in one field, design alternatives and other market forces can prompt variations of it, either in the same field or in another. I have also been instructed that if a POSA can implement a predictable variation and would see the benefit of doing so, that variation is likely to be obvious. I have been instructed that in many fields, there may be little

discussion of obvious combinations, and in these fields market demand may drive design trends. I have been instructed that, when there is a design need or market pressure and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue those known options.

17. I have been instructed that there is no rigid rule that a reference or combination of references must contain a “teaching, suggestion, or motivation” to combine references. But I also have been instructed that a “teaching, suggestion, or motivation” found in the prior art can be a useful guide in establishing a rationale for combining elements of the prior art.

18. I have been instructed that it is impermissible to rely on the ’935 patent’s teachings to combine prior art references, as such analysis would involve impermissible hindsight.

19. Furthermore, I have been informed that where there is a reason to modify or combine the prior art to achieve the claimed invention, the claims may be obvious provided there is also a reasonable expectation of success—though not an “absolute predictability” of success. The teachings of the prior art can provide a sufficient basis for a reasonable expectation of success.

II. BACKGROUND

A. Testing of artificial heart valves

20. When a person's heart beats, every expansion and contraction of the heart causes valves in the heart to open and close, directing blood to the lungs, through the body, and back to the heart. When heart valves fail, their failure causes a corresponding failure in blood flow, which can be harmful or fatal. Artificial prosthetic heart valves provide a lifesaving solution to this problem.

21. Designers of artificial heart valves face many challenges. The critical functions the heart provides means that prosthetic valves must last for years and be incredibly reliable and safe throughout their lifespan. Designers must minimize the risk to human subjects when designing new artificial heart valves.

22. Various kinds of test fixtures have been developed to evaluate the safety, effectiveness, and durability of artificial heart valves. To test durability, “accelerated” test fixture devices move fluid through the valve—opening and closing the valve—repeatedly at an “accelerated” rate, sometimes much higher than a typical heart rate. These accelerated testers can inflict and simulate years of stress on a valve in only months, allowing designers to validate their designs without implanting them into real people. Such testers commonly include a pump, fixtures to attach one or more valves to, and a closed loop for fluid to flow through.

23. Because the fluid in an accelerated tester moves much faster than in the human body, the stresses on the test valve are different than those in the human body. *See, e.g.*, Ex-1005, 186-87. Designers of accelerated testers therefore use ordinary fluid mechanics principles to control for various parameters, like the flow rate, pressure, and volume, to apply standardized forces to the valves being tested.

B. Compliance in testing artificial heart valves

24. One such parameter is compliance. 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. For example, the blood vessels can provide compliance by being elastic—they expand and contract to maintain blood pressure. In the same way, a tester can be designed with “compliance” to absorb pressure increases caused by the pump or motor in the tester.¹

25. The “compliance” of a tester is an important design parameter for an accelerated tester. The 2005 ISO/ANSI standard for testing heart valves (and

¹ The '935 patent explains the term consistent with my opinion: “As used herein, ‘compliance’ refers to the ability of the cavities forming the compliance chambers 135 to *absorb some of the pressure* placed upon the fluid in the test chamber 106 and further to *control recoil* toward the original volume dimensions upon removal of the compressive force.” Ex-1001, 9:11-16.

applicable at the priority date) recommends compliance chambers and certain specifications for them in both hydrodynamic and durability testing, Ex-1017, 37-38.² The standard also refers to two kinds of durability testing cycle rates that fall within what the standard refers to as “durability testing”—it can be “accelerated” or “quasi-real time” durability testing. Ex-1017, 13 (Section 7.2.4.2). Quasi-real time rates range from as low as 30 beats per minute (“bpm”) to 200 bpm. Ex-1017, 13 (Section 7.2.4.2, referring to “conditions specified in Table 1”); Ex-1017, 8 (Section 6.2.1 showing Table 1 and range of “Heart rate” of 30-200 bpm). By 2003, all the “most common” accelerated testers had “adjustable ... compliance.” Ex-1005, 186.

26. A common way to provide compliance in a tester was to use an air-filled compliance chamber. The operating principle behind an air compliance chamber is that a gas is compressible, while a liquid fluid (e.g., water) is incompressible under most conditions. When a sudden pressure change occurs in a sealed system with fluid, the incompressible fluid cannot absorb the pressure

² Annex F is titled “In vitro procedures for testing unstented or similar valves in compliant chambers,” and it is designated “informative.” Ex-1017, 37. Section F.3.4 provides that “Wear/durability” testing of valves “*should be* tested in the low compliance chamber.” Ex-1017, 38.

change, causing stress on the system holding the fluid as the pressure change passes through the system. This problem, known as the “water hammer,” can be solved by adding an air-filled chamber to the sealed fluid system so that the air can compress or expand to absorb the shocks to the fluid. Devices to prevent water hammer have been known and used for over 100 years.³ So-called “water hammer arrestors” operate on the same principle as the compliance chamber and are routinely sold as plumbing parts at hardware stores.⁴

³ For example, a 1902 patent teaches an “air-chamber for pumps” where “the water will enter the air chamber ... and will operate to compress the air in the ... chamber ... to obviate the recoil of the water in the pump at each stroke, and so relieve the strain on the pumping machinery caused by the sudden starting of the entire column of water in the pump.” Ex-1021, 1:83-96.

⁴ For example, Lowe’s sells a water hammer arrestor, stating: “Water hammer occurs when the flow of water is abruptly stopped by a fast-closing valve, if there is *no air to absorb the shock* the pressure will rattle and shake your pipes and your fixtures and appliances can be damaged by *the pressure spike*. Installing a water hammer arrestor provides *an air pocket* to give the pressure somewhere to go”
<https://web.archive.org/web/20240119004228/https://www.lowes.com/pd/SharkBit>

27. The water hammer effect was a known problem for accelerated prosthetic valve testing, too. The high cycle rates and opening and closing of the “valve” lead to unnatural pressure shocks that can cause a valve to fail an artificial test (“in vitro”) when it would not fail inside a real patient (“in vivo”). Ex-1005, 186. These failures are undesirable because they cause designers and manufacturers to reject good valves due to faulty test conditions. Ex-1005, 186-187. Common ways to add “compliance” to a system include deformable materials, bellows, and air chambers. In an accelerated tester, the relationship between pressure changes, system volume, and flow rates are well understood, and can be modeled using ordinary fluid mechanics principles. *See* Ex-1005, 188-190.

28. Like a water hammer arrestor, an air compliance chamber in a prosthetic valve testing system provides some extra space in the tester for fluid to flow, mimicking the expansion and contraction of blood vessels in a person, rather than by using a compliant *material* to simulate the vessels. Since the pressure and volume of a closed system are related, the volume of air in the compliance chamber can absorb pressure spikes in the tester. Ex-1005, 188 (“[T]he compliance component can reduce the effects of the water hammer”).

e-1-2-in-dia-Copper-PEX-Hammer-Arrestor-Crimp-Fitting/1000183009 (last visited Jan. 23, 2024).

C. Selection of prior art documents teaching compliance in various test devices

29. Since the water hammer was a well-known phenomenon with a well-known solution, even outside the specific field of testing prosthetic valves, it is no surprise that the well-known solution was also applied *within* the field, too. Some of the prior art discussing compliance and air compliance chambers are discussed here. I understand from counsel for ViVitro that the prior art references themselves also serve to document the level of ordinary skill in the art, so a review of what they teach is appropriate.

1. Xi

30. Xi is a 1997 Chinese patent (I have used the English translation provided by counsel) teaching an accelerated test system for heart valves. It teaches using air chambers on both sides of the prosthetic valve being tested. Xi explains the known problem of increased forces or load on valves during accelerated testing: “When accelerated, the forces caused by the inertia and fluid inertia of the moving parts of the valve will increase dramatically, with the inertial forces and the trans-valve pressure differential together forming the total load on the valve.” Ex-1004, 7.

31. Xi proposes solving this problem by, among other things, “adjust[ing] the compliance and impedance of the circulation loop system.” Ex-1004, 7. Xi provides adjustable compliance by “air chambers” C₁ 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.

32. During operation, the valve opens when the valve frame is moved up and closes when the frame is pushed down. Ex-1004, 7. “[L]iquid flows from each test section (2) to its respective corresponding air chamber C_1 (11) and needle valve damper R_2 ,” 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 .” *Id.*

33. Xi teaches that the accelerated test system can be tuned using the compliance to perform physiologically accurate testing:

Using the total load on the valve as the monitoring parameter, i.e., by adjusting the compliance and impedance of the circulation loop (30), the drive waveform, frequency, and amplitude are adjusted so that the total load experienced by the prosthetic heart valve after acceleration is similar to the total load experienced under physiological conditions[.]

Ex-1004, 5.

34. Xi explains that its “system works optimally with pulsating flow, having a good balance of inertia and compliance.” Ex-1004, 7. Xi also teaches that

its structure can “greatly reduce the occurrence of *the water hammer effect*.”⁵ Ex-1004, 6. Xi teaches that its system results in improved “valve back pressure” and “no water strike is produced when the valve is opened and closed.” Ex-1004, 7.⁶

35. A POSA would have recognized Xi’s “air chambers” as the same kind of “compliance chamber” that BDC admitted was “well known” in the art. A POSA would have understood that the water hammer effect is reduced in Xi by the presence of the air compliance chambers for water to flow into and thereby absorb pressure spikes. A POSA would understand that Xi’s air chambers provide the compliance that allows the user to adjust the “total load experienced by the valve” as taught by Xi.

36. Thus, Xi teaches that air chambers benefit test systems for heart valves by (1) modeling the compliance of the physiological circulator system; (2) preventing water hammer; and (3) controlling the “total load” (i.e., pressure waveforms) on the valve.

⁵ All emphasis inside quotations in this Declaration is added unless other indicated.

⁶ The phrase “water strike” in the translation of Xi would have been recognized, in view of the other disclosures of Xi, as referring to the water hammer—i.e., “no water hammer is produced.”

2. Lu

37. “Lu” is a 2003 article titled “On Accelerated Fatigue Testing of Prosthetic Heart Valves” (from *Frontiers in Biomedical Engineering*). Ex-1005, 185. Lu shows that a POSA understood: (1) the benefits of accelerated testing of artificial heart valves, (2) the mathematics behind designing accelerated testers with compliance, and (3) how compliance could be used in an accelerated tester. Lu explains that the disclosed system and experimental protocol help achieve accelerated testing “without creating ... excess forces on the test valves and to predict the durability of prosthetic heart valves with physiological considerations.” Ex-1005, 185 (Abstract).

38. Lu teaches that the benefits of accelerated testing were well known to a POSA. “At accelerated test rates, sufficient amounts of data can be collected within a reasonably short time period” to speed up the development of heart valves. Ex-1005, 185 (Abstract). By 2003, “[t]he design of an adequate AT system ha[d] 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 “[t]he systems all have adjustable resistance, compliance, amplitude, and cycle rate.” Ex-1005, 186.

39. Lu further shows that a POSA would understand the fluid mechanics principles used to design accelerated testers. Lu describes the mathematical

relationships between fluid pressure and extra volume in an accelerated test system. Lu also explains 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.

40. Lu teaches that the “Vol is the original volume of the control volume, and ΔVol is the extra volume [that] correlates to the E_c compliance.” Ex-1005, 189. A POSA would thus understand from Lu that compliance and “extra volume” of an accelerated tester were correlated and that accelerated testers could be designed with an appropriate amount of compliance by adding space for the extra volume of fluid to flow in the system.

41. Lu teaches that the change in pressure in an accelerated test system when a valve closes is a function of the elasticity, an “extra volume” of fluid (delta Vol) (i.e., the fluid that flows into an “excess volume area”) and the original volume (Vol) in the below formula (7) published in Lu (2003). Ex-1005, 189.⁷

$$\Delta p = E_c \frac{\Delta Vol}{Vol}$$

⁷ Lu further describes the principle of operation of Xi. *See* Ex-1005, 190 (Fig. 1).

42. Lu teaches that “under accelerated conditions, the inertial effects of the valve and fluids are significantly enhanced.” Ex-1005, 189. Lu then teaches that the closing force of the valve F_c can be determined by multiplying the delta p from Lu’s equation 7, above, with the known area of the heart valve being tested (A).

$$F_c = \Delta p \cdot A_s = M \frac{dU}{dt}$$

43. In sum, Lu teaches that, by varying the delta Vol term in equation 7, a designer can design an accelerated test system with any closing force F_c . From this, a POSA would understand from Lu how to adjust the compliance of an accelerated test system to generate a desired closing force for a prosthetic valve. Thus, Lu would have informed a POSA how to create accelerated testers with sufficient compliance to be used to test prosthetic valves under accelerated conditions.

3. Iwasaki

44. Iwasaki is a journal article titled “Implications for the Establishment of Accelerated Fatigue Test Protocols for Prosthetic Heart Valves,” published in 2002, describing “accelerated fatigue tests of prosthetic heart valves.” Ex-1019, 420. Iwasaki describes three models of accelerated tester: a Helmholtz Institute-

type accelerated tester, a Rowan Ash accelerated tester and a Tsinghua-type accelerated tester.⁸ Ex-1019, 421-23

45. Iwasaki explains the “original [Rowan Ash] tester was designed without a compliance element,” so that it “fail[ed] to model the elastic effects of the aorta” and “resulted in an insufficient opening motion of the ... valve membrane.” Ex-1019, 422. “Therefore, the upper casing of the tester was modified to incorporate an air compliance chamber as shown in Fig. 5,” shown below. Ex-1019, 422.

⁸ I note that the Tsinghua-type tester of Iwasaki appears to have a similar design to that disclosed in Xi, however they do not appear (from the limited view available in Iwasaki) to be identical. My opinions here are based on what a POSA would understand from each reference, and I reserve the right to amend these opinions should further information about prior art Tsinghua testers become available in the future.

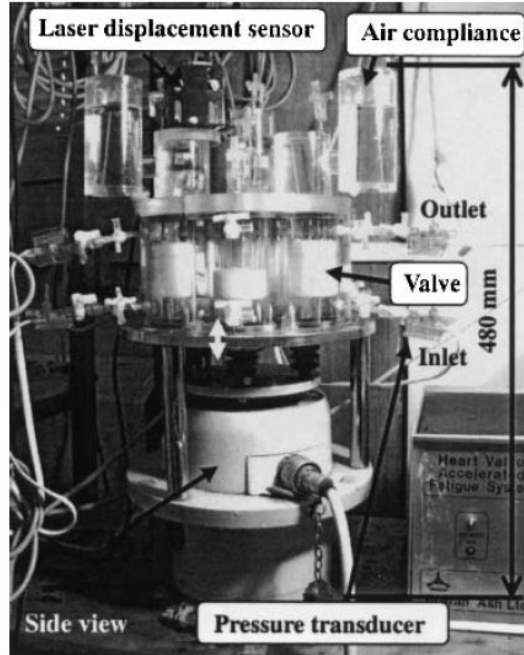


FIG. 5. A modified version of the Rowan Ash accelerated fatigue tester for prosthetic heart valves is shown. A compliance element was added to the original system.

46. Iwasaki further explains that the air compliance affects the pressure waveform on the valve: “[c]hanges in pressure waveforms as a function of air volume under the same maximum pressure difference of 120 mm Hg at valve closure are shown in FIG. 6.” *Id.*

4. Dynatek

47. The Dynatek M6 is an example of a prior art accelerated tester. I have experience using the Dynatek M6 tester.

48. The 1993 Dynatek M6 Manual discloses the use of a “capacitance tank.” Ex-1006, 5. A POSA would understand “capacitance” to refer to the

capacitance element of the Windkessel model of the circulatory system,⁹ and that “capacitance” is equivalent to the “compliance” of the physiological system.

49. Dynatek explains that the “capacitance tank” buffers pressure changes, which is one of the purposes that compliance provides in other accelerated test systems: “An acrylic capacitance tank is used to buffer small variations in the systemic pressure which arise from transient small leakage and thermal effects.” Ex-1006, 19. Thus, a POSA would have recognized the Dynatek manual as disclosing an example of an accelerated tester with a compliance chamber component.

5. Goldstein

50. Goldstein teaches a “closed, sterile pulsatile flow loop for studying tissue valves.” Ex-1007, Abstract. Goldstein discloses a “piston pump” that pressurizes the system by “squeez[ing]” a “flexible bladder” to “propel the blood analog fluid out through the aortic valve.” Ex-1007, 9:57-65. Goldstein explains that, in the closed loop system, “[a]n adjustable resistance and compliance element

⁹ The Krynauw thesis provides a brief introduction to the Windkessel model. Ex-1015, 29-32 (Section 2.4.2); *see also* Ex-1015, 14 (Glossary, defining “C” as “Capacitance (electrical) or compliance (hydrodynamic)”). A POSA in 2009 would have been familiar with the Windkessel model.

(FIG. 3) is placed downstream [of the prosthetic valve] to simulate the peripheral resistance of the circulation.” Ex-1007, 10:27-30. Goldstein further explains that the compliance can be “provided by allowing the fluid to collect in a Lexan tank and to push against a flexible membrane.” Ex-1007, 10:30-35.

51. Goldstein explains that its “downstream compliance and resistance” can “be adjusted to provide physiologic aortic pressures of 120 mm Hg systolic and 80 mm Hg diastolic, duplicating the back pressure on the aortic valve.” Ex-1007, 10:44-47. Goldstein further explains that “a compliant volume of roughly 900 cm³ should adequately duplicate the physiologic capacitance.” Ex-1007, 10:36-37. Thus, Goldstein discloses that compliance has the benefit of adjusting the back pressure on the valve and simulating the physiologic aortic pressures.

6. Reul

52. Reul is a 1998 article titled “Durability/Wear Testing of Heart Valve Substitutes.” Ex-1020, 151.

53. Reul explains that the importance of compliance was well known as an important quantity for designing testers, stating that “[f]or all testers, time history of loading and pressure difference across the valve are a function of test frequency, compliance and other factors.” *Id.*

54. Reul describes the design of a “new fatigue tester” and explains that, in the new design, “an adjustable compliance chamber was added for additional

control of loading forces.” *Id.* at 153. Reul further describes how “impact force” during testing can be adjusted by four factors, one of which is the “air compliance” of the system. *Id.*

55. Reul further explains how a POSA would be motivated to adjust the adjustable compliance to work in different contexts. For example, Reul teaches that when an accelerated tester “is intended for use with all kinds of valve sizes,” including larger valves with “higher loading forces,” then an air compliance chamber can provide “additional control of loading forces.” Ex-1020, 153-54.

56. Further, Reul explains that in the disclosed system “peak load decreases linearly with increasing compliance volume, and can be easily adjusted for physiologic loading conditions.” Ex-1020, 154. Thus, a POSA would understand from Reul the relationships between valve sizes, peak load, and compliance, and would understand the benefits of adding compliance to control the pressure on the valve and model the compliance of physiological systems.

7. Pickard

57. U.S. Patent 4,682,491 to Pickard (“Pickard”) is titled “Apparatus and Method for Testing Prosthetic Heart valves.”¹⁰ Pickard discloses an embodiment including a lead screw pump with variable “stroke length, duty cycle, and other

¹⁰ Pickard was cited during prosecution of the ’935 patent.

parameters” that moves fluid cyclically through a valve being tested. Ex-1018, 4:60-62.

58. Pickard discloses a compliance chamber, aka “compensation chamber” with “a fluid compensation reservoir having one resilient side wall defined by a diaphragm [sic] that expands to receive excess fluid.” Ex-1018, 3:46-55. “Excess fluid pressure is compensated by means of air pressure on an opposite side of the diaphragm [sic]” *Id.*; *see also* Ex-1018, 5:58-62 (“[A] compensation chamber ... provides both an *excess fluid* compensation reservoir and which may be adjusted *to selectively apply pressure to the fluid* in the flow channel”). Pickard explains that a computer can “adjust ... air pressures in the compensation chambers to tune the fluid flow and pressure waveform.” Ex-1018, 14:26-29.

59. Pickard labels FIG. 8 a “compliance chamber,” and it includes an “air chamber 530” that absorbs some of the pressure from the fluid and applies a spring force onto it. Ex-1018, 6:67-68, 12:57-13:9.

D. A variety of drive systems were used in the prior art

60. As noted above, testers (both real-time and accelerated) use some type of pump to cause the fluid motion that opens and closes the valve under test. The prior art teaches a wide variety of pump and drive systems used in valve test systems, as summarized in the table below.

Reference	Motor/mechanisms disclosed
Xi	“The <i>linear motor</i> is located at the top of the device, and a drive signal drives the linear motor to drive the reciprocating motion of the link rods and valves in the test sections through the spindle disc.” Ex-1004, 1 (Abstract).
Lu	• “electromagnetic linear actuator” Ex-1005, 192. • “Rigid Crank Shaft Drive Mechanism” Ex-1005, 193, 195 (Fig. 15).
Iwasaki	• “Rotary pump” Ex-1019, 421. • “Pneumatically driven blood pump” <i>Id.</i> at FIG. 1.
Goldstein	“[A] flexible elastomeric bladder containing a fluid that is mounted inside of a fluid-filled chamber, the pump serving to displace the fluid within the chamber so as to simulate a pulsatile flow within the bladder and to shield the fluid within the bladder from contamination by the pump” Ex-1007, 24:17-23.
Dynatek M6	Bellows and Swashplate. Ex-1006, 7 (Fig. 1A).
Elizondo (US Patent 5,916,800)	“Diaphragm or pneumatic pump 64 functions by forcing a compliant membrane or balloon-like structure within the housing of the pump against a conduit or fluid flow path that runs through the housing.” Ex-1027, 10:48-51. “When air is pumped into the balloon, it expands and presses against the conduit, forcing any fluid in the conduit toward container 12 and container 13.” Ex-1027, 10:51-54.
Rousseau	“The physiological conditions near the valve are obtained by varying the pressure in the volumes of air in the reservoirs.” Ex-1035, 145. “To reduce the phase difference between the flow and pressure curves, the pressure variations in the volumes of air in reservoirs 1 and 2 are obtained with the help of the two control mechanisms CM ₁ , and CM ₂ .” <i>Id.</i>

Reference	Motor/mechanisms disclosed
Krynauw (Literature Review)	• Membrane pump (Liu 2006). Ex-1015, 28. • Rotary shaft (Davila 1956). <i>Id.</i> • Linear motor (Dynatek Dalta). <i>Id.</i>

III. OVERVIEW OF THE '935 PATENT

A. Overview of the patent disclosure

61. The '935 patent relates to a system and method for fatigue/durability testing of prosthetic devices (such as heart valves). Ex-1001, 1:19-22. Like other durability testing systems, it operates at accelerated cycle rates. *E.g.*, Ex-1001, 1:63-67. As described and annotated by BDC,¹¹ the system includes a drive mechanism (in pink) that moves a piston and diaphragm up and down to pump fluid into and through the system. *See, e.g.*, Ex-1001, 11:43-59.

¹¹ 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.

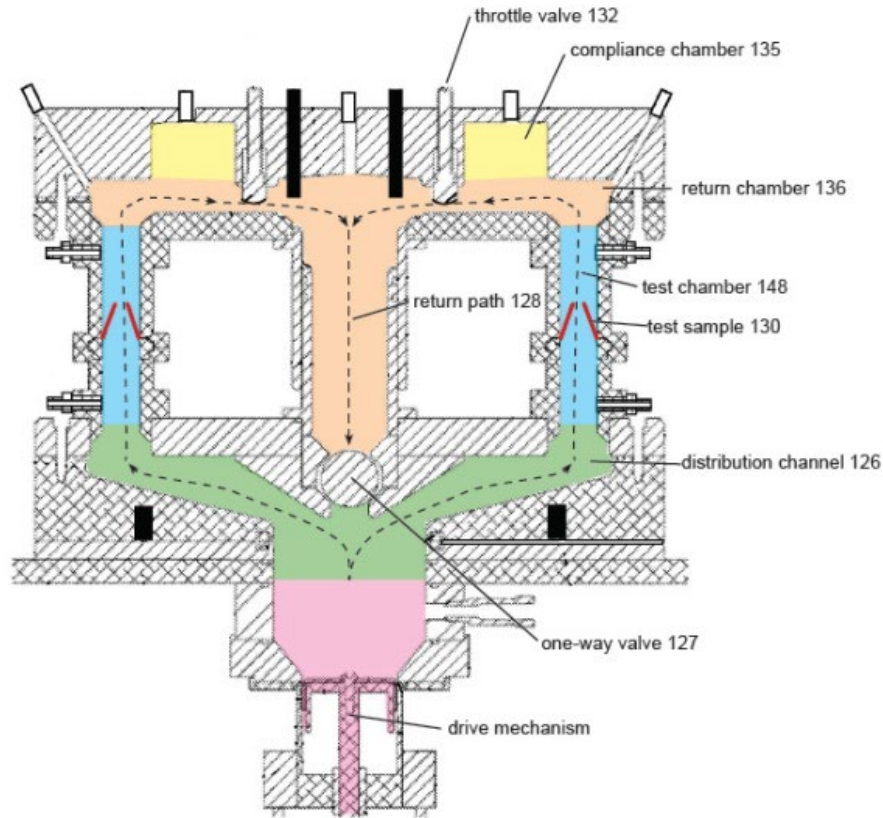


Figure 3 of the '224 Patent
(colorized and labeled with reference numerals removed)

62. Fluid enters distribution chamber 126 (labeled “channel,” in green) and moves up to the left and right of one-way valve 127 in the center. Ex. 1001, 11:60-12:3. The fluid continues moving up through the two test samples (heart valves) 130 (red) mounted in test chambers 148 (blue section) and then enters return chamber 136 (in orange). *Id.* Since the channel (green, blue, and orange sections combined) is full of fluid at the start, when the drive mechanism pumps more fluid into the system, it increases the pressure. Ex-1001, 11:43-59. Some volume of excess fluid (i.e., in addition to that already in the channel) is displaced

into compliance chambers 135 (in yellow). Ex-1001, 12:4-9. Throttle valves 132 can be used to restrict the rate of the return flow. Ex-1001, 12:9-11.

63. Next, the piston and diaphragm move down, and the one-way heart valve 130 closes. Ex-1001, 12:25-33. The volume of excess fluid leaves compliance chambers 135 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.

64. Compliance chambers 135 may be filled with a gas the pressure of which can be adjusted to alter the “spring factor provided by the compliance chamber[s].” Ex-1001, 12:33-39. Thus, by controlling the pressure in the compliance chambers and the position of the throttle valves, pressure spikes can be mitigated. Ex-1001, 12:12-18; 12:52-58.

65. An alternative embodiment is shown in the annotated Figure 6 below using corresponding colors. In this embodiment, “a single compliance chamber 235 is axially centered over the test chamber 206 and provides a compliance volume for all of the sample holders 230.” Ex-1001, 14:8-15.

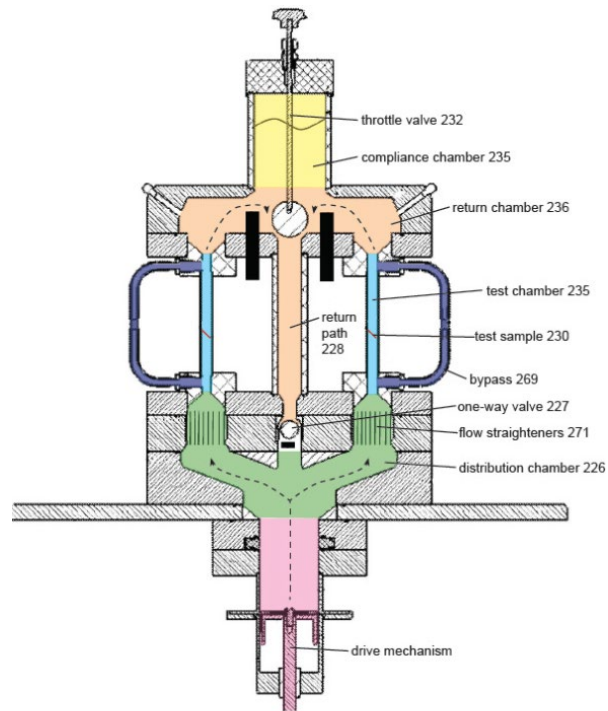


Figure 6 of the '224 Patent
(colorized and labeled with reference numerals removed)

66. Similar to Figure 3, Figure 6 depicts a drive mechanism (pink), distribution chamber 226 (green), return chamber 236 (orange), compliance chamber 235 (yellow), and test chamber 236 (blue) which holds test samples 230 (e.g., heart valves) (red). Ex-1001, 12:59-13:9. On the compression stroke, additional fluid is introduced into the channel and the fluid flow moves to the left and right of one-way valve 227 through flow straighteners 271 and into test chamber 248 (blue). Ex-1001, 13:28-43. Fluid passes through test samples 230. Ex-1001, 12:65-13:4. The excess volume introduced into the channel displaces fluid into compliance chamber 235 (yellow). Ex-1001, 13:57-14:14. During the decompression stroke, heart valves 230 close and the excess fluid volume re-enters

the channel and flows around throttle valve 232 and returns to distribution chamber 226 (orange). Ex-1001, 13:57–13:63. This completes one cycle. As with Figure 3, throttle valve 232 may be adjusted to change the resistance on the fluid returning to the lower chamber (orange) via the central return conduit, thus, aiding in controlling the differential pressure across the heart valves. Ex-1001, 13:67-14:4. As before, the amount of gas inside compliance chamber 232 may be adjusted to “control the damping of the system and provides an additional tool calibrate the ideal test conditions.” Ex-1001, 14:4-8. The embodiment of Figure 6 additionally includes bypass pathways 269 (purple) which measure the pressure differential across heart valves 230. Ex-1001, 13:44-56.

B. Summary of the patent’s prosecution history

67. The ’935 patent issued in January 2016 from Patent Application No. 14/137,313 filed December 20, 2013, claiming the benefit (as a continuation) of Patent Application No. 12/718,316 filed March 5, 2010, and Provisional Application No. 61/158,185 filed March 6, 2009. A child continuation application No. 14/523,104 was also filed February 12, 2015.

1. The provisional application

68. The 2009 provisional application disclosed one embodiment with figures and description corresponding to the “alternative” embodiment in Figure 6

of the '935 patent described above. *Compare* Ex-1001, Fig. 6, *with* Ex-1008, 21 (Figure 2).

69. The provisional application discloses 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].¹² And the “gas inside the compliance chamber 35 allows the user to control the damping of the system and provides an additional tool used to obtain the ideal valve test condition.” *Id.*

70. There is no mention of an “excess volume area.” *See generally* Ex-1008.

2. First nonprovisional application (parent application of the challenged patent)

71. The '316 application claimed priority to the provisional application and added a new embodiment and additional text in the specification 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.

¹² I note that the introductory phrase in this sentence, “Those who are skilled in the art will appreciate,” was not included in the corresponding description in '935 patent issued. *See* Ex-1001, 12:40-43.

72. The original disclosure of the '316 application used the phrase “excess volume area” one time and referred to “excess volume” in another sentence in the next paragraph: “The compliance chambers 135 provide *excess volume area* for fluid to move into [O]n the downward stroke, the pressure in the test chamber 106 returns to an initial level and *excess volume* returns to the compliance chambers 135.” Ex-1009, 25 ¶¶ [0059]-[0060].

73. Among the originally filed claims in the '316 application, two independent claims recited “a compliance chamber”—not an excess volume area—“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 (claim 1), 36 (claim 17); *see also* Ex-1012, 17:23-27, 19:23-27 (claims 1 and 17 of issued patent).¹³

74. During prosecution, the examiner rejected the claims as obvious, citing the Pickard reference 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.

¹³ I also note that the Abstract of the Disclosure states that the *compliance chambers* “regulate the pressure gradient and back pressure across the prosthetic devices being tested.” Ex-1009, 28.

75. BDC argued that Pickard’s compliance chamber had a different “purpose” because Pickard is a “real-time” test system, not an *accelerated* tester. Ex-1009, 63, 71. According to BDC, the “compliance” in Pickard “is used to shape the systemic pressure waveform to mimic the circulatory system distensibility,” while the purpose of the compliance chambers in the application was to “to prevent or minimize the kinetic energy of fluid flow from translating into high static fluid pressure in the test system during the accelerated frequency testing.” Ex-1009, 71.

76. The examiner’s Notice of Allowance did not mention the compliance chamber feature. Ex-1009, 88. Instead, the examiner appeared to be persuaded by BDC’s arguments distinguishing its claims as directed to “accelerated” rather than real-time testing, according to the examiner’s Interview Summary and amended claims. Ex-1009, 60, 62, 65, 71. That application issued as Patent 8,627,708 (the ’708 patent).

3. The ’313 continuation application is filed (the application that issued as the ’935 patent)

77. 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” of the disclosed device that include “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).¹⁴ The originally filed claims also recited the excess volume area limitation. Ex-1010, 31-32.

4. '104 application is filed as continuation of '313 application

78. 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 '313 application (and back to the provisional). Ex-1011, 5, 10. This new application included a "Track One" request for prioritized examination, Ex-1011, 35. It received substantive actions from the examiner before the still-pending parent '313 application.

79. 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 on May 7, 2015, where, according to the examiner, "the discussion centered around the term 'accelerated' in the preamble of claim 1." Ex-1011, 45.

80. BDC filed its response to the office action on June 17, 2015. BDC's interview summary described the "purpose" of the now-claimed "excess volume area" in nearly identical terms as the "compliance chamber" claimed in the

¹⁴ As shown in Ex-1013, the disclosure was otherwise generally the same.

(grandparent) '313 application: “Dr. Weinberg noted the purpose” of the now-claimed excess volume area is “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”).

81. The differences between “accelerated” and “real-time” systems were a focus of BDC’s Response. BDC again did not dispute that Pickard discloses a compliance chamber or even the “excess volume area” as recited. BDC argued the Pickard reference disclosed a system for “real-time testing of cardiac valves to examine fluid mechanical performance” but “not a method in an accelerated system as claimed for the purposes of evaluating leaflet wear and implant durability.” Ex-1011, 52 (emphasis in original). BDC contended that “real-time and accelerated testing have completely different requirements and use completely different methodologies.” Ex-1011, 52-53.

82. BDC also addressed the cited art’s compliance or compliance chamber features as disclosing the “excess volume area” limitation. BDC stated 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.

83. BDC characterized prior art *accelerated* 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, 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, 51, 55, 57.

84. BDC thus argued that 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.

BDC stated its “method *in an accelerated cyclic test system* that uses an excess volume area is *entirely new*.” Ex-1011, 54.

85. A few months later, on September 17, the examiner issued a Notice of Allowance in the ’104 application. The examiner was persuaded that an “accelerated cyclic test system ... when combined with the limitations of an excess volume area (*which is a term of art*, see remarks of 06/17/2015 p.8, final ¶) and its location also in independent claim 1 distinguish the present invention” from 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).

5. The allowance of the ’313 application

86. 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 in the ’313 application, stating BDC intended “to place the [sole independent] claim in better condition for allowance” in view of the action in the continuation application. Ex-1010, 48.

87. An examiner interview was held two weeks later, on October 15, which again focused on the difference between accelerated and non-accelerated testers—specifically “the limits of non-accelerated compliance chambers as they relate to the claimed excess volume area.” Ex-1010, 58.

88. The examiner issued a first-action allowance in the ’313 application on November 12, 105, and the ’935 patent issued in January 2016.

IV. LEVEL OF SKILL IN THE ART

89. I have been asked to consider the background and level of skill possessed by a person of ordinary skill in the subject matter of the ’935 patent at the time of its (claimed) invention, which as discussed above I assume to be around March 2009.

90. The patent is titled “Fatigue testing system for prosthetic devices” and defines its relevant “Technical Field” as “systems and methods for fatigue testing of prosthetic devices, in particular, but not limited to, prosthetic vascular and heart valves, under simulated physiological loading conditions and high-cycle applications.” Ex-1001, 1:19–23. Ex-1002 ¶¶ 89, 91

91. Based on my experience, it is my opinion that the POSA in the relevant art would have at least: (a) a bachelor’s degree in biomedical engineering, or a related field, such as mechanical engineering, biomechanical engineering, or bioengineering, who also has 3 years of experience with cardiovascular devices; or (b) an advanced degree in the same areas of academic study with at least 1 year of experience with cardiovascular devices.

92. Additionally, in my experience, the POSA would have been familiar with test systems for artificial heart valves and at least been aware of government standards for testing artificial heart valves. Additionally, the person of ordinary skill in the art would have understood how test systems for artificial heart valves model the human circulatory system.

V. CLAIM CONSTRUCTION

A. fluid communication

93. Claim 1 recites the phrase “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.” Ex-1001, 17:29-50.

94. The patent does not expressly define the term “fluid communication.” But the plain and ordinary meaning of “fluid communication” in the context of the claim simply means that fluid can flow from one referenced element to another. It does not require any direct connection or specific spatial relationship between elements.¹⁵ This meaning is consistent with its usage in both the ‘935 patent and

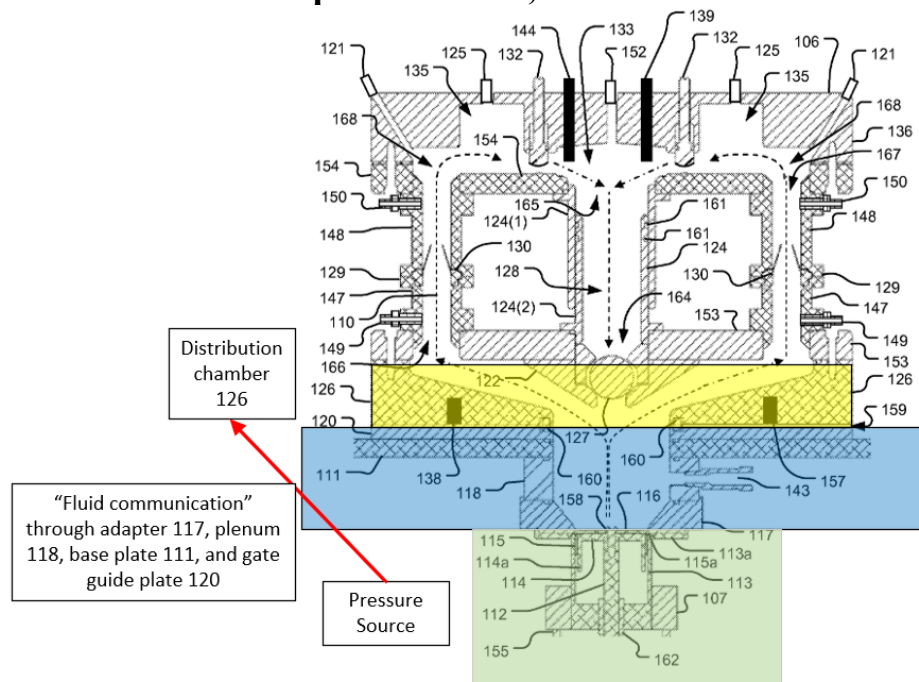
¹⁵ I observe that other claims in this patent and its family members *do* require specific spatial relationships. Claim 1 orients the distribution and chambers on the “first” and “second side” of the valve; claim 9 recites a “cavity within” the return chamber. In the parent of the ‘935 patent (which mostly shares the same specification, other than the additions of excess volume area as I described above), BDC recited these chambers as 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. These other claims further suggest to a POSA that “fluid communication” does not refer to any particular spatial relationship.

the conventional meaning of “fluid communication” in the field of designing systems including fluids (i.e., fluid mechanics).

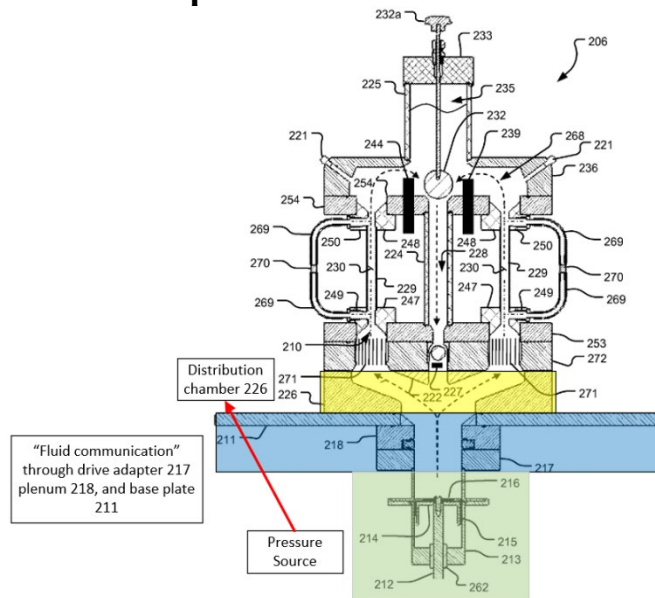
95. The patent itself uses the term “fluid communication” to refer to indirect relationships between elements that are not directly connected and to refer to fluid flow from one point to another. The patent describes (and claims) the “pressure source” and “distribution chamber” are “in fluid communication” with one another. *E.g.*, Ex-1001, 2:40-46. I note that the “pressure source” is not labeled with a reference number in the ‘935 patent. But a POSA would understand that the piston (element 114 and 214 in FIGS. 3 and 6 respectively) would be the pressure source.

96. But the embodiments of FIGS. 3 and 6 (below) illustrate that the distribution chamber and piston (i.e., pressure source) are separated by intermediate components, including a plenum, base plate, and drive adapter, as shown in the below annotations. *See generally*, Ex-1001, 7:12-8:5.

‘935 patent FIG. 3, annotated



‘935 patent FIG. 6 annotated



97. Since the claims recite "fluid communication" between the pressure source and distribution chamber, and neither embodiment shown in the '935 patent includes a pressure source directly connected to the distribution chamber, it

strongly suggests to one of skill in the art that “fluid communication” does not mean a “direct connection.”

98. 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.

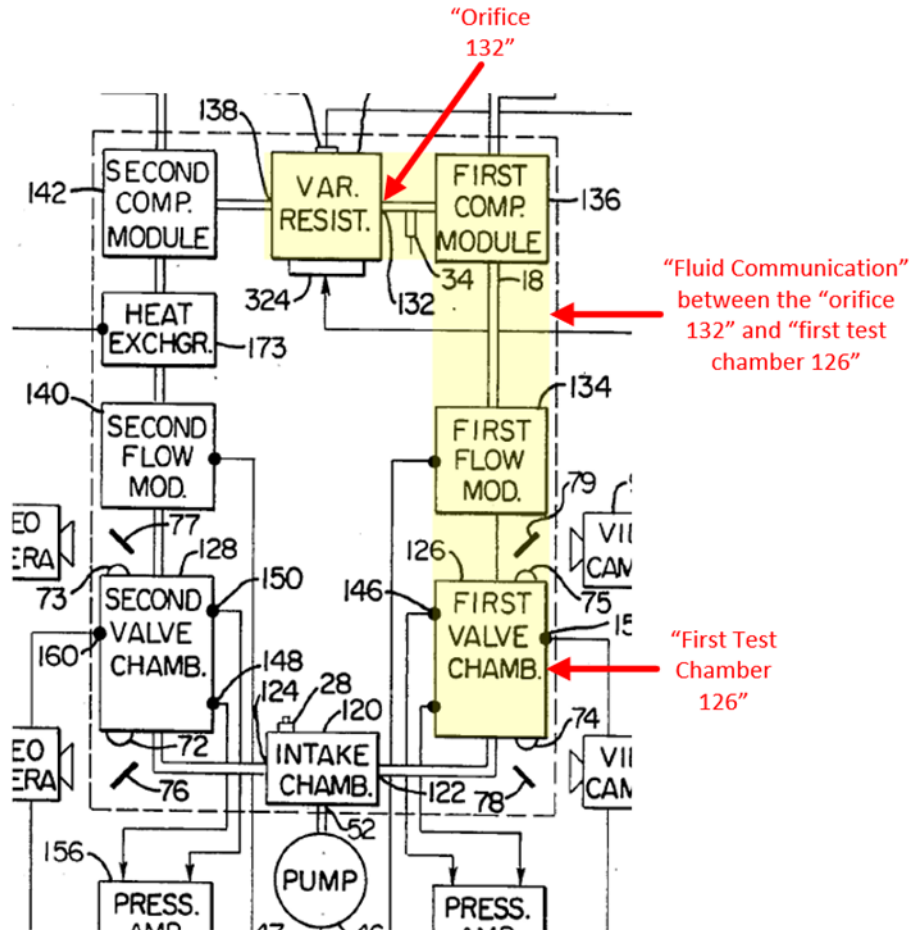
99. And, as still another example, the ‘935 patent teaches the device’s “drive system ... may include a linear actuator or magnetic-based drive motor coupled to a flexible rolling diaphragm. The drive system is coupled to a lower opening in the test chamber *and is in fluid communication with* the fluid reservoir in the test chamber.” Ex-1001, 2:11-16. “[D]rive motor 105 is housed within the base housing 157.” Ex-1001, 4:60-63. So the patent teaches that the drive motor, part of the drive system, is “in fluid communication” with the fluid in the reservoir even though they are not directly connected. Thus, it is reasonable to infer that the fluid reservoir is not directly connected to the drive system (i.e., the “pressure source”).¹⁶

¹⁶ See Ex-1001, 3:66-4:14 (describing the linear actuator or magnetic-based drive is coupled to a flexible rolling bellows diaphragm and that they “operate together to act as a fluid pump ... [to] provide the absolute pressure and/or differential pressure and flow conditions”).

100. The patent disclaims any particular type of “position, orientation, or use” for “directional references,” and it disclaims any direct connection or relationship for “[c]onnection references” in the patent. Ex-1001, 16:63-17:9. While the term “fluid communication” is not specifically a “directional” or “connection” reference, the usage of the term implies *less* of a *directional* or *connection* reference than those do. So the “fluid communication” term should not be limited in those ways, either.

101. Other prior art references in the field suggest the POSA would have understood the plain meaning of “fluid communication” to merely refer to fluid flow—including through intermediate components.

102. Pickard’s “piston reservoir 50 is filled with fluid which *communicates with* circulatory loop 18 *through* an intake opening 52 extending between reservoir 50 and circulatory loop 18.” Ex-1018, 7:42-53, Fig. 1. And its “[r]estriction chamber 130 has a first restriction chamber flow orifice 132 is *in fluid communication* with first test chamber 126 *by conduit means formed by* first flow module 134 and first compliance module 136.” Ex-1018, 8:24-32, Fig. 2 (annotated below).



103. Likewise, Fig. 3 of Elizondo shows a “circuit 60 includes a pneumatic pump 64 ... *in fluid communication* with chamber 11 *through* conduit 62.” Ex-1027, 4:65-5:2. Elizondo teaches the sterility of its “fluid communication path ... is not adversely 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.

104. 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.

B. excess volume area

105. In my opinion, the ’935 Patent’s claimed “excess volume area” is synonymous with a “compliance chamber,” which provides a structure where fluid can flow to absorb pressure changes.

106. Prior to my involvement with this case, I was not familiar with the exact term “excess volume area” used in the context of describing spaces for excess test fluid to be stored in a fluid system. It is not a common term in the field, so I do not believe a POSA (either in 2009 or now) would have used or been familiar with an “excess volume area.” Instead, designers of accelerated testers commonly refer to the “compliance” of a system. *See generally, e.g.*, Ex-1005, 187-191. POSAs commonly refer to the areas of a system that provide the compliance using terms like “compliance chambers” or “compliance elements.” *See, e.g.*, Ex-1017, 37-38 (ISO standard describing “compliance chamber[s]”); Ex-1018, 6:66-67 (“compliance chamber” in a circulatory loop) and 8:24-32 (describing “compliance module[s]”); Ex-1019, 422-423 (referring to both “an air

compliance chamber” and “compliance element”); Ex-1007, 10:27-30

(“compliance element”).¹⁷

107. 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. As discussed above, the term “excess volume area” only appeared once in BDC’s applications nearly five years after the priority date, when BDC amended the specification to include additional “summary” referring to it.

108. I understand that BDC has argued that a compliance chamber is “one” way but “not the only way” to provide an excess volume area. Ex-1022, 31; Ex-1023 ¶ 7 (stating “[o]ne type of ‘excess volume area’ is a ‘compliance chamber’” and “our patents describe *a variety of types* of excess volume areas”). But I have found no other examples of “excess volume areas” disclosed or taught in the ’935

¹⁷ Additionally, some designers refer to the “compliance” as “*capacitance*” in reference to the “Windkessel Model,” which is well known in the field. *E.g.*, Ex-1015, 29-32 (Section 2.4.2).

patent (besides the compliance chamber), nor have I seen any reference to something called or described as an “excess volume area” in the prior art I have reviewed.

109. Accordingly, in my opinion a POSA would understand that an “excess volume area” is simply a “compliance chamber.” At minimum, however, it is apparent that a compliance chamber is encompassed by the term, “excess volume area.”

C. under compression

110. Claim 1 recites the excess volume area performs its function “when the test system fluid is under compression.” Ex-1001, 17:45-50. As stated earlier, fluid in a system like this is (generally) incompressible. See Paragraph 26 above. So a POSA would not understand the fluid is literally “compressed” when it is “under compression” as recited in the claim.

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.” See Ex-1001, 17:31-34. So, in my opinion, the claim only requires a “pressure source” that “drive[s]” the fluid through the device to place it “under compression.” So a POSA would understand the term to mean the fluid is “under pressure”—or, as BDC’s expert opined, that “compressive

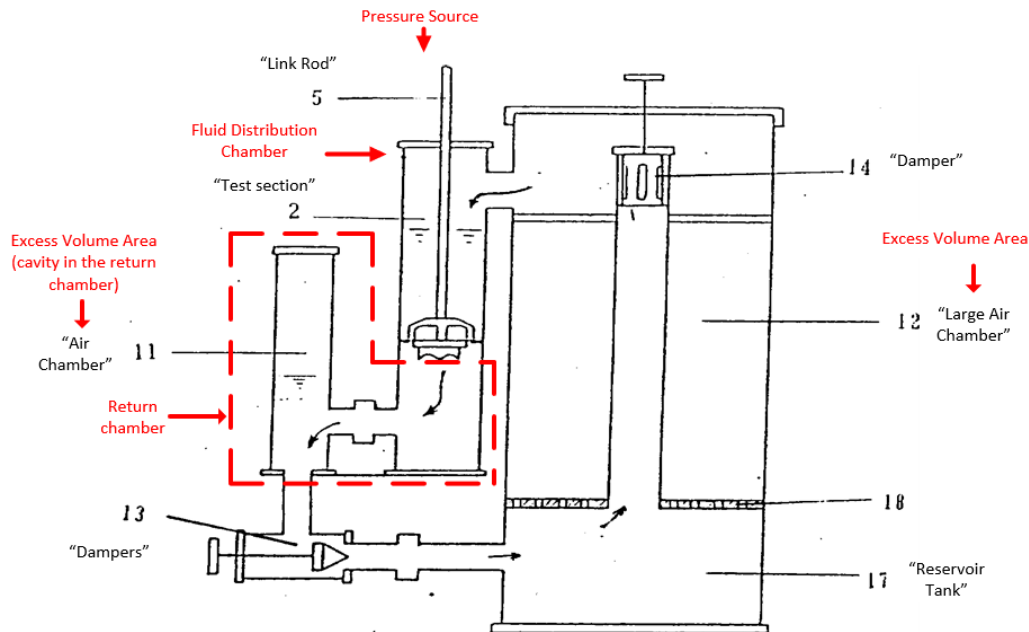
forces are being placed on” the fluid—from the recited “pressure source.” See Ex-1024 ¶ 22.

112. This understanding is also consistent with the patent’s description of the compliance chambers (i.e., the excess volume area) as absorbing “some of the *pressure placed upon the fluid* in the test chamber” and helping “to control recoil toward the original volume dimensions *upon removal of the compressive force.*” Ex-1001, 9:11-16. So the patent specification likewise refers to “pressure” or “compressive force” being placed on the fluid.

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

113. In my opinion, Xi discloses all of the elements of claims 1-4, 8-9, and 12-13. I provided an overview of Xi in Section II.C.1 (Paragraphs 30-36) above. And below is an annotated version of Xi’s FIG. 4 illustrating the elements of claim 1, as detailed below.

Annotated Xi FIG. 4



A. Independent Claim 1

1. [1pre] – “A device for accelerated cyclic testing of a valved prosthetic device comprising” and
2. [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;”

114. Xi discloses [1pre], a device for accelerated cyclic testing of a valved prosthetic device, because it discloses a “prosthetic heart valve fatigue life test device” where the “circulation frequency can reach 2,000 beats/min.” Ex-1004, 6. A POSA would understand that Xi is referring to accelerated durability testing of prosthetic heart valves, like in the '935 patent.

115. For element [1a], I note that the ‘935 patent claims do not specify how the pressure source drives the test system fluid or how the pressure source is connected to the test system. Claim 1 only recites that the pressure source is “in fluid communication with” the fluid distribution chamber. Thus, in my opinion, a POSA would understand “a pressure source” to refer to any pressure source in fluid communication with the distribution chamber.

116. Xi discloses: “linear motor (1) is driven by the drive signal, through the main shaft (3) and the spindle disc (4) to drive 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 valve closes, “[t]his also *pushes* the liquid down” and eventually it is “diverted back to each test section through the adjustable damper R₂ (14).” Ex-1004, 7-8.

117. In other words, the link rod, valve frame, and valve are pushed through the fluid to generate pressure within the system and drive the fluid through the device back to the “test section” at the top. Xi therefore discloses a pressure source that drives fluid cyclically through the system at rates (up to 2000 bpm) well above those recited in the claim.

3. [1b] “a pressurizable test chamber for containing the test system fluid and”

118. Xi discloses the “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 (2) on the back side of the valve When pressure is *not being measured*, it is opened to atmosphere and zeroed.” Ex-1004, 9.

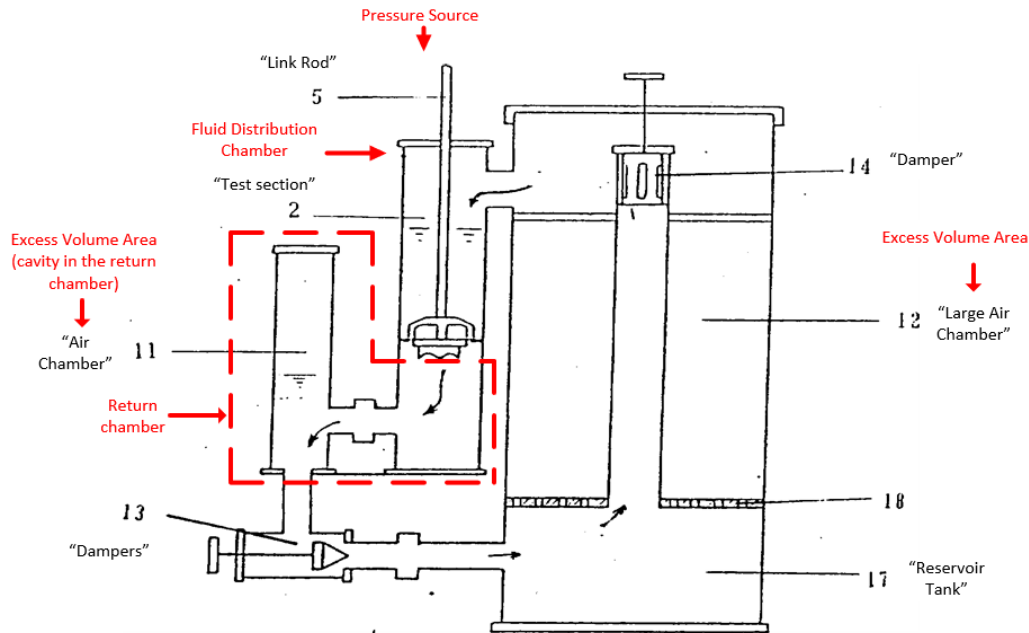
119. A POSA would understand that the test section—at minimum the portion on the back side of the valve—must be pressurized when the valve is moved downward and pressure is being measured. The pressure rise closes the valve as explained: “The valve (16) closes due to fluid resistance as the valve frame (6) moves down.” Ex-1004, 7. This understanding is also consistent with Xi’s express teaching that its system “reduces the water hammer effect.” Xi’s teachings about sealing performance further indicate that Xi contemplated a closed system, and a POSA would view the drawings of Xi as illustrating a closed system with no opening to the atmosphere. So a POSA would understand Xi to disclose a system that is “pressurizable test chamber” as recited in element [1b].

4. **[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;”
and
[1d] a fluid return chamber positioned on a second side of the valved prosthetic device;**

120. In my opinion, “distribution chamber” element is disclosed by the area of Xi above the valve (on the “first side”), and the “return chamber” element

is the area below and downstream of the valve (on the “second side”), as illustrated below.

Annotated Xi FIG. 4



121. As noted above, Xi describes that when “reciprocating motion of the link rod (5) and valve frame (6)” pulls the valve 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” until the fluid flows through the tank (17) and “back to each test section through” damper (14). Ex-1004, 7-8. A POSA would accordingly understand the arrows shown in Fig. 4 to indicate the direction of fluid flow described in Xi. *Id.*

122. The “distribution chamber” and “return chamber” of Xi are the areas upstream and downstream of the valve, respectively. They are where the fluid (a) is

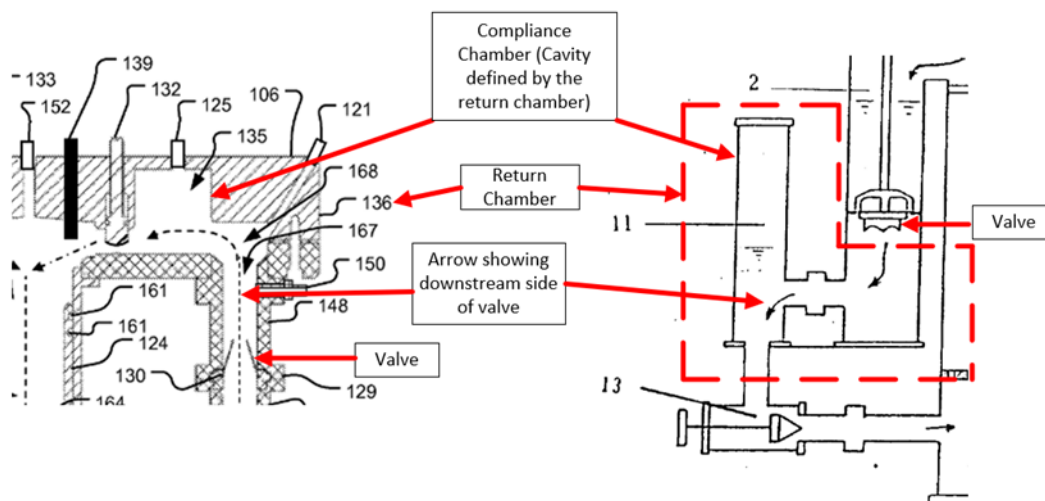
distributed to the valve and (b) returns from after passing through the valve.¹⁸

Nothing in the claims requires any specific structure or function of the “distribution” or “return” chambers aside from their relationship to other elements, such as being “in fluid communication” with the pressure source or excess volume area, discussed below. *See also* Section V.A (discussing meaning of “in fluid communication” as meaning that fluid can flow from one element to another without any direct connection or spatial relationship).

123. This identification of the distribution and return chambers in Xi is consistent with the '935 patent's identification and 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”); *see also* Ex-1001, 4:31-35 (describing “*return flow* ... from the *outflow* section of the sample holders,” through the return chamber, through a “central return flow channel,” back to the distribution chamber). Annotated figures comparing Xi to the parallel structures in the '935 patent are below.

¹⁸ Fluid propelled via the single motor is distributed among the multiple fluid pathways and valves being tested and then returned to complete the cycle after flowing through the valves.

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



124. My opinion of how a POSA would interpret Xi is also consistent with BDC’s witnesses and counsel, who have described the return chamber as “downstream” of the valve. Dr. Weinberg, one of the inventors, described the ’935 patent’s design (and an alleged embodiment of the claims, the VDT-3600i) as having a compliance chamber “in a *return* chamber, *downstream* of the valve.” Ex-1023 ¶¶ 7, 9. BDC’s expert witness in the litigation, Mr. Girard, illustrated and labeled elements of the patent’s FIG. 3 and described how the excess volume area helps “return the downstream volume to the pump.” Ex-1024 ¶¶ 13-14; *see also* Ex-1014, 10-12 (BDC annotating FIGS. 3 and 6 with upstream distribution chamber in green, test sample in red, and downstream return chamber in orange); Ex-1022, 6-7 (describing the alleged invention as including an excess volume area “on the *outflow* side” of the valve that “releas[es] fluid *downstream* of the valve during the *return* phase”).

125. As discussed in the claim construction of “fluid communication,” the claim reciting the “distribution chamber ... in *fluid communication* with the pressure source” merely requires there to be a fluid flow path between the distribution chamber and pressure source, or that the fluid is communicated by a force or pressure from the pressure source to the distribution chamber. See Section V.A above.

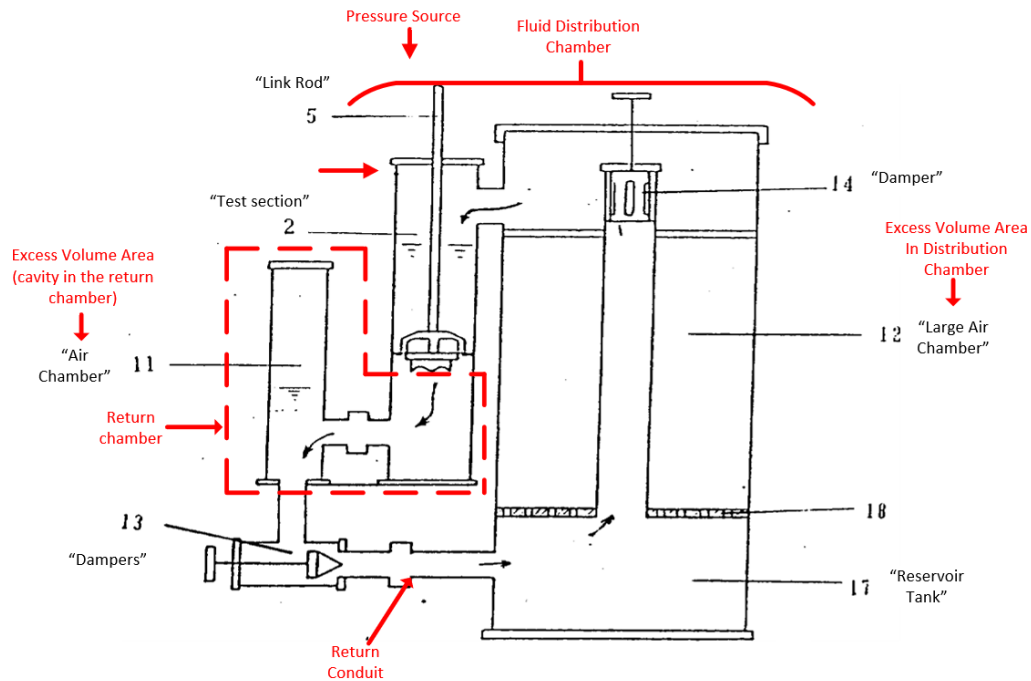
126. Accordingly, Xi’s distribution chamber is also “*in fluid communication* with the pressure source” for multiple reasons. **First**, valve frame (6) occupies some amount of the cross-section of the test section (2), so that when the link rod moves up and down, the frame structure itself applies a force or pressure while moving against and through the fluid in each direction. That is, the valve frame 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*. (Of course, during the downstroke, the closed valve moving through the fluid applies additional pressure.) Thus, the distribution chamber is both above and in fluid communication with the valve frame. **Second**, the link rod, valve frame, and valve move up and down *through* a portion of the identified distribution chamber (part of test section (2)) to cause the fluid flow from one side of the valve to the other. That is, fluid flows from the fluid distribution chamber, past the link rod and valve frame, and then through the valve. Each of these elements (no matter which

individually or in combination make up the “pressure source”) are in fluid communication with the distribution chamber.

5. [1e] a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and

127. Xi discloses a return conduit that structurally and fluidly connects the return chamber to the distribution chamber. Fluid “flows from each test section (2) to its respective corresponding air chamber C_1 (11) and needle valve damper R_1 (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 exits through the return conduit before flowing into and through other elements and back to the distribution chamber, just as in the ’935 patent. *Cf.* Ex-1001, 11:60-64 (describing fluid flow 110 as passing through “sample holders 129 to *exit through* the return conduit 168”). The return conduit in Xi therefore structurally connects (they are physically connected) and fluidly connects (in fluid flow path) the return chamber and the distribution chamber.

Xi FIG. 4 (annotated):



6. [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.

128. In my opinion, Xi's air chamber (11) meets all the limitations of the recited excess volume area.

129. **First**, the excess volume area is part of an accelerated tester "capable of operating at an accelerated rate." *See generally* Ex-1004; *see also* element [1pre] and [1a] above. Xi teaches its device, including the air compliance chambers, is capable of "greatly reduc[ing] ... the water hammer effect" that occurs at accelerated rates. Ex-1004, 6.

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

131. **Third**, Xi’s excess volume area “provid[es] a volume for storing a volume of a test system fluid when the test system fluid is under compression.” A POSA would have recognized Xi’s air chamber as an example of the “well known” *compliance chamber* in the art of test systems for prosthetic heart valves. Ex-1011, 54 (BDC admitting these were well known). The structure in Xi is the same one shown in other prior art known to a POSA, as described above in Section II.C (Paragraphs 29-59) (identifying air compliance chambers). And a POSA would have understood that a compliance chamber in an accelerated tester would provide a volume (or space) to “store” amount of test system fluid when the test system fluid is under compression (i.e., under pressure, as I understand “under compression” to mean, see Section V.C (Paragraphs 110-112)).

132. BDC itself stated that compliance chambers in valve test systems are known to perform this same function. During prosecution, BDC argued to the examiner: “[W]hile the concept of using a compliance chamber to store excess volume of test fluid in a real-time, physiologically accurate, cardiac valve test system is well known for the purpose of substituting for the arteries of the human circulatory system ..., a method in an accelerated cyclic test system that uses an

excess volume area is entirely new.” Ex-1011, 54. As shown by Xi and other prior art discussed above (and below), using a compliance chamber in an accelerated system was not “new.” 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] ... the valve closing dynamics and differential pressure spikes,” “minimiz[es] ... pressure spikes,” and “alleviate[s] some of the system pressure during the drive phase”). And Inventor Weinberg declared in the litigation that a compliance chamber is a “type of ‘excess volume area’” that “permits a change in its volume with an associated change in system pressure.” Ex-1023 ¶ 7.

133. A POSA would accordingly recognize Xi’s air compliance chamber performs these same functions. 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 (“At the higher frequencies of accelerated testing, the inertial acceleration and transvalvular pressure both increase. In order to maintain a constant transvalvular pressure, the compliance component can reduce the effects of the water hammer”). And Xi discloses that

its air chamber compliance components solve that problem: It expressly teaches that its device “reduce[s] the occurrence of the water hammer effect.” Ex-1004, 6. Xi teaches: “In order to make the distribution of maximum stress [“during the in vitro acceleration test”] similar to the maximum stress distribution of the prosthetic heart valve under physiological conditions, we can *adjust the compliance* and impedance of the circulation loop system,” along with other parameters, “so that the opening and closing motion of the heart valve is close to the physiological conditions and so that the movement pattern of the system after acceleration can be close to the normal physiological conditions.” Ex-1004, 7. “The valve back pressure waveform is close to the aortic pressure waveform under normal physiological conditions, *and no water strike is produced* when the valve is opened and closed.” Ex-1004, 7.

134. Thus Xi teaches that its air compliance chamber addresses the water hammer problem, and it does so in the same way disclosed and claimed in the ’935 patent—by providing a volume for storing a volume of fluid when the fluid is under compression.

B. Claims 2 and 4

135. Claim 2 adds to claim 1 “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.” Claim 4 depends from claim 2 and adds, “wherein the drive motor comprises a linear motor.”

136. Xi’s “linear motor (1)” discloses the “drive motor” and “linear motor” of claims 2 and 4. The motor “drive[s] the reciprocating motion of the link rod (5) and valve frame (6) ... The valve (16) closes due to fluid resistance as the valve frame (6) moves down” which “pushes the liquid down.” Ex-1004, 5, 7-8. Xi therefore discloses a fluid displacement member, driven by the linear motor, that exerts pressure on the fluid (increasing the pressure when moving down and decreasing the pressure when the valve moves up). Accordingly, Xi anticipates claims 2 and 4.

C. Claims 8-9 and 12

137. Claims 8-9 (which depend from claim 1) and 12 (depending from claim 9) recite additional or implied features of the excess volume area. **Claim 9** adds that it “comprises a compliance chamber defining a cavity within the fluid return chamber.” And **claim 8** recites the excess volume area “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.” **Claim 12** similarly adds that claim 9’s 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.”

138. In Xi, when the fluid is under compression/pressure and flowing into the air compliance chamber, the air inside the compliance chamber is compressed by the fluid. A POSA would have known that, as the gas is compressed, it provides a “spring force” back against the fluid, resisting that compression. The spring force of the air provides the “compliance” that mitigates the water hammer effect. As shown above, Xi’s air compliance chamber is within the area identified as the “return chamber.” Accordingly, Xi anticipates claims 8, 9 and 12.

D. Claim 3

139. Claim 3 recites “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.”

140. Xi discloses an “arbitrary waveform generator (9)” that “can provide an *arbitrarily selected* drive waveform to ensure the movement of the linear motor (1).” Ex-1004, 7-8. Xi teaches that a user can “select the appropriate drive waveform to drive the linear motor to move according to a certain waveform, frequency, and amplitude” to create the desired “valve back pressure waveform.” Ex-1004, 7. A POSA would understand Xi’s teaching that it can create “arbitrary

waveform” means that *any* “appropriate drive waveform” can be “select[ed]”—which could include cyclic, acyclic, and mixed fluid pressures.

141. I also note that this understanding of “arbitrary waveforms” taught by Xi is consistent with the ’935 patent’s discussion of the potential waveforms that the patent’s embodiments can generate. The patent teaches that “any *arbitrary* pressure waveform may be generated and can be utilized to drive the motor and thereby the piston,” including a “regular sine wave” or a “non-regular pressure waveform.” Ex-1001, 14:25-34.

142. Xi also teaches that its device can achieve load waveforms “close to” or “similar to the total load experienced under physiological conditions.” Ex-1004, 5, 8, 14 (Fig. 6).

143. My opinion about how a POSA would understand Xi is reinforced by Lu’s description of the Tsinghua “TH2200” tester, with its design *highly* similar to Xi, as having a “*random* wave generator to create the driving waveform” to affect “the loading on the test valve.” Ex-1005, 190-191.

144. Accordingly, Xi’s linear motor connected to Xi’s arbitrary waveform generator can output waveforms that are cyclic, acyclic, or both to generate corresponding pressures within the system. Xi therefore anticipates claim 3.

145. Even if Xi did not expressly disclose cyclic and acyclic waveforms, in my opinion 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. So a POSA would understand that an arbitrary waveform *could* be adjusted to generate waveforms that are acyclic, cyclic, or a combination of both. See also Ex-1036, 3:26-34 (a 1993 patent teaching an accelerated tester with a “signal generator” and “piston driver or pressure generator” that could produce “sinusoidal, triangular, square wave or random pulses” to provide corresponding pressures to the fluid. See.

E. Claim 13

146. Claim 13 depends from claim 1 and adds, “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.”

147. Xi includes a “monitoring system” comprising “a valve load measurement, a valve displacement measurement, and a valve back pressure measurement.” Ex-1004, 8. Xi teaches a “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.

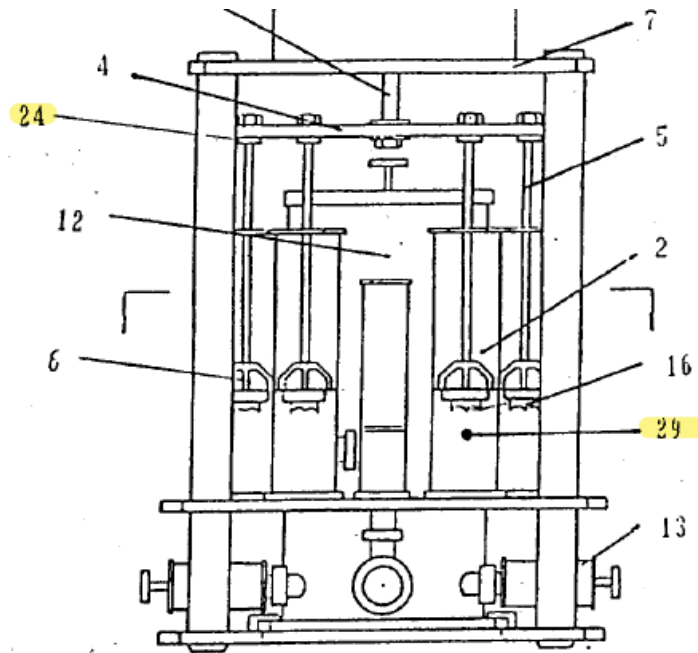


Fig. 2

148. A POSA would have understood these transducers are types of sensing devices. *Cf.* Ex-1001, 10:61-64 (identifying “pressure transducers” as an example “sensor[.]”). Thus, Xi expressly discloses sensors on first and second sides of the valve. And transducer (29) is received through a “hole” on the “second side,” so that hole is the “second port” claim 13. *See* Ex-1004, 5, 9.

149. Xi does not expressly disclose whether transducer (24) is inserted through a “hole” or port in the device. But it would have been obvious to a POSA, however, to add a second port/hole to the test section (2) upstream of the valve to receive another sensor.

150. Multiple references expressly teach measuring the pressure on both sides of the valve, in both real-time and accelerated valve testing systems. For example, Pickard teaches “measuring the pressure of the fluid upstream and

downstream of the heart valve to generate channel pressure data”. Ex-1018, 21:33-35 (claim 33); *id.* at 6:7-15 (teaching such data is useful to “calculate the ... pressure waveform of the fluid through the flow channel”); *see also* Ex-1007, 11:34-37 (Goldstein: “Absolute pressure transducers will be located *both upstream and downstream* of the valve ...”); Ex-1020, 152 (Reul: “[T]he pressure difference across the valve ... is *measured upstream and downstream* of the valve by two semiconductor pressure transducers ...”); Ex-1006, 15, 18 (Dynatek: “Pressure transducer *ports* are provided in the *top and bottom* manifolds,” which are on either side of the valve, “for [pressure] transducers.”).

151. And modifying Xi to add a second hole and using the *two* sensors taught by the prior art in place of the single transducer (with known force on the other side) of Xi would have been a mere substitution of a known alternative option for measuring trans-valve differential pressure. And according to those same references, it would have required no more than ordinary skill by a POSA.

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

A. Overview of Dynatek

152. Dynatek is a manual that describes how to use the Dynatek M6 Six-position Heart Valve Durability Testing device. Dynatek is dated September 1993.

153. Throughout my career, I have worked with and used prosthetic heart valve testers from various manufacturers. In my experience, it is standard practice

for testing device manufacturers to provide user manuals together with the product (e.g., inside its packaging) or make the user manual available on the manufacturer's website, so that anyone interested in testing prosthetic heart valves would be able to successfully use the tester. That experience specifically includes the M6 tester from Dynatek and its manual(s).

154. Dynatek simulates the pumping of the heart using a set of mechanical bellows that are driven by a motor and swashplate. The motor and swashplate move the bellows up and down to open and close the valves.

155. When the Dynatek bellows is extended, it pulls fluid from the upper head through the valve being tested into the lower head. Ex-1006, 5. When fluid is pulled through the valve being tested, the valve being tested opens. *Id.*

156. When the Dynatek bellows are compressed, the valve being tested is closed by the reverse pressure. *Id.* The fluid being compressed by the bellows flows through a bypass port and into the central reservoir to the upper head. *Id.*

157. To manage the pressure on the system, Dynatek discloses a "capacitance tank" that is in fluid communication with the test chamber to buffer the pressure changes in the system. *Id.* at 19.

B. Motivation to combine Dynatek and Xi

158. As I described above in Section II.C.4, Paragraphs 48-49, in my opinion Dynatek's "capacitance tank" is another example of a "compliance

chamber” well known to a POSA. And, like Xi, Dynatek’s compliance chamber teaches the claimed “excess volume area” of the patent. I understand that BDC disagrees with my opinion and contends that Dynatek does not teach using a “compliance chamber” or “excess volume area.”

159. But even if Dynatek does not teach use of a compliance chamber—or *especially* if it does not—then a POSA would have been motivated to combine the teachings Xi and Dynatek to arrive at the claimed invention.

160. As discussed in Section II.C above, the art teaches that accelerated testers should include compliance chambers to help control loading forces and mitigate the water hammer effect. **Reul** teaches that a POSA should include an air compliance chamber to control “loading forces”—especially for a tester “intended for use with all kinds of valve sizes” because larger valves have “higher loading forces.” Ex-1020, 153-154, Fig. 5. And **Iwasaki** teaches that *if* an accelerated test is originally “designed *without* a compliance element”—as BDC argues Dynatek is—then a POSA knew to “modif[y]” that tester “to *incorporate an air compliance chamber* as shown in Fig. 5.” Ex-1019, 422. **Lu** taught that a “compliance

component can reduce the effects of the water hammer,” which otherwise alters “transvalvular pressure.” Ex-1005, 188.¹⁹

161. Dynatek and Xi both explain that the pressure across the valve is an important parameter in testing. Dynatek explains that “the most important pressure measurement during the cycle is at valve closure.” Ex-1006, 23. Dynatek explains to the user that the “valve closure loading pressure (closing pressure) is a function of the speed, the magnitude of the bellows compression, and the setting of the center throttle valve” in Dynatek’s system. *Id.* Thus, a POSA would understand from Dynatek that measuring and adjusting the valve closure loading pressure was desirable to a POSA. Likewise, Xi taught a device with adjustable air chambers for compliance that “greatly reduce[s] ... the water hammer effect.” Ex-1004, 6. Xi also teaches that its compliant system helps improve the “trans-valve pressure differential.” Ex-1004, 7. Thus, a POSA would understand from Dynatek that adjusting or setting the back pressure (or loading pressure, or trans-valve pressure differential) of the valve is desirable, and the POSA would understand from Xi that a way to control back pressure is to add an air chamber that can improve the “trans-valve pressure differential” and prevent the undesirable back-pressure on

¹⁹ Lu also teaches that, among the accelerated testers “on the market” in 2003, “*all* have adjustable ... compliance.” Ex-1005, 186.

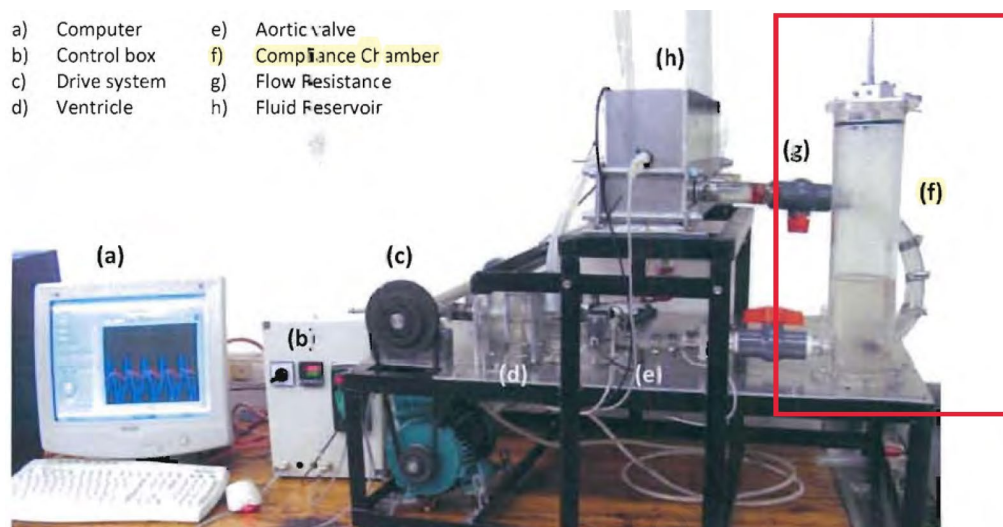
valves known to the POSA as a “water hammer effect.” Therefore, a POSA would have been motivated to use the downstream air chambers from Xi to improve Dynatek's back pressure by putting compliance on the lower head. At a minimum, a POSA would understand from Xi and Dynatek that compliance was an effective way to adjust back pressure on valves, and that adjusting the back pressure on valves was desirable for testing valves. In sum, a POSA would therefore be motivated to combine Xi’s teachings with Dynatek.

162. I understand that BDC has argued that a POSA would not have been motivated to combine Dynatek and Xi, 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. I also understand BDC has argued that Dynatek “teaches away” from the combination. *Id.*; *see also id.* at 49.

163. It was well within a POSA’s level of skill to combine these references. As discussed above, the prior art generally shows POSAs incorporated compliance chambers into real-time *and* accelerated testers of diverse designs. And Iwasaki itself is evidence that a POSA would have been able to (and did) modify a tester to incorporate an air compliance chamber into a device lacking one. Ex-1019, 422-23.

164. The 2009 Krynauw thesis also shows *a graduate-level student* designing and building a combined real-time and accelerated test system shortly

before/around the priority date.²⁰ Krynauw’s work displays a generally sophisticated understanding of issues and skill to address them. *See generally*, Ex-1015; *id.* at 3 (“This device is to be used primarily for fatigue and limited hydrodynamic testing ...”), 22-35 (surveying literature and theory of operation). Krynauw shows awareness of (a) the “effect of water hammer on the valve” during accelerated testing and (b) that adding compliance “reduced” those “pressure spikes.” Ex-1015, 33, 68, 82, 87-90. Krynauw’s design accordingly employed an air compliance chamber. Ex-1015, 37-38 (Fig. 3.2, annotated below), 40-42 (describing design of chamber). And Krynauw’s compliance chamber is *downstream* of the valve like the challenged patent. *Id.*



²⁰ I understand from Dr. Krynauw’s declaration that his thesis represents research and development that he performed between 2007 and May 2009, when he submitted it for review. Ex-1016 ¶¶ 4-5.

165. Thus, whatever design differences exist 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.

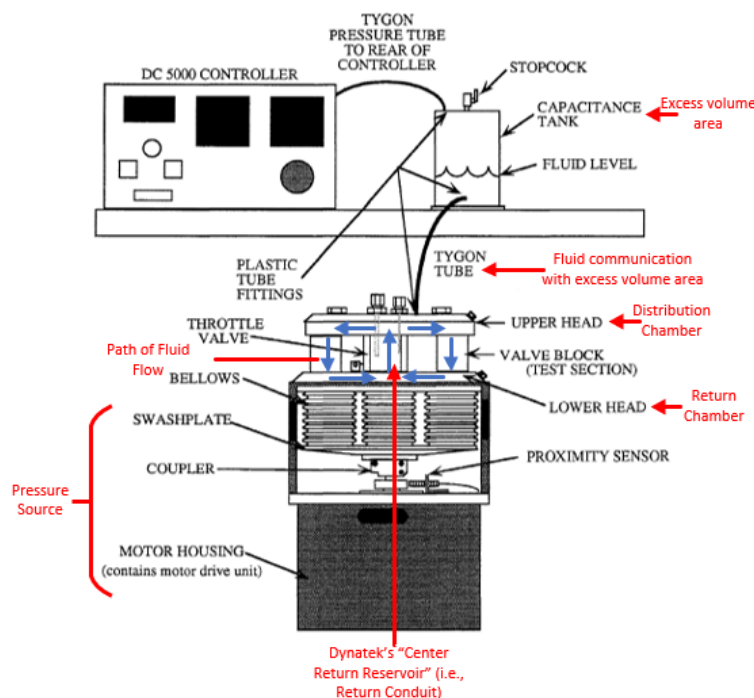
166. I understand that BDC asserts that Dynatek's "instructions contain 13 steps [numbers 5-11, 14-17, 24 and 33] devoted to *removing* all gas from the Dynatek test chambers," so that it "repeatedly warns users that all air must be removed." Ex-1022, 49, 53 (emphasis in original).

167. A POSA would not understand these instructions to criticize, discredit, or otherwise discourage a POSA from adding a compliance chamber. Instead, these steps are part of the "debubbling" process for the machine. As shown by *subsequent* steps 34-35, 40-41, 43, and 45, users are expressly instructed to "add air" to pressurize and prepare the capacitance tank for use. Ex-1006, 14-16. These instructions are similar to other teachings with air compliance chambers. Ex-1018, 7:54-59 (Pickard teaching that "Pressurized air is provided for pressure compensation" by an air compressor.); Ex-1007, 10:33-35 (Goldstein teaching, "[t]he pressure in the air space above the membrane [in its compliance chamber] can be varied to adjust the compliance through a physiologic range of values."); Ex-1019, 422-424 (Iwasaki teaching varying "air volume" in compliance chamber changes pressure waveforms); Ex-1004, 2 (Xi teaching its large air chamber C₂ (12) "is adjustable").

168. In sum, a compliance chamber was a known technique to address the water hammer effect across a variety of devices, including in multiple accelerated test systems. A POSA would have therefore looked to Xi to combine with the teachings of Dynatek.

C. Claim by claim analysis

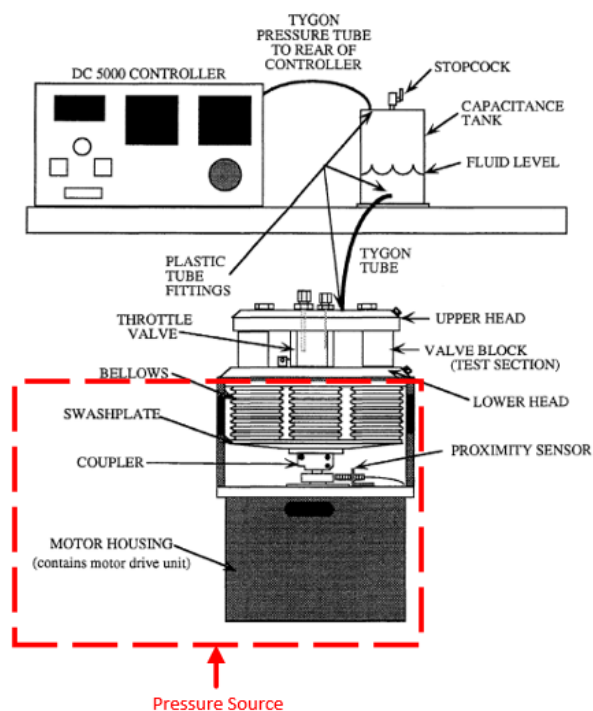
169. As stated in Ground A, in my opinion Xi discloses every element of the claims 1-4, 8-9, and 12-13. I incorporate my analysis of Xi's teachings here for my analysis of the combination of Dynatek and Xi. Accordingly, I rely on the above descriptions of Xi for corresponding claims and claim elements, in addition to the discussion of Dynatek's teachings contained here. An annotation of Dynatek's Figure 1 is provided here indicating the presence of several elements of the claims, as discussed in more detail below.



1. Claim 1

a. Elements [1pre] and [1a]

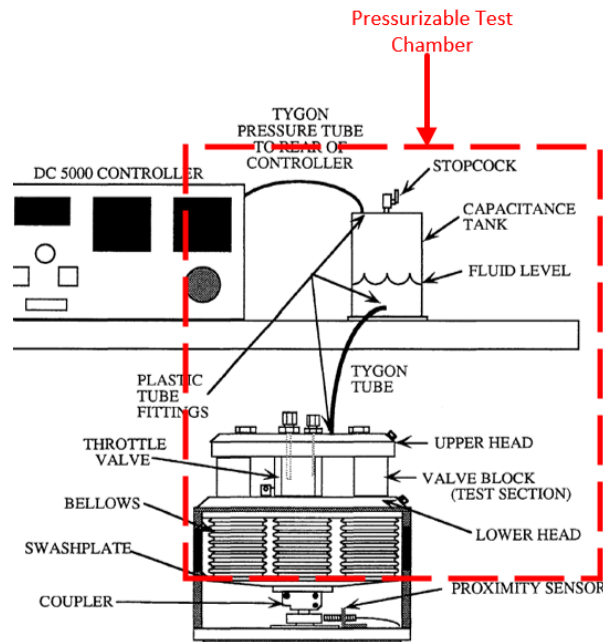
170. Dynatek discloses a “heart valve durability/fatigue testing machine” that is “capable of speeds to 2000cpm” (cycles per minute). Ex-1006, 5, 23. Dynatek’s “swashplate drive is used to compress six bellows” to cycle fluid through the system. Ex-1006, 5. The “bellows compression increases pressure behind the valve, loading the leaflets” during each cycle. *Id.*



b. Element [1b]

171. 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).

172. Dynatek's system has a "systemic operating pressure" that can be adjusted, in part, by "pressurizing the capacitance tank." Ex-1006, 15 (Step 41); *see also* Ex-1006, 21 (describing the "pressure operating range" of the device), 23-25 ("Setting the Pressure and Flow Rate"), 26 ("Pressurize the system again."). Thus, Dynatek teaches or suggests a pressurizable test chamber for containing the test system fluid.



c. Element [1c]

173. 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). *See* Ex-1006, 5 (describing bellows compression causes fluid to flow to the upper head). Dynatek's upper head therefore teaches the claimed "fluid distribution chamber."

d. Element [1d]

174. Dynatek's "lower head is ported from the valve discharge region into the center return reservoir." Ex-1006, 7 (Fig. 1A), 18. The lower head teaches the claimed "fluid return chamber."

e. Element [1e]

175. 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. Dynatek thus teaches a "return conduit" as claimed.

f. Element [1f.1]

176. 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 another example of the well-known compliance chamber. And Dynatek teaches its capacitance tank is "capable of operating" at an accelerated rate because the purpose of the system is for accelerated fatigue testing. See generally Ex-1006.²¹

²¹ In my personal experience operating a Dynatek M6 device, I have observed fluid flowing in and out of the capacitance tank when the Dynatek M6 is operating at accelerated rates.

177. Even if Dynatek's capacitance tank were not a compliance chamber, Xi also teaches using an air compliance chamber. See Sections II.C.1 (overview of Xi) and VI.A.6 (element [1f] disclosed by Xi, specifically Paragraphs 131-134), above.

178. A POSA would have therefore found it obvious to use either of Dynatek or Xi's air chambers as a compliance chamber in a combined system to provide additional control of loading forces and address the well-known water hammer effect. See Section VII.B (motivation to combine Dynatek and Xi, specifically including Paragraphs 160-161). Thus the combination of these two accelerated testers teaches an excess volume area capable of operating at the accelerated pulsed rate.

g. Element [1f.2]

179. A POSA would have found it obvious to connect a compliance chamber of Dynatek or Xi to the lower head, downstream of the valve, either as a substitute for or in addition to Dynatek's upstream capacitance tank.

180. In Dynatek, the capacitance tank provides a common compliance element, upstream of all six valves.

181. 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. Xi teaches that each valve test section (2) has its *own, independent* air compliance chamber

(11), although there is a larger, common air compliance chamber (12) as well. *See, e.g., Ex-1004, 11-12 (Figs. 2-3, depicting the multiple air chambers).* Other prior art references teach that placing a compliance chamber downstream of the valve was a known configuration for many kinds of valve testing. *Ex-1007, 10:25-35, FIG. 3; Ex-1015, 37-38 (Fig. 3.2); Ex-1018, 22:15-19 (teaching “a compensation chamber ... downstream of the heart valve”).*

182. Thus, a POSA would have found it obvious to place an air compliance chamber immediately downstream of each valve, within and “in fluid communication with” the return chamber (as in Xi) for at least the reasons discussed in the Motivation to Combine above. The fact that Dynatek includes a common compliance element upstream of the valve would not deter a POSA from this course. The upstream compliance can provide additional control over the pressure waves in the fluid that emanate from the pressure source. An additional compliance element upstream of the valve (as in the original Dynatek) would dampen undesirable signals going *towards* the valve, while the downstream compliance element in the return chamber would provide the “spring” effect to mitigate undesirable water hammer and control the valve back pressure.

h. Element [1f.3]

183. Finally, for the reasons described above with respect to Xi, an air compliance chamber downstream of the valve (i.e., within the return chamber)

would provide a space to store excess volume of test fluid when the fluid is under compression. *See* Section VI.A.6 (element [1f] disclosed by Xi, specifically Paragraphs 131-134); *see also* Ex-1011, 54 (BDC admitting that a compliance chamber is used “to store excess volume of test fluid”).

184. Additionally, Dynatek teaches: “[C]ompressing the bellows[] caus[es] the fluid to reverse direction and close the valve. Further bellows compression increases the pressure behind the valve, loading the leaflets or occluders.” Ex-1006, 5. Thus, the system fluid in Dynatek is “under compression” because it is “under pressure” as that term is properly construed. *See* 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”).

185. Thus, the obvious use of a compliance chamber in a system according to the combination of Dynatek and Xi would meet the limitation of [1f.3] and perform the same function recited in the claim. *See, e.g.*, Ex-1004, 6-7 (discussing “reduc[ing] the water hammer effect” and preventing “water strike”); *see also* Section VI.A.6, above.

186. In sum, in my opinion claim 1 is obvious over the combination of Dynatek and Xi.

2. Claim 2

187. In addition to Xi’s “linear motor,” Dynatek also teaches a “motor drive unit.” Ex-1006, 5, 7 (Fig. 1A). Dynatek discloses, “[a]s 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 bellows compression increases the pressure behind the valve” Ex-1006, 5, 7-8 (Figs. 1A and 1B). Dynatek therefore (in addition to Xi) teaches a fluid displacement member (the bellows) driven by the motor that increases and decreases the pressure on the fluid.

3. Claim 4

188. Dynatek’s swashplate and rotary motor drive the fluid by moving the bellows “upward” and “down.” Ex-1006, 5. This “upward” and “down” motion is a linear motion. *Id. See also* Ex-1024 ¶ 41 (Mr. Girard illustrating the up-and-down motion of the bellows caused by the swashplate).

189. Xi discloses a “linear motor (1)” that drives the link rod and valve frame up and down. Ex-1004, 5; *see also* Section VII.B.1.c.

190. It would have been obvious to use a known linear motor (as in Xi) as a drive motor in a system according to the combination of Dynatek and Xi. In

particular, one known way to achieve the linear motion of Dynatek's bellows is to use a linear motor (or a series of them).

191. As described above in Section II.D, Paragraph 60 above, the prior art teaches a diversity of pumps and drive systems were known to be used in various kinds of artificial valve test systems. It was therefore within the skill of a POSA to select a linear motor to substitute for or incorporate into Dynatek's drive system. And the result—providing the motive force to drive the fluid—would have been predictable.

192. Therefore, it would have been obvious to a POSA to combine Xi's linear motor with the accelerated tester of Dynatek to obtain a predictable result of an accelerated tester with a linear motor.

4. Claim 3

193. Dynatek does not expressly disclose the limitation of claim 3. But Xi discloses an “arbitrary waveform generator (9)” that “can provide an arbitrarily selected drive waveform” to move the motor and create the desired “valve back pressure waveform.” Ex-1004, 7-8.

194. Accordingly, a POSA would have found it obvious to select and configure Xi's arbitrary waveform generator to drive the motor to operate cyclically, acyclically, or a combination of both to provide those corresponding waveforms and pressures. *See* Section VI.D (Paragraphs 140-145 discussing Xi

teaching claim 3). And it would have been within the level of skill in the art to do so by 2009. Aside from Xi, Eberhardt also taught that POSAs knew of and could incorporate a “signal generator” and “piston driver or pressure generator” in an accelerated valve tester to produce “sinusoidal, triangular, square wave or *random* pulses” to provide corresponding pressures to the fluid. See Ex-1036, 3:26-34.

5. Claims 8-9 and 12

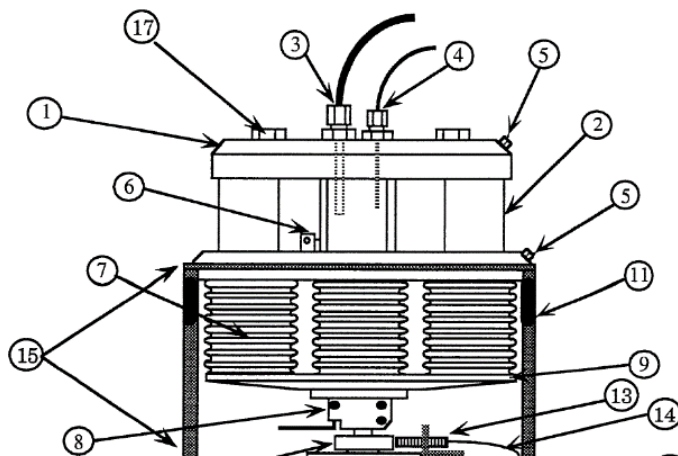
195. As explained above, Xi’s air chamber (11) and Dynatek’s capacitance tank each disclose compliance chambers and, consequently, the claimed excess volume area. The air in both chambers provides compliance in the system, so that it is “compressed” and provides a “spring force” to mitigate the water hammer effect. *See* element [1f.3]; *see also* Section VI.C (Paragraphs 137-138 explaining how Xi teaches these claim elements). The combination of Dynatek and Xi therefore teaches the limitations of claim 8. *See* Ex-1006, 19 (Dynatek’s capacitance tank “buffer[s] small variations in the systemic pressure”).

196. For the same reasons, they disclose “a volume for holding a gas ... that compresses under a pressure placed on the fluid” as recited in claim 12.

197. Last, as discussed above in Paragraphs 161 and 179-182, it would have been obvious to locate an air compliance chamber downstream of the test valve to be “a cavity within the fluid return chamber” as recited in claim 9.

6. Claim 13

198. Dynatek includes “[p]ressure transducer ports ... in the upper and lower heads 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.



199. In sum, in my opinion claims 2-4, 8-9, and 12-13 are all obvious over the combination of Dynatek and Xi.

VIII. GROUND C: CLAIMS 1-4, 7-10, AND 12-13 ARE OBVIOUS OVER GOLDSTEIN AND LU

A. Overview of Goldstein

200. Goldstein teaches a “closed, sterile pulsatile flow loop for studying tissue valves.” Ex-1007, Abstract. Goldstein explains that, in the closed loop system, “[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 the compliance can be “provided by

allowing the fluid to collect in a Lexan tank and to push against a flexible membrane.” Ex-1007, 10:30-35. Goldstein discloses a “piston pump” that pressurizes the system by “squeeze[ing]” a “flexible bladder” to “propel the blood analog fluid out through the aortic valve.” Ex-1007, 9:57-65.

201. Goldstein FIG. 3 illustrates the “in vitro flow loop for analyzing aortic valve function,” including the piston/pump chamber that cycles fluid (1) through a conduit to the “aortic test section,” (2) to a resistance and compliance unit; and (3) from the resistance and compliance unit back to the pump chamber:

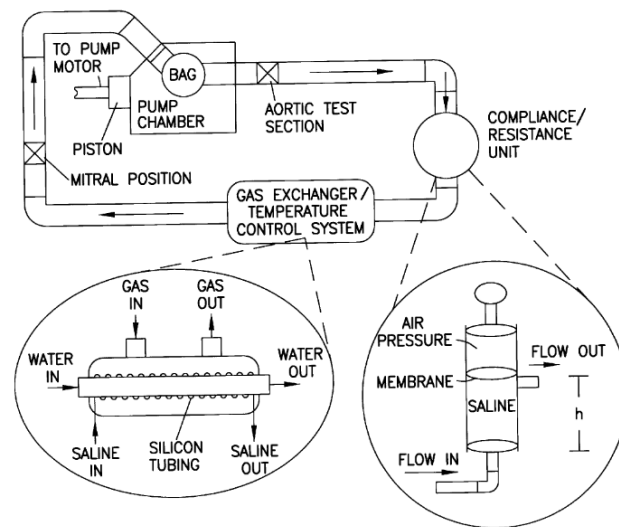


FIG. 3

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

B. Overview of Lu

202. See Section II.C.2 (Paragraphs 37-43) above for an overview of the teachings of Lu.

C. Motivation to combine Goldstein and Lu

203. Goldstein only expressly discloses using its system at cycle rates up to 120 beats per minute (bpm). Ex-1007, 9:67-10:4. But a POSA would be motivated by Lu's teachings about the benefits of accelerated testing (as well as other background knowledge and other art discussed above teaching accelerated systems) to speed up the rate to at least "an accelerated pulsed rate of greater than 200 [bpm]" as recited in claim 1. See Section II.C.2 (Paragraphs 37-43).

204. In view of the teachings of Lu, Iwasaki, and Xi at minimum, 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 effects that would become more pronounced during accelerated testing. A POSA could have used Lu's formulae to model how Goldstein's compliance might affect its performance. Ex-1005, 189. And running the system at the accelerated rate would result in Goldstein's compliance chamber performing the same functions, as the claimed "excess volume area." That is, it does what a POSA would have expected a compliance chamber to do.

205. Finally, a POSA would have been able to, and would not be deterred from, accelerating Goldstein above the expressly disclosed rates. Goldstein discloses that, at least as of its March 1997 filing date, it used a commercially available ViVitro Model WG 5891 waveform generator and ViVitro

Model SPS 3891 pump to drive the pulsatile flow in the system, which “allow[] the flow waveform to be changed easily.” Ex-1007, 9:57-60. A POSA around 2009 would expect that either (1) these components would enable rates of well over 200 bpm,²² and/or (2) that other components capable of operating at accelerated rates could be substituted for these off-the-shelf, ViVitro components.

206. Such a modification or replacement of the waveform generator to operate at accelerated speeds would have been within the level of skill of a POSA around 2009. In either case, a POSA would have reasonably expected to be able use the combined teachings of Goldstein and Lu to arrive at a system capable of accelerated rates of over 200 bpm.²³ This may include, for example, adjusting

²² For example, an archived version of a 2011 product page for ViVitro’s

“SuperPump” indicates that it supported cycle rates up to 220 bpm.

<https://web.archive.org/web/20110611072641/http://vivitrolabs.com:80/products/superpump>.

²³ The Krynauw thesis corroborates my opinions about the POSA’s ability to select and modify components to build a system capable of accelerated rates. Krynauw describes his selection, modeling, and development of the motor, pump, and control of a system capable of speeds up to 400 bpm that he developed between 2007 and 2009. Ex-1015, 36-56, 66.

Goldstein's system to decrease stroke volume as frequency is increased. *See, e.g.*, Ex-1005, 187 (discussing effect of increasing "amplitude (stroke volume)"). A POSA would simply change the waveform generator driving the piston to one with smaller amplitude and higher frequency. This would move the piston back and forth at a frequency for accelerated testing. The smaller stroke volume would be consistent with commercial accelerated wear testers. Adjusting the throttle and compliance is all that would be necessary to establish desired loading conditions. Thus, it would have been an obvious and simple modification, within the level of skill of a POSA, to modify Goldstein to operate the device at an accelerated rate—at minimum, at a "rate of greater than 200 beats per minute" as recited in claim 1.

207. Goldstein also discloses that its device can be used as a bioreactor for testing or conditioning implantable valves, Ex-1007, 1:41-49, but this disclosure would also not deter a POSA from accelerating the process. Elizondo discloses another bioreactor that is operated at accelerated speeds. Ex-1027, 1:1-10 (Title and Field), 11:33-12:54 (Examples including "Bioreactor Evaluation Equipment"). Thus, a POSA would have understood from Elizondo (in addition to Lu) that the benefits of accelerated testing could have been applied to bioreactor devices/testers like Goldstein's as well. And Elizondo shows the POSA would have had (at least) a reasonable expectation of success in accelerating a bioreactor device.

208. Finally, I understand that 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. In my opinion and based on my experience, I believe this is, at minimum, overstated. While there are certainly some different considerations, they are not “completely different” or “inherently at odds.” In my opinion, the Krynauw thesis indicates that POSAs would have considered *and did consider* developing devices combining features of both types of systems and/or capable of operating in both ranges. Krynauw’s thesis *title* itself reflects his goal to develop “an apparatus for hydrodynamic and fatigue testing of prosthetic aortic valves.” Ex-1015, 1. And it clearly states his goal was “to provide theoretical physiological loads from *physiological speeds* of 60BPM through to *accelerated speeds up to 1000BPM*.” Ex-1015, 3; *see also id.* at 17 (stating the “objectives outlined by the Tygerberg Cardiology Unit were to design, build and test an apparatus that can ... [a]llow the assessment of aortic valves under physiological conditions” and to “[a]llow for accelerated testing at speeds up to 1000BPM in order to test for cyclical load failure such as fatigue”).

D. Claim by claim analysis

1. Claim 1

209. An annotated version of Goldstein's FIG. 3 is shown below identifying the primary elements of claim 1. As illustrated, and discussed in detail below, Goldstein's device includes all the structures of claim 1 and the combination of Goldstein and Lu renders the claim obvious.

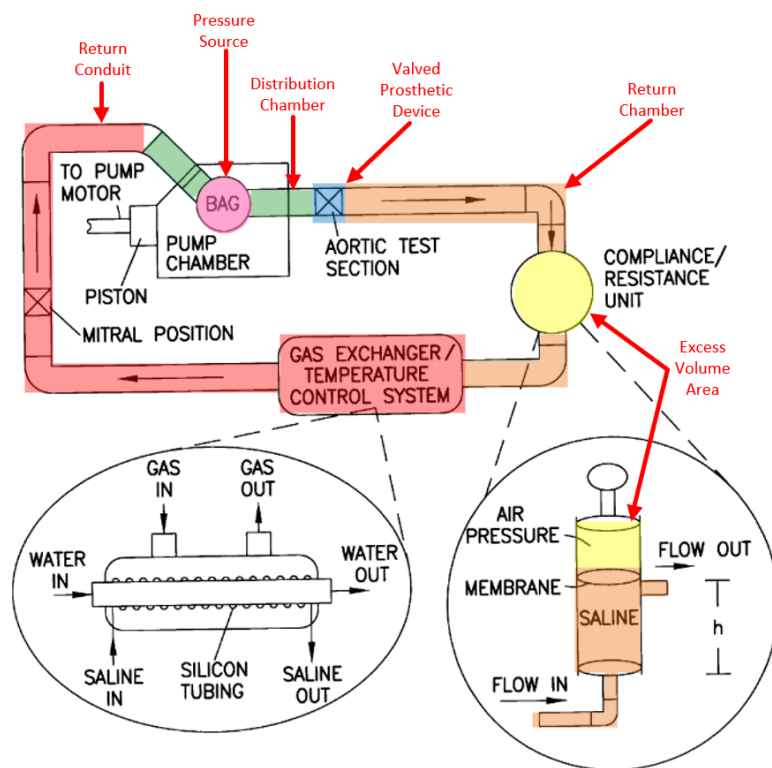


FIG. 3

a. Elements [1pre] and [1a]

210. Goldstein teaches a “closed, sterile pulsatile flow loop for studying tissue valves.” Ex-1007, Abstract. Goldstein teaches, “A piston pump (Vivitro Model SPS 3891) can be used to drive the pulsatile flow.” Ex-1007, 9:57-58. A “flexible rubber bladder” is “mount[e]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. The piston and/or “flexible rubber bladder” teach the claimed “pressure source.”

211. 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” using the off-the-shelf waveform generator and pump and/or others within the skill of a POSA. Ex-1007, 7:63-64, 9:57-60.

212. As explained in the Motivation to Combine section above, a POSA would be motivated by Lu (and Elizondo and others) to use an accelerated cycle rate with Goldstein’s device for testing heart valves, using an appropriately programmed waveform generator. *See* Ex-1007, 9:58-60 (teaching waveforms can “easily” be changed using off-the-shelf waveform generator).

b. Element [1b]

213. Goldstein discloses a “*closed*, sterile pulsatile flow loop.” (i.e., a test chamber). Ex-1007, Abstract. Goldstein further teaches that pressures can be formed in the loop by clamping the tubing or by raising the compliance chamber. Ex-1007, 10:38-42. A POSA would have therefore understood that Goldstein’s “closed” flow loop is pressurizable because Goldstein discloses creating pressures

inside the closed loop. Goldstein therefore teaches the claimed “pressurizable test chamber.”

c. Element [1c] to [1e] — distribution chamber, return chamber, and fluid return conduit

214. Claim 1 of Goldstein recites: [c] “a fluid conduit leading from the bladder to a test section,” [d] “a fluid conduit leading from the test section to a downstream compliance and resistance element,” and [e] “a fluid conduit leading from the compliance and resistance element to the bladder.” Ex-1007, 24:14-39 (claim 1).

215. These three elements of claim 1 (shown in FIG 3.), respectively, teach the claimed [c] distribution chamber on one side of the valve, which is in fluid communication with the pump/bladder (i.e., pressure source); [d] return chamber on the other side of the valve; and [e] fluid return conduit that structurally and fluidly connects the return chamber to the distribution chamber.

d. Element [1f]

216. Goldstein teaches: “An adjustable resistance and compliance element (FIG. 3) is placed downstream to simulate the peripheral resistance of the circulation.” Ex-1007, 10:27-30. “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. “The downstream compliance and resistance will be adjusted” to “duplicat[e] the back pressure on the aortic valve.” Ex-1007, 10:44-47.

217. A POSA would recognize Goldstein’s “compliance element” as a familiar air compliance chamber structure. And a POSA would have been able to use Lu’s teachings (in addition to its background knowledge) of various formulae relating compliance to other parameters in such a test system to adapt the Goldstein device for accelerated speeds. Ex-1007, 2:8-14 (teaching POSAs could examine the effect of and optimize for many parameters).

218. 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-1007, 10:30-47. The combination of Goldstein and Lu therefore teaches the claimed excess volume area.

219. In sum, in my opinion, claim 1 is obvious over the combination of Goldstein and Lu.

2. Claims 2 and 4

220. Goldstein teaches the piston pump “can displace the water; this in turn will squeeze the flexible bladder and propel the ... fluid In this way the piston pump controls flow through the system” Ex-1007, 9:63-67. Goldstein claim 1 also recites that “the pump serv[es] to displace the fluid within the chamber so as

to simulate a pulsatile flow.” And Goldstein FIG. 3 identifies a “pump motor” connected to the piston. The pump is therefore connected to a motor and provides the pressure source to increase and decrease pressure on the fluid. Goldstein therefore teaches **claim 2**.

221. 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; *see also* Ex-1019, 423 (describing both the “Rowan Ash” and “Tsinghua-type” accelerated fatigue testers as having a “linear motor”).

222. As described above in Section II.D, Paragraph 60 above, the prior art teaches a diversity of pumps and drive systems were known to be used in various kinds of artificial valve test systems. It was therefore within the skill of a POSA to substitute a linear motor for Goldstein’s pump motor, and the result—providing the motive force to drive the fluid—would have been predictable. It would have therefore been obvious to a POSA to use a linear motor recited in **claim 4** to drive the piston in a device according to Goldstein.

3. Claim 3

223. 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.

224. Lu illustrates transvalvular pressure measurements and forces including cyclic and acyclic components. Ex-1005, 193-194. And Lu teaches use of a "random wave generator to create the driving waveform," which "directly effects the loading on the test valve." Ex-1004, 190-191.

225. 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 one such as taught by Lu, to arrive at the limitation of claim 3. And it would have been within the level of skill in the art to do so by 2009. For example, Eberhardt (a 1993 patent), teaches that POSAs knew of and could incorporate a "signal generator" and "piston driver or pressure generator" in an accelerated valve tester to produce "sinusoidal, triangular, square wave or random pulses" to provide corresponding pressures to the fluid. See Ex-1036, 3:26-34. See also Ex-1004, 7 (Xi teaching its "arbitrary waveform generator" to produce the "required waveform").

4. Claims 8-9 and 12

226. 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 pressurized air inside is compressed and exerts a spring force back onto the membrane and fluid. The spring force of the air provides the “compliance” that mitigates the water hammer effect, particularly (but not only) at accelerated rates. Goldstein therefore teaches the limitations of **claims 8 and 12**.

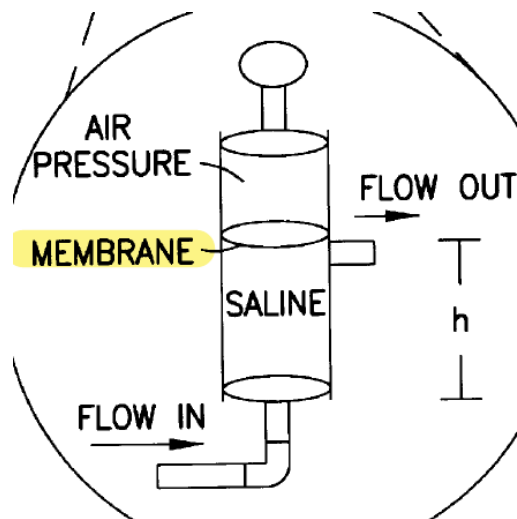
227. Goldstein’s “compliance” chamber is “downstream” of the valve, within the identified return chamber. Ex-1007, 9:52-57, FIG. 3. Thus Goldstein teaches the limitation of **claim 9**.

5. Claims 7 and 10

228. Claims 7 and 10 of the ’935 patent require an “elastomeric material” or “membrane” that separates the excess volume area (or “compliance chamber,” in claim 10) from the fluid. Claim 7 recites that the material “expands and contracts in response to” the fluid pressure changes.

229. Goldstein’s teaches its compliance chamber has a “flexible membrane” separating fluid from air, so that the fluid “push[es] against” the membrane. Ex-1007, 10:30-32. While Goldstein does not expressly teach what kind of material comprises the “flexible membrane” in the compliance chamber, it

does teach that the piston action “squeeze” the “*flexible rubber* bladder” to propel fluid through the system. Ex-1007, 9:61-67. Claim 1 of Goldstein also expressly recites the “flexible *elastomeric* bladder.” Ex-1007, 24:17. So a POSA would have found it obvious to use an “elastomeric” material to form the “flexible membrane” of the compliance chamber. Thus, Goldstein teaches or discloses claims 7 and 10.



6. Claim 13

230. Goldstein teaches “two pressure taps” for “pressure transducers ... located both upstream and downstream of the valve being tested.” Ex-1007, 11:31-37. Thus, Goldstein teaches the first and second “ports” on either side of the valve that are configured to receive sensors.

231. In sum, in my opinion claims 2-4, 7-10, and 12-13 are all obvious over the combination of Goldstein and Lu.

IX. CLAIMS 7 AND 10 ARE OBVIOUS OVER THE COMBINATIONS OF XI AND GOLSTEIN (*GROUND D*) OR DYNATEX, XI, AND GOLDSTEIN (*GROUND E*)

232. As stated above, in my opinion Xi discloses the limitations of claims 1 and 9, and the combination of Dynatek and Xi renders obvious claims 1 and 9, from which claims 7 and 10 depend. And I discussed above how Goldstein's flexible membrane within the compliance chamber, separating the air and fluid, teaches the elastomeric membrane/material limitations of claims 7 and 10.

233. In my experience, POSAs conducting long-term durability testing were and are motivated to keep the operating fluid sterile or at least clean to prevent the growth of bacteria or mold. After some time of conducting tests (e.g., a week) operators stop the machine, drain the fluid, and replace it with clean fluid. *Dynatek* expressly teaches a need that "[m]achine sterility should be maintained *throughout* testing." Ex-1006, 31. A POSA is therefore motivated to maintain the sterility or cleanliness of the fluid. But Goldstein teaches that its flexible membrane "separates the sterile fluid from the unfiltered air." Ex-1007, 10:30-33.

234. A POSA would have therefore recognized from Goldstein that using a membrane to separate the fluid from the air would help preserve the sterility/cleanliness of the fluid in either (1) Xi or (2) an accelerated tester according to the combined teachings of Dynatek and Xi. Doing so would keep the fluid cleaner for longer and therefore reduce the number of times the drain and

refill process needed to be completed. Further, the air compliance chambers of Goldstein and Xi are similar structures that operate in the same way. So using Goldstein's simple technique of a flexible, elastomeric membrane to preserve sterility of the fluid would improve the similar devices of Xi and Dynatek combined with Xi in the same way. Accordingly, a POSA would have found the limitations of claims 7 and 10 obvious in view of the combination of (1) Xi and Goldstein (Ground D) or (2) Dynatek, Xi, and Goldstein (Ground E).

X. CONCLUSION

235. For the reasons described above, it is my opinion that the Challenged Claims of the '935 patent are unpatentable.

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code

Executed on: January 24, 2024

By:

 LAKSHMI DAS