

Exhibit 2003

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 MICHAEL J. GIRARD

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I, Michael J. Girard, hereby declare and state as follows:

1. I have been retained by Plaintiff Biomedical Device Consultants & Laboratories of Colorado, LLC (“BDC”) to offer technical analysis and opinions regarding various issues relevant to this proceeding, including validity of U.S. Patent No. 9,237,935 (“the ’935 Patent”). I have personal knowledge of the facts herein, and if called as a witness, I could and would testify competently thereto.

2. My education includes a Bachelor of Science in Civil (Structural) Engineering from the University of Illinois, and a Master of Business Administration from the University of St. Thomas. I have been a licensed engineer in both Minnesota (Reg. No. 0170354) and California (Reg. No. C 043378).

3. I have 44 years of experience in engineering, thirty-four of which are in the medical device industry. Within the medical device industry, I have focused specifically on the development and testing of cardiac valves and related devices for over 26 years. In 1990, I began working for St. Jude Medical (now part of Abbott Laboratories) as a Senior Design Engineer and performed structural and mechanical design and analyses of heart valves and components. My work included analyses using simulation of structural/mechanical heart valves utilizing ANSYS software, and I also led efforts involving simulation activities for blood flow through heart valves utilizing FIDAP computational fluid dynamics methods. In the decades that followed, I took on many roles in development and testing of heart valves, including

as Senior Director of Research & Development of St. Jude Medical (now part of Abbott Laboratories), where I was responsible for the management and leadership of all research and development activities for the cardiac surgery business, and as Vice President of Research & Development at HLT, Inc., where I oversaw the redesign and design verification testing of a failed product design, and ultimately brought the redesigned product back into a US clinical trial.

4. I am a named inventor on 52 issued U.S. Patents, with additional applications pending. All of these patents are in the field of cardiovascular medical devices and related technology.

5. I am currently the President of my own consulting firm, Girard Technical Services, Inc. My firm provides research and development, engineering, and technical management consulting services in the medical device industry.

6. I am very familiar with heart valve testing utilizing pulse duplicator test equipment for physiological conditions, as well as both real-time (or quasi-real time) and accelerated durability test equipment and the requirements of such testing. My experience includes more than 26 years of heart valve experience, including work for several medical device companies in the role of development and testing of both surgical and transcatheter delivered prosthetic heart valves. Testing of prosthetic heart valves includes pulse duplicators for hydrodynamic testing using equipment like the Goldstein system identified by Petitioner (Ex-1007) that can be used for real-

time or quasi-real time durability testing, or durability testing at accelerated rates using equipment like the system described in the '935 Patent. The development of heart valve replacements requires the evaluation of the devices using pulse duplicators and durability test systems. I have been involved in the testing and evaluation of numerous heart valve designs at every company where I have been employed involving heart valve products (*e.g.*, St. Jude Medical, JenaValve Technology and HLT) and many of the companies where I have provided consulting support to test and evaluate devices in accordance with ISO 5840 and FDA requirements. This testing has involved both internal testing and utilization of test services provided by outside test labs like BDC Labs, VIVITRO Labs, the Helmholtz Institute in Aachen (HIA) Germany and their spin-out company ac.biomed. I have written test protocols and reports and either performed or coordinated tests for real-time and accelerated durability evaluations. The test equipment used has included custom developed proprietary systems and commercial systems, including both BDC and VIVITRO equipment. I am very familiar with the advantages and disadvantages involved with the use of various test equipment for both real-time and accelerated durability testing.

7. Therefore, I am very familiar with both real-time and accelerated durability test equipment and the requirements of such testing. My curriculum vitae is attached hereto as Exhibit A.

I. PERSON OF ORDINARY SKILL IN THE ART

8. In its Petition, ViVitro suggests that a person of ordinary skill in the art “would have had at least (i) a bachelor’s degree in biomedical engineering, or a related field, such as mechanical engineering, biomechanical engineering, or bioengineering, who also has at least 3 years of experience with cardiovascular devices; or (ii) an advanced degree in the same areas of academic study with at least 1 year[] of experience with cardiovascular devices.”

9. ViVitro does not provide a full list of what it considers to be “related fields.” I note that ViVitro’s preferred expert has a bachelor’s degree in Civil Engineering (like myself), and does not have any degrees in biomedical engineering, biomechanical engineering or bioengineering. I assume that ViVitro considers civil engineering to be a “related field” and, in my opinion, a degree in civil engineering could supply appropriate education for a POSA, if the person also has adequate experience relating to the testing of heart valves within flow-based test systems.

10. I believe that a POSA would have more years of experience than what ViVitro describes, and would have experience that is more specific than ViVitro proposes. A person who has experience with “cardiovascular devices” would include, for example, a person who works on stents or pacemakers but has no experience with heart valves or testing of heart valves using a flow-based system. Therefore, I believe that a person of ordinary skill in the art would have a bachelor’s

degree in engineering and 4 years of experience with evaluating heart valves or valve repair devices in flow-based test systems or an advanced degree in engineering with 2 years of that experience.

II. BACKGROUND OF THE FIELD

11. This proceeding concerns equipment used for durability or accelerated wear testing of heart valves. Before any medical device, such as a prosthetic heart valve, is marketed, it must meet certain regulatory standards. International bodies, such as the International Organization for Standardization (“ISO”), set certain standards, such as those for testing the durability of medical devices, including heart valves. The specific standards for heart valves are defined in ISO 5840.

A. Different Types of Testing

12. Prosthetic heart valves must be tested to ensure that they will function for the anticipated life of the patient by opening and closing the valve leaflets under flows and pressures that are present within the human vascular system. The normal human heart beats about 40 million times each year.

13. The test requirements for evaluating prosthetic heart valves according to the above-mentioned standards require that the valves be able to survive and function for hundreds of millions of cycles (*e.g.*, at least 5 years or 200 million cycles for biological heart valve replacements). The valves must also be able operate over

a specific range of opening and closing pressures that simulate physiological conditions.

14. Testing requires fluid flow through the valve and creating a pressure differential across the test valve when closed at a certain minimum pressure for a certain length of the cycle. Therefore, testing standards require that a specific pressure differential be generated across the valve when closed for at least 5% of each cycle. This is commonly referred to as “back pressure.”¹

15. There are different types of testing: real-time, quasi-real time and accelerated. Real-time testing, as it sounds, tests valves using a number of beats per minute (“bpm”) that approximates the typical normal heart rate. Generally, real-time testing is performed for short periods of time to evaluate hydrodynamic valve performance. Quasi-real time, as defined by ISO 5840 (2005) (Section 3.44), ranges

¹ Because the *differential* pressure requirements necessitate a variance between the pressures on each side of the valve, it is important to know the pressure at each side of the valve. In a closed system, two measurements are needed (one on each side of the valve). As will be discussed below, in Xi—an open system—only one measurement is discussed in determining the differential pressure, because the pressure on the side of the valve open to atmosphere is already known—atmospheric pressure.

from rates that correlate to normal (typically 70bpm) to high normal rates of 200 bpm.² Durability testing at rates as high as 200 bpm has traditionally been referred to as quasi-real time durability testing, but the most recent ISO 5840 describes this testing as real-time durability testing. Accelerated testing involves running the tester at rates much higher than a normal heart rate. Most accelerated testers today are designed to run at 600-1200 bpm—roughly 8-17 times as fast as a normal heart rate.

16. Durability testing performed at an accelerated rate allows the user to complete the required hundreds of millions of cycles in a commercially viable timeframe. Using current technology at a typical accelerated cycle rate of 800 bpm, testing takes approximately six months to simulate the equivalent of 5 years (i.e. 200 million cycles).

B. Operation of Early Systems

17. Testing systems—whether operating at real-time or accelerated rates—must manage different pressure differentials.

- a. A test system is designed to operate at a prescribed **System Operating Pressure**, which is the prescribed system pressure that the test system is operating at. This system pressure may be above atmospheric

² Dr. Dasi states that quasi-real time can include speeds as slow as 30 bpm. *See* Dasi

¶ 25. This is incorrect.

pressure for various reasons, such as to suppress cavitation. The System Operating Pressure is established and set prior to the system cycling and describes an operating state required for the system. For example, the Dynatek system allows for systemic pressure to be established and maintained through the capacitance tank. Dynatek at 11 (Step 41) (“Adjust the systemic pressure by pressurizing the capacitance tank to 2-3 psig as indicated on the pressure gauge.”); *id.* at 15 (“An acrylic capacitance tank is used to buffer small variations in the systemic pressure which arise from transient small leakage and installed between the controller box and the testing unit via Tygon tubing. Whenever the system pressure is adjusted or released it should be done through the stopcock on the capacitance tank.”). The ’935 Patented invention also allows the system pressure to be set and adjusted. ’935 Patent at 11:21-27 (“Once fluid has been filled to a desired level, in some scenarios, the fatigue testing system 100 may be additionally pressurized with air or another gas via an air source 131, *e.g.*, an air compressor or sealed pressurized volume, connected to the air inlet 152 in the return chamber 136 or via the compliance access ports 125 in the compliance chambers 135. ...”).

- b. In addition, each system must manage the **Differential Pressure** across a closed valve (also called “back pressure”), which is the pressure applied across the closed valve to define the loading conditions. This Differential Pressure must be controlled by the system such that there is sufficient Differential Pressure to be within the testing parameters required (i.e., above the minimum target for at least 5% of the cycle), but the system should not apply excess pressure that could cause the valve to fail during testing when it would not fail in *in vivo* conditions.
- c. As described in Section III below, the '935 Patent references yet another type of pressure that does not exist in the prior systems. This pressure, which I will refer to as **Excess Volume Pressure**, is generated by the fluid drive mechanism displacing fluid in the system and changing the total available volume of the test system. That is, as a result of the drive stroke, there is less volume for the contents of the system (such as air and fluid), creating pressure or, stated another way, putting the system under compression.

18. The way in which real-time testers operate is very different than the way in which the early accelerated testers operated.

19. Some real-time testers, such as Pickard (1987), had a system that essentially imitated the circulatory system, with a mounted test valve in a “mock

circulatory loop,” through which fluid flowed. *See, e.g.*, Ex-1018 at Abstract. These are sometimes referred to as closed system pulse duplicators, and are intended to run at physiological rates and conditions. However, it is not possible to convert a real-time tester such as Pickard into an accelerated tester simply by speeding up the rate; it cannot maintain the pressure conditions needed (i.e. the back pressure necessary to test the valve). As the system is operated faster, the fluid flow and fluid momentum will prevent the system from creating adequate back pressure at the test valve. Real-time pulse duplicator test systems are designed to create physiological conditions, including flow rates as well as system pressures. Running these systems at speeds higher than physiological rates, one encounters issues that may vary depending on the system design and configuration. These issues may include drive system difficulties, flow rates and/or pressures that are required for achieving conditions required for performing accelerated durability testing.

20. Instead of replicating the physiological test systems (because they could not), the accelerated testers available at the time of the '935 Patent invention—ViVitro's prior HiCycle Durability Tester and the Dynatek Labs device—used other mechanisms to effect the opening and closing of the test valve. These products aimed to create pressure differentials of a given amount and duration to satisfy the testing standards using alternative means.

21. ViVitro's prior product (like the Xi reference ViVitro now cites), relied on movement of an artificial heart valve to create the valve opening and closing. Instead of moving the fluid in a circulatory system through the valve, the ViVitro HiCycle moved the valve up and down through the fluid.

22. The Dynatek device did not use a pulse duplicator method either; it used a swash plate to transfer fluid back and forth amongst different chambers and relies upon the lengthening of bellows to draw fluid through (and thus open) the test valve.

23. Many prior accelerated durability testers were generally able to meet the minimum backpressure requirements for accelerated durability testing, but they had disadvantages. For example, the ViVitro HiCycle tester introduced undesirable dynamic loads depending on the test valve design configuration and cycle rate. The Dynatek tester does not isolate the conditions between adjacent test valves, which in some cases requires the backpressure across some valves being set higher than desired to maintain a minimum backpressure across another valve being tested. This can reduce the durability life of the valve experiencing higher than the desired minimum backpressure that is required. In addition, these systems and others had issues with high frequency pressure noise in the system related to undesirable gas bubbles or pressure spikes.

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

ago. They would not have come up with different ways to operate an accelerated tester, such as using a swashplate or using the valve as pressure source.

C. Compliance

25. The concept of “compliance” is important in this proceeding. The Dasi Declaration spends many pages addressing how the term “compliance” appears in descriptions of prior standards and the prior art. I understand Dr. Dasi to use “compliance” to mean the ability to absorb pressure. *See* Ex-1002 (“Dasi Decl.”) ¶¶

24. Dr. Dasi then erroneously concludes that, because certain compliance mechanisms were known, the specific excess volume area claimed in the ’935 Patent that also provides a type of compliance was also known.³ This is incorrect, for the reasons described in detail below. But perhaps more fundamentally, Dr. Dasi’s analysis incorrectly conflates several very different problems and solutions.

26. The term “compliance” is a general category, much like the term vehicle. Just as the disclosure of a drivetrain in the Model T in the 1920s did not disclose all patentable inventions related to the drivetrain in the 2024 Tesla, the use

³ *See, e.g.*, ’935 Patent at claim 1 (“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 test system fluid when the test system fluid is under compression”).

of compliance in some prior instance to avoid a water hammer effect or some other dynamic issue does not anticipate or render obvious the claimed excess volume area of the '935 Patent and all of its features.

27. For example, old-fashioned fire trucks used compliance chambers to mitigate the effects of the water hammer effect—to dampen high frequency variations from a valve shutting. More specifically, the water hammer effect is caused by the rapid closing of a valve or abrupt change in direction of the fluid. The momentum of the fluid creates a pressure wave that propagates throughout the system.

28. As described in Section II.B above, there are multiple types of pressure sources and issues in both real-time and accelerated durability testers. Accordingly, there are different types of compliance methods to address different issues. Two examples are below:

- a. Real-time pulse duplicator systems can simulate conditions for testing any of the four valves of the heart, but early systems were primarily focused on the testing and evaluation of the aortic valve. Therefore, the following description of operation and configuration is focused on configurations for testing the aortic valve. These real-time pulse duplicator systems sought to replicate the conditions of the circulatory system by including compliance that would mimic the distensibility of

arteries and resistance of flow to the venous system. In the vascular system, blood flows from the arteries to veins by passing through arterioles, capillaries and then arterioles. These small vessels restrict flow from the high-pressure arterial system to the low-pressure venous system. Early pulse duplicator systems primarily utilized compliance to simulate the flow resistance from arterial distensibility and the small vessels between the arterial and venous systems. This resistance helps control the pulse duplicator System Operating Pressure by increasing pressure in the system and regulating the backpressure across the closed valve when the pump retracts. These pulse duplicator systems commonly utilized a flow restriction such as a control valve in combination with a compliance chamber to optimally control the pressures within physiological ranges.

- b. In addition to helping to control the System Operating Pressure, compliance was also used to reduce pressure spikes when testing rigid valve designs such as mechanical valve replacements. These valves generally have rigid components that close quickly and stop abruptly when subjected to back-pressures. This closing action can create a water hammer effect that results in dynamic high frequency pressure spikes and attenuations that are undesirable in the pressure signal. The

addition of compliance in the pulse duplicator was utilized to absorb and damp out the high frequency noise in the pressure signal. Some systems incorporated the use of multiple compliance chambers to reduce both high frequency pressure fluctuations and provide the resistance described above.

29. In addition, the term “compliance” may be used in ways that are completely unrelated to fluid flow dynamics. For example, in the context of testing stentless valves, a tester must have *mechanical* compliance that would correspond to *in vivo* vessel compliance at the implant location, as outlined in ISO 5840.⁴ Most replacement valves include a relatively rigid stent or housing that support the leaflets that interact with the blood flow. Although stentless homografts were utilized for some early valve replacements, bioprosthetic stentless valves were not very successful or common until the 1990s when companies developed new devices. The regulatory agencies that review and approve stentless valves for clinical use realized that the performance of these devices in pulse duplicators and accelerated

⁴ The fact that Dr. Dasi cites this provision, as evidence supposedly related to compliance of fluid dynamic pressures, Dasi Decl. ¶ 25, illustrates that Dr. Dasi is improperly equating all different variations within a category (*i.e.*, equating a Model T to a Tesla).

durability systems were impacted by the method of supporting them in the holders of these test systems. These stentless devices rely on the stiffness of the native tissue when surgically sewn into the body. Therefore, Annex F of ISO 5840:2005 provides requirements for the mechanical compliance of the holder that the stentless valve is supported by in the pulse duplicator or accelerated durability tester, so that it simulates how the valve is supported *in vivo*. The compliance that is required by Annex F of ISO 5840 is a mechanical requirement and entirely different from fluid compliance.

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

31. Dr. Dasi focuses on prior art compliance that can “absorb pressure.” *See, e.g.,* Dasi Decl. ¶¶ 25-27. In doing so, Dr. Dasi ignores the fact that, in the context of the '935 Patent, “compliance” must *also* be able to accept volume that is displaced due to operation of the drive mechanism. Thus, Dr. Dasi creates a false

equivalence between use of the word “compliance” in the prior art and use of the specifically-defined term “compliance” in the ’935 Patent.

32. In other words, not all compliance mechanisms are the same. The *location* and *structure* of the compliance mechanism and the configuration of the test system affects how it will operate and what types of pressures it can absorb.

III. OVERVIEW OF THE ’935 PATENT

A. Problems in Prior Art Technology

33. The ’935 Patent identifies several problems with the prior art testers, which included those using metallic bellows, or piston and cylinder arrangements. ’935 Patent at 1:27-43.

34. Driving mechanisms in the prior art had limited control over closing rates and would often produce “pressure spikes” when the systems maintain pressure above the testing threshold for the amount of time required by testing standards. These pressure spikes are undesirable because they wear out valves during testing faster than they would be worn out in the human body, causing false early test failures.

35. Prior art valve testing devices also experienced operational problems. For example, the ’935 Patent references a prior art system that, like the Dynatek reference, used a flexible metallic bellows to drive fluid through the system. ’935 Patent at 1:34-36. However, a higher load is required to drive the metallic bellows

(than, say a drive mechanism with a piston like the '935 Patent invention) and can thus, impact the reliability of the test system and increase maintenance requirements which increases the already lengthy durability testing process. '935 Patent at 1:37-38. Bellows systems can also resonate at frequency which makes them harder to run at higher speeds. '935 Patent at 1:39-40. As another example, prior art devices that use piston and cylinder arrangements are problematic because the seals are subjected to friction and have a “severely limited life in high cycle applications.” '935 Patent at 1:40-43.

36. The '935 Patent describes a fundamentally different way of operating an accelerated durability tester that avoids these problems: the system mitigates pressure spikes and operates more effectively and efficiently than the prior systems. In other words, since the '935 Patented invention operates with better control than the prior art systems, it can run closer to the target testing range and thus operate more efficiently.

B. Overview of the '935 Patent

37. The '935 Patent covers a device for accelerated testing of valved prosthetics with several components including a pressurizable test chamber and an “excess volume area” that is in fluid communication with a return chamber.

38. The test fluid in the system is driven by a fluid drive member—the piston. The fluid drive member drives fluid upward and laterally into the fluid

distribution chambers. The test fluid then passes through the prosthetic valve being tested and into the fluid return chamber. The excess volume area, which is in fluid communication with the fluid return chamber, accepts excess volume during the drive stroke, and the test fluid then proceeds downward through the fluid return conduit.

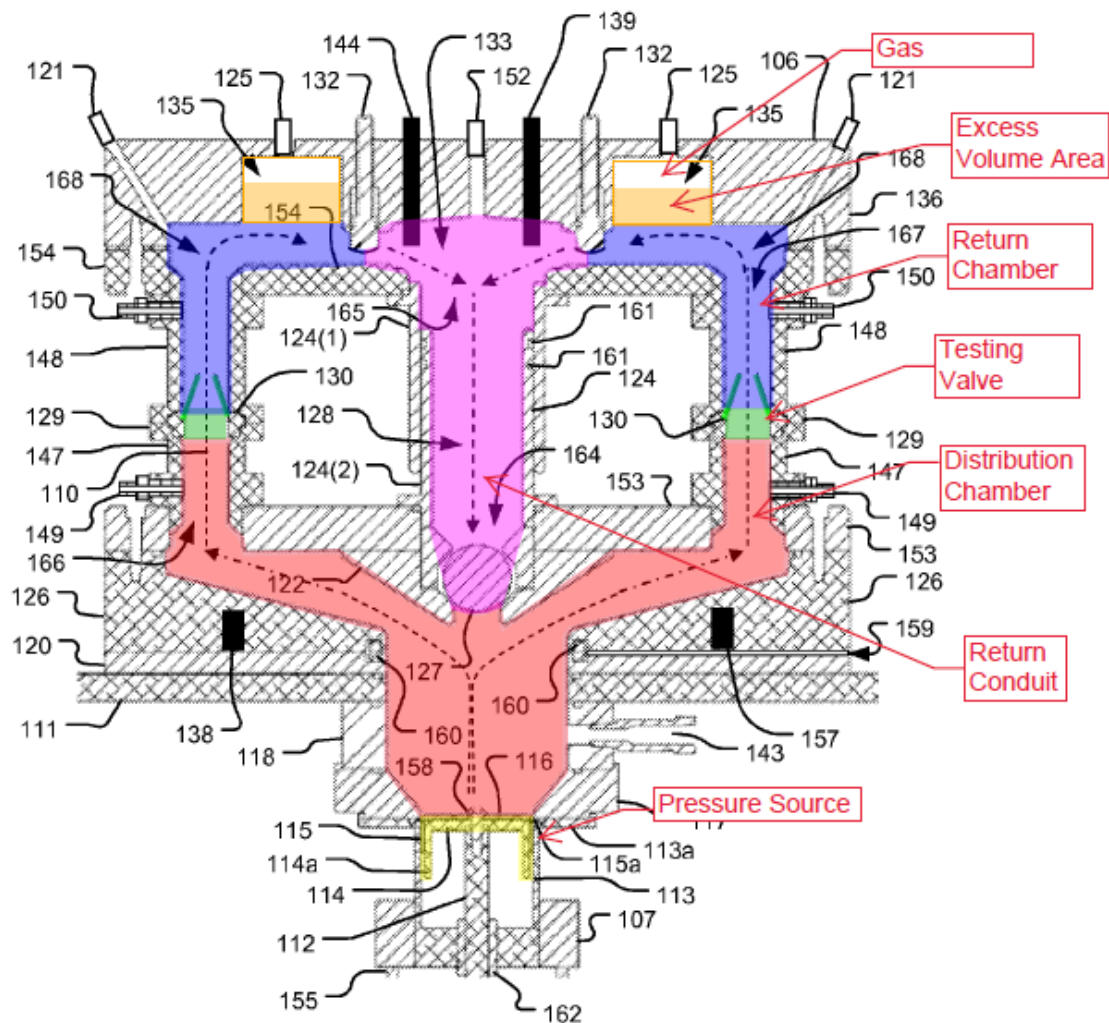


Fig. 3

39. The language of claim 1 describes this flow of the test fluid through the system:

A device for accelerated cyclic testing of a valved prosthetic device comprising

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

a pressurizable test chamber for containing the test system fluid and further comprising

a fluid distribution chamber positioned *on a first side of the valved prosthetic device* and *in fluid communication with the pressure source*;

a fluid return chamber positioned on *a second side of the valved prosthetic device*;

a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and

an *excess volume area* capable of operating at the accelerated pulsed rate, wherein the excess volume area is *in fluid communication with the fluid return chamber* providing a volume for storing a volume of a test system fluid when the test system fluid is under compression.

40. The design of the '935 Patented invention is such that the volume of the test chamber changes depending on whether the system is in a drive stroke or a return stroke.

41. During a drive stroke, the fluid drive member presses upward and decreases the total volume of the test chamber. During a return stroke, the fluid drive member moves downward and the total volume of the test chamber increases.

42. The '935 Patented invention is a closed pressurizable system; the boundaries of the test chamber are defined by structure at all points. Liquid—such as the test fluid in the '935 Patented invention—is incompressible, meaning that it generally does not decrease in volume when pressure is applied to it. Without an excess volume area that provides compliance, the compressive forces could either cause a break and leakage or cause the motor to become overwhelmed by system pressure and no longer be able to operate.

C. The Excess Volume Area

43. The claimed excess volume area in the '935 Patent performs a critical function for the system—it provides a space to store extra volume. The excess volume area also dampens the effect of pressure changes. The previous examples of compliance mechanisms cited by Dr. Dasi do not perform this first function—to store excess volume.

44. As described above, during the drive stroke, the fluid drive member moves upward and decreases the total volume of the test chamber. Per the '935 Patent, *“an excess volume area capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid communication with the fluid return*

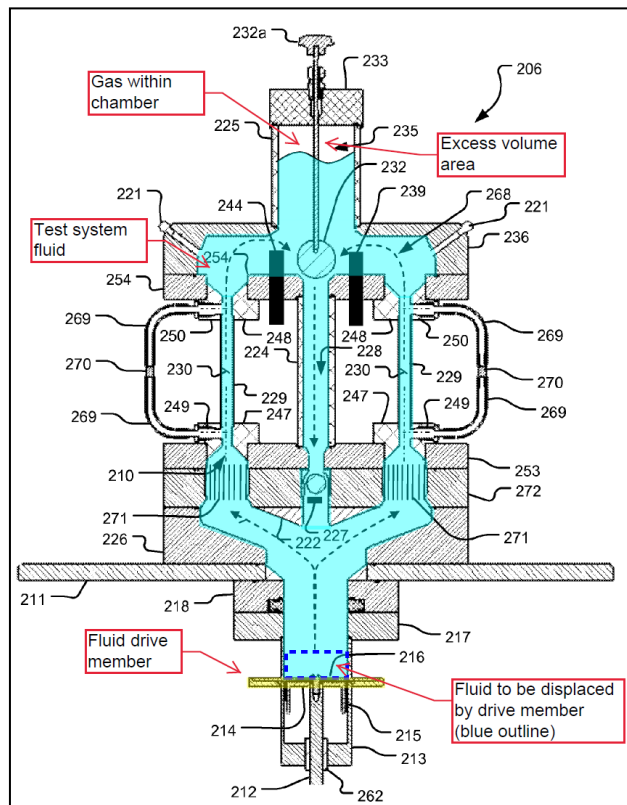
chamber providing a volume for storing a volume of a test system fluid when the test system fluid is under compression.” In understanding this term, it is important to take into account the phrase, “under compression”, which results from a scenario whereby, the pressurizable test chamber is filled by an incompressible fluid and then is subjected to a change in its volume. The **change in the volume** of the test chamber is being imparted by the pressure source. ’935 Patent at 13:10-13 (“The fluid drive member, i.e., the piston 214, is provided within the cylinder 213 to pressurize and drive the working fluid upward through the drive adapter 217 and the plenum 218.”).

45. The excess volume area allows the ’935 Patented invention to accommodate the fluid that is displaced when the test chamber decreases in total volume, and is made possible by a 3-dimensional space in the test chamber. Gas (unlike liquid) is compressible, and can decrease in volume when pressure is applied to it. Thus, when the drive member applies pressure and reduces the volume of the test chamber, the gas can compress to create extra volume for the incompressible fluid to flow into.

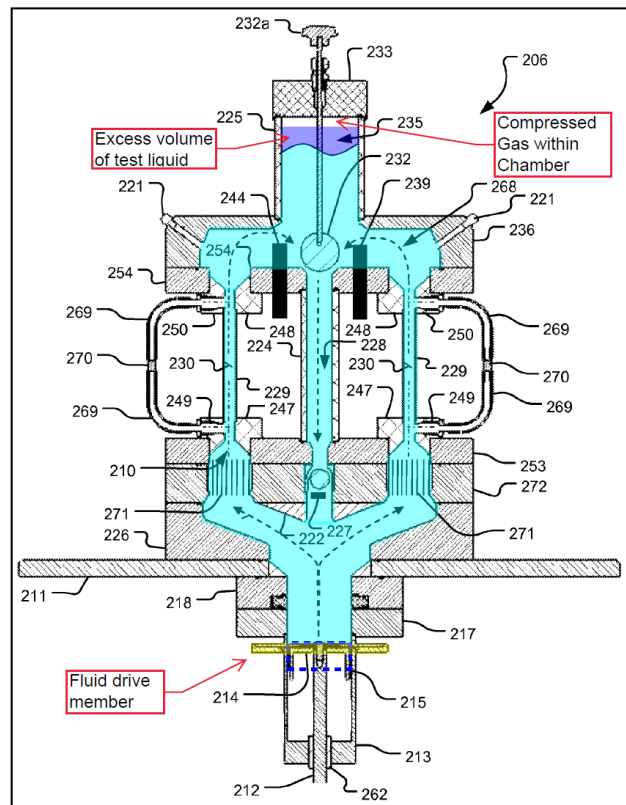
46. When the piston is applying compression to the system, the excess volume area is occupied by fluid that has entered it from the fluid return chamber. When the piston is retracted on its backstroke, the excess volume area returns to being occupied by a compressible gas. The space referred to as the excess volume

area is in “fluid communication with the fluid return chamber” when the gas is displaced during system compression. This principle is illustrated below:

Return stroke:



Drive stroke:



47. When the system is driving test fluid through the prosthetic valve, the excess volume area is able to store the excess volume downstream of the prosthetic test valve. This can alleviate some of the system pressure during the drive stroke (what I called the “Excess Volume Pressure” in paragraph 17-c above).

48. During the forward flow phase, the excess volume area also provides compliance in that it provides some resistance to help regulate flow and pressure, while minimizing unnatural and undesirable pressure noise or spikes. Therefore, the

excess volume area improves the testing environment by minimizing unnatural and undesirable pressure spikes and provides advantages of speed and longevity in the drive system.

49. At the top of the stroke, the gas is compressed to its greatest pressure and stored energy. As the stroke of the pressure source reverses, the stored energy is converted and recoils the fluid stored within the excess volume area back towards the original volume. This action causes the valve to close and returns the remaining excess downstream volume to the pump. The compliance provided by the excess volume area also helps to minimize unnatural and undesirable valve closing pressure spikes (i.e. water hammer, vibration or leaflet bounce, etc.), that can negatively impact the durability of the prosthetic test valve.

50. The excess volume area provides a number of functions throughout each test cycle, and without the excess volume area, the '935 Patented system would not function.

IV. CLAIM CONSTRUCTION

51. I understand that claim terms are to be given the ordinary and customary meaning of the term as evaluated from the perspective of one of ordinary skill in the art at the time of the invention. I further understand that the claim term is to be read in context of the claim itself and in the context of the entire patent,

including the specification, but that limitations from the specification should not be read into the claims.

52. Most of the language used in the relevant claims—claims 1-4, 8-9 and 12-13—can be readily understood by a person of ordinary skill in the art without any construction by a court, and the plain and ordinary meaning should suffice.

A. “in fluid communication”

53. I understand that Dr. Dasi and Petitioner contend that two elements are “in fluid communication” regardless of their proximity, spatial relationship, or intervening structures so long as fluid eventually flows throughout the entire system. In my opinion, this is not how a POSA would understand the use of that term in the context of the ’935 Patent. By their very nature, all elements of a fluid system contain fluid that is part of the fluid system. If this interpretation were applied, the phrase would be meaningless.

54. Based on context, including both the claims and the specification, the person of ordinary skill would understand the term “in fluid communication” to denote the relative position of two elements to permit fluid to pass unimpeded between the two elements at all times during the test cycle.

55. The plain and ordinary meaning of “communicate” – both in the ’935 Patent and in common usage – means “to cause to pass from one to another” and “to open into each other.” Ex-2004 (<https://www.merriam->

webster.com/dictionary/communicate). In other words, fluid can move from one area to another unimpeded. Thus, the phrase “in fluid communication” denotes the relative position of two elements to permit fluid to pass unimpeded between the two elements; not that they are simply within the same larger fluid system, as ViVidro argues.

56. As understood in the context of the specification, the portions “*in* fluid communication” are constantly in fluid communication with each other; the flow is not impeded during the cycle. For example, claim 1 recites a device for accelerated testing that comprises “a pressurizable test chamber for containing the test fluid system” (limitation 2) that is further comprised of sub-parts, some of which are described as “in fluid communication” (limitations 2a and 2d), with others not “in fluid communication” but instead “structurally and fluidly connecting” (limitation 2c) or “on the opposite side” (limitations 2b).

57. There are multiple elements within the system that restrict fluid flow and communication at times during each cycle. For example, during the piston’s forward stroke, the one-way valve (127, in yellow) is closed which prevents direct fluid communication between the distribution chamber (126) and the return flow elements (*e.g.*, 128, 133, 165). Likewise, during the piston’s reverse stroke, the one-way valve (127) opens and the test valve closes (blue), which then prevents fluid

communication between the distribution chamber (126) and the test valve return conduits (168).

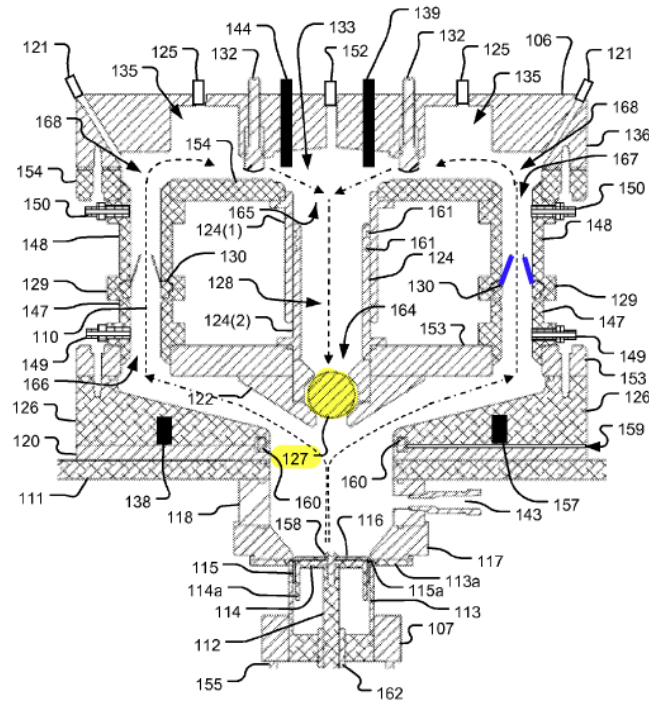


Fig. 3

58. The fluid distribution chamber is “in fluid communication” with the pressure source; this makes sense, because the pressure source is driving the fluid into the distribution chamber to then flow through the test valve. They are also “in fluid communication” when the pump reverses since the path between the pressure source and distribution chamber is not interrupted. By contrast, the fluid return chamber is described as “on the opposite side of the valve” from the fluid distribution chamber; it is not described as “in fluid communication” because, when the valve is

closed, the fluid return and fluid distribution chambers are separated and the flow between them is impeded.

59. The location of the excess volume area is defined by the claims. The '935 Patent does ***not*** describe the excess volume area as being “in fluid communication” with either the pressure source or the fluid distribution chamber, and indeed it could not be. As explained above, it is necessary for the excess volume area to be on the downstream side of the test valve; if it were upstream, the device would not function.

60. The excess volume area cannot be located solely on the pump side of the valve because it would provide a space to contain the stroke volume of the pump and no flow would be driven across the valve (or at most a minimal amount). Without flow through the valve, it would not open, and upon the reverse stroke of the pump there would inadequate backpressure across the valve to achieve proper closure.

61. For these reasons, a POSA would understand the term “in fluid communication” to denote the relative position of two elements to permit fluid to pass unimpeded between the two elements at all times during the test cycle.

B. “excess volume area”

62. Based on context, including both the claims and the specification, the person of ordinary skill would understand the term “excess volume area” to have its

plain and ordinary meaning: “a space for storing pressurized fluid displaced by the driving of fluid by the pressure source that opens the valved prosthetic device.” As described in paragraphs 43-50 above, the excess volume area in the ’935 Patent provides an area to store the excess fluid during the drive stroke, when the volume of the test chamber is smaller. The excess volume area functions to avoid over-pressurization of the incompressible fluid in the closed system when under compression from the pressure source operating at an accelerated rate.

63. Petitioner incorrectly argues that an “‘excess volume area’ is just a compliance chamber.” Petition, at 23; *see also* Dasi Decl. ¶¶ 47-49. This is incorrect; these two terms are **not** the same.⁵

64. As described in paragraphs 25-32 above, test systems involve a number of different types of pressure, and compliance mechanisms may be used to mitigate these different pressures. Compliance mechanisms may mimic the distensibility of arteries, may buffer long-term changes in systemic pressure, may mitigate pressure spikes due to the water hammer effect, or may dampen noise in the system. In other

⁵ In fact, dependent claim 9 recites a further limitation “wherein the excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber,” further emphasizing that “excess volume area” and “compliance chamber” are not the same thing.

words, compliance mechanisms may be used to manage System Operating Pressure and Differential Pressure, *see* paragraph 17 above, which existed in prior art systems. But the '935 Patent disclosed a new and specific type of compliance (an excess volume area) designed to mitigate a certain type of pressure in an accelerated durability test system when the test fluid is placed under compression, existing only in the '935 Patented invention (Excess Volume Pressure).

65. A compliance chamber may—or may not—contain an excess volume area. In other words, while an excess volume area may provide compliance, not all compliance chambers provide an excess volume area as they are not capable of storing fluid displaced during the drive stroke of the pressure source that opens the valved prosthetic device in a closed accelerated test system. Instead, some compliance chambers merely provide damping to minimize dynamic pressure spikes and mimic distension of the circulatory system.

66. The '935 Patent makes clear that the purpose of the excess volume area is *to provide a volume to accept the additional volume of fluid* when the system is in a drive stroke, as I explained in Section III.C above. *See* '935 Patent, 12:4-9 (“The compliance chambers 135 provide excess volume area for fluid to move into when the piston 114 performs a compression stroke. As the pressure of the gas in the compliance chamber 135 increases, the volume occupied by the gas decreases to provide additional volume for displacement of the ... fluid within the test

chamber.”); *see also id.*, 3:9-19 (“The excess volume area is in fluid communication with the fluid return chamber and provides a volume for storing a volume of a test system fluid when the test system fluid is under compression. ... A volume of test system fluid is stored in an excess volume area during a system driving stroke that opens the valved prosthetic device. The stored volume of test system fluid is then released during a return stroke that closes the valved prosthetic device.”); and 17:45-49 (final element of claim 1).

67. For these reasons, a POSA would understand the term “excess volume area” means “a space for storing pressurized fluid displaced by the driving of fluid by the pressure source that opens the valved prosthetic device.” This function does not describe a typical compliance chamber.

C. “under compression”

68. The person of ordinary skill would understand that the plain meaning of “under compression” is that the test system fluid, as a whole, is under compressive forces as a result of the driving of the pressure source, which reduces the system volume and forces fluid through the test valve. Incompressible liquids cannot easily be compressed to a smaller volume (absent very strong force), but incompressible liquids can be placed “under compression.” This is the principle behind the field of hydraulics and hydraulic systems: pressure is created and transmitted by placing compressive forces on incompressible fluids.

69. “Under compression” must be read in the context of “pressurizable test chamber,” of which it is a sub-limitation. A pressurizable test chamber is one that can withstand compression of the total volume; not the ordinary variable pressures of different portions of fluid in an open system or in a non-pressurized system. The pressure source acts upon fluid on the first side of the valved prosthetic device to drive that fluid. The position of the piston changes—driving upward—and thereby decreases the total volume of the test system. ’935 Patent, 11:30-33. The pressure source thereby drives the fluid in one direction due to reducing the lower portion of the system volume, which places the entire closed system under compression. This “drive[s] the pressurized fluid through the prosthetic devices being tested” where it can then be stored within the excess volume area while under compression. *Id.*, Abstract. The system is then released from compression as the pressure source withdraws, increasing the system volume, and the process is then repeated.

70. Contrary to Petitioner’s arguments, the term “under compression” does not refer to a situation in which some molecules of fluid are subject to positive pressure and others are subject to negative pressure, for a “net neutral” effect. *See* Petition at 26, 55 (stating that Dynatek is “under compression”).

71. Petitioner’s “net neutral” argument does not make sense in the context of the claim or the specification. If some of the test fluid is under positive pressure (compression) and some is under negative pressure (vacuum), then fluid would

simply move from areas of high pressure to low pressure, rather than flow into the excess volume area. *See* '935 Patent, 12:4-9. In fact, this is how Dynatek operates. Thus, “under compression” means that the test system fluid is under compressive forces as a result of the driving of the pressure source, which reduces the system volume and forces fluid through the test valve.⁶

V. VIVITRO’S PRIOR ART REFERENCES

72. Vivitro has identified several prior systems it contends anticipate or render obvious the '935 Patented invention. In my opinion, none of these references anticipates the '935 Patent claims, nor does any combination of them render the claims obvious. The prior systems cited by ViVitro operate in a fundamentally different way than the '935 Patent. The accelerated testers do not change the volume of the test chamber, and thus do not create an excess volume, and thus do not have (or need) an excess volume area. For example, the Dynatek capacitance tank is for accommodating small volume changes over time to maintain System Operating Pressure, and the “compliance” in Xi is intended to reduce high frequency pressure

⁶ In my declaration in the District Court litigation, my description of “under compression” was less detailed. Given the confusion over the meaning of this term, I am providing more explanation here. The two explanations are substantively consistent; one is simply more detailed than the other.

spikes and sloshing in the storage tank. The real-time prior art systems (such as Pickard and Goldstein) use compliance to mimic the distension of arteries and cannot be operated at an accelerated rate. While some of these prior systems have some form of “compliance,” it is not the same type of compliance as the claimed excess volume area. Simply, they do not have the claimed “excess volume area.”

73. As I explained above, when the '935 Patented system is driving test fluid through the prosthetic valve, the volume of the test chamber decreases and the excess volume area is able to store the excess volume from the drive stroke downstream of the prosthetic test valve. This can alleviate some of the system pressure during the drive stroke, and also provides compliance in that it reduces/impacts the resistance and the forward flow pressure gradients across the valve, minimizing unnatural and undesirable pressure noise or spikes. During the reverse stroke of the motor when the valve is closing, the excess volume area and its ability to provide compliance helps to build back pressure on the valve, return the downstream volume to the pump and continue to minimize unnatural and undesirable valve closing pressure spikes that can negatively impact the durability of the prosthetic test valve. The pressure source within the '935 Patent invention places the test system fluid under compression, which then takes advantage of the excess volume area.

74. The prior systems identified by ViVidro operate in fundamentally different ways:

- a. The Xi system uses a piston to drive the heart valve attached to a link rod down and then up through the fluid. This results in the valve acting as the fluid drive mechanism with the valve closed during the driving stroke and opening during the return.
- b. The Dynatek M6 system from 1993 uses a swashplate design, essentially moving fluid by using a see-saw type mechanism, without impacting the overall (“net”) system pressure, *i.e.*, the test system fluid in Dynatek is not “under compression.”
- c. Goldstein and Pickard are real-time pulse duplicator systems.

75. By contrast, the '935 Patent claims a system that allows driving fluid through a stationary test sample valve at an accelerated rate by compressing the fluid within the test chamber—something none of the systems cited by ViVidro were able to do in a similar fashion. The '935 Patented invention can operate in this manner because of the presence of the excess volume area, as specifically proscribed in the claims.

A. Xi / Lu

76. The Xi test system includes a linear motor which drives the movement of the valve to create pressures and flows. Unlike the '935 Patent invention, which

uses a piston and bellows to drive fluid through the system and the valve, the Xi system moves the valve through the fluid. In Xi, the test valve is connected to the motor via a link rod that extends through an open (i.e., a non-pressurizable test chamber). The test valve itself is the pressure source; it is the element driving the fluid through the system.

77. Dr. Dasi incorrectly labels Xi to suggest that the top of the piston is the pressure source. This is incorrect; the top of the piston is not driving fluid through the system; the fluid is being displaced by the closed valve, itself.

78. Because the Xi pressure source is the test valve itself—instead of the pressure source and valve being two separate elements as described in the '935 Patent—Xi cannot be effectively mapped onto the claims of the '935 Patent. Below, I provide a few examples of how this mapping fails.

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

80. First, in trying to map the Xi reference onto claim 1, ViVidro requires the test valve to satisfy two elements and be in two locations simultaneously (1a and 1b1/1b2). Claim 1 requires a “pressure source” and a “pressurizable test chamber,” and the test chamber is further comprised of “a fluid distribution chamber positioned on a first side of the valve prosthetic device and in fluid communication with the pressure source.” But ViVidro requires the valve to be both the “pressure source” (1a) and also the “valve prosthetic device” that exists within the test chamber (1b1/1b2).

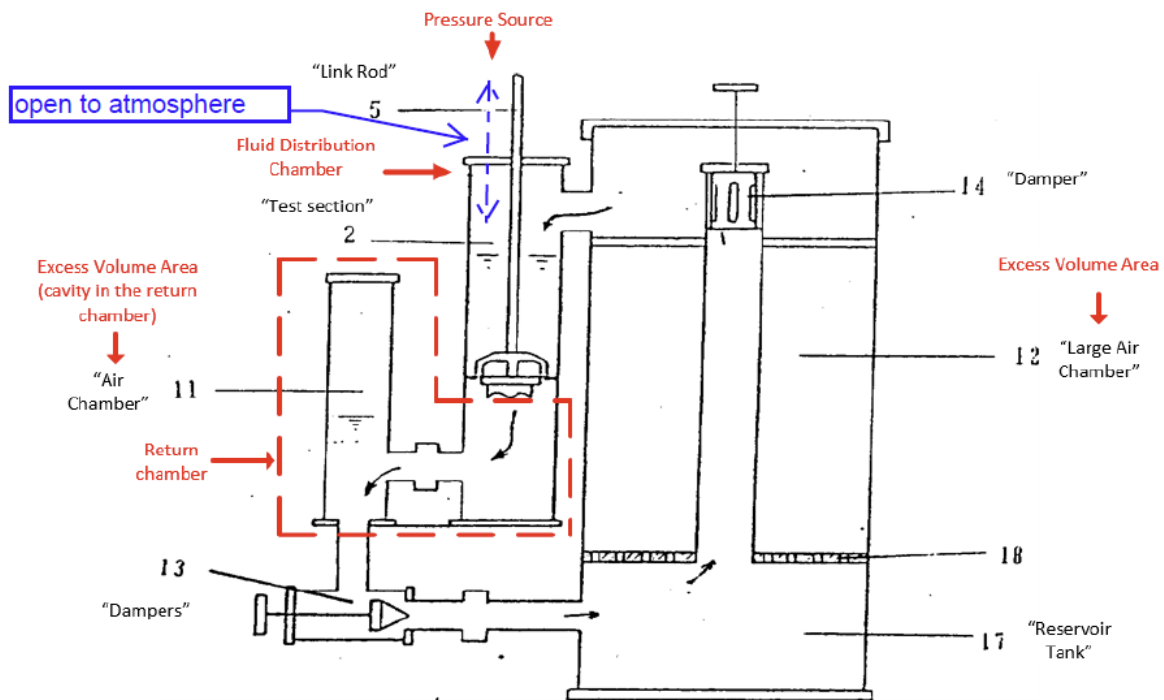
81. Second, I disagree with Dr. Dasi’s labeling of the fluid return chamber. Dasi Decl. ¶¶ 53-58. Dasi identifies the area downstream of the valve including the compliance chamber of Xi as the fluid return chamber. Like the fluid distribution chamber, it is hard to compare this to the system described in the ’935 patent. Fluid is being driven by the valve in Xi downstream of the valve and is not comparable to the passive collection and return chamber described by ’935. It is not clear what part of Xi would be considered a return chamber, but it certainly is not in the area below the valve that is being driven actively during the drive stroke (*i.e.* the valve pushing fluid downward).

82. Third, the Xi system does not have a “pressurizable test chamber,” as described in claim 1b, because Xi is an open system. In Xi, the inflow side of the valve includes a fluid reservoir that is open to atmosphere and not pressurized. The

system is actually open to atmosphere between the damper (14) and the valve chamber (2). As Figure 4 shows, the link rod moves up and down to open and close the valve. To create a pressurizable system, there would need to be a seal that prevents the air above the fluid from escaping through the link rod's movement. There is no description anywhere in the Xi reference of such a seal. Moreover, Xi discusses taking a single valve back pressure measurement below the valve using a blood pressure transducer (29). Ex-1004 at 2. However, there is no description of any reference measurement above the valve to determine the pressure across the closed valve. Xi does not need to measure that pressure because the small volume of fluid above the valve in the test section (2) is open to atmospheric pressure and, therefore, the reference measurement (atmospheric) is already known. Furthermore, Xi does not indicate that there is any friction associated with the movement of the link rod (5) through the top of the test section (2), which would need to be taken into account if there were a seal to atmosphere. The load applied to the valve (16) through the link rod (5) is measured using a force transducer (24) that is outside the test section (5). Thus, the system described by Xi is not a closed system, and is not pressurizable on both sides of the valve.

83. To state it another way, the fluid above the valve is not pressurized (or pressurizable) because that portion of the system is open to the atmosphere. Below

is an annotated version of Xi Figure 4 (red by ViVitro, blue by BDC), Ex-1004 at Fig. 4; *see also* Petition at 32:



84. Fourth, Xi does not have an “excess volume area” as claimed in the ’935 Patent. In attempting to map an excess volume area in Xi, Dr. Dasi uses his incorrect interpretation that compliance chamber is synonymous with excess volume area and that the only function of the compliance chamber is to alleviate the water hammer effect. As explained at length above, the excess volume area accepts a volume of fluid that exists when the total volume of the test chamber is reduced. *See* paragraphs 43-50, above. Xi does not, and need not, perform this function, because there is continuous flow through the dampers R1 (13) and R2 (14). Throughout the

drive cycle flow is allowed to move through the dampers and fluid returns to the test chamber open to the atmosphere above the valve.

- a. In Xi, the volume of the test system does not change; the valve merely drives the fluid through the system in a cyclical fashion. Where there is no change in the overall volume of the system, there is no need for an “excess volume area.”
- b. Further, since Xi is an open system, as described in paragraph 82 above, it would be unnecessary for Xi to have an “excess volume area” within the test system even if the volume of the test system did change. An “excess volume area” as defined by the '935 patent is only necessary in a closed system where there is a change in volume.

85. The air chambers in the Xi reference serve a different purpose than and are not the excess volume area in the '935 Patented invention. In Xi, the valve is closed during the drive stroke and the closed valve acts as a pressure source, i.e., the end of the piston. To the extent the air chambers C1 provides some “compliance”, it is to prevent the closed valve from experiencing excessive dynamic pressures spikes (e.g., water hammer effects) during the downward stroke. In other words, the air chamber serves to mitigate Differential Pressure. However, neither of the compliance chambers C1 and C2 is intended to store the fluid volume from each stroke of the valve downward. The system allows continual flow through

valve/dampers (13 and 14) to return to the test section 2, and thus no “excess volume area” as defined by the ’935 patent is included or needed by Xi. The air chamber 11 positioned upstream of the damper prevents the valve from collapsing upon itself while the valve is used to push fluid through the system.

86. Petitioner alleges that a POSA would have understood that Xi’s compliance chamber reduces water hammer by providing a volume to store “some” excess fluid. It is not clear that the compliance chambers included in Xi are storing any significant fluid volume produced from the downward driving stroke of the closed valve. Since the system allows a continuous flow and is open to the atmosphere, the Xi compliance chambers are not required to store fluid volume, but only provide some small volume change to add compliance for reducing the dynamic effects described above. Because Xi is open, energy from the momentum of the fluid can be more readily dissipated. Regardless, the Xi compliance chambers are not intended for storing fluid volume from the driving downward stroke to release volume and close the test valve because the Xi test valve is closed during the driving stroke, so the Xi compliance chambers are clearly not providing an “excess volume area” as defined by the ’935 patent.

87. The Lu publication (Ex-1005) does not change this analysis. Dr. Dasi refers to the Lu publication that describes the mathematical relationships between the dynamic inertial loads and the relationship of compliance in helping to control

the pressures in accelerated testers like Xi. Dasi Decl. ¶¶18-20. Lu suggests compliance that would allow testing at both physiological and accelerated rates to control loads on the valve if the amplitude or displacement of the valve in the Xi system. Although these mathematical relationships certainly apply to setting the compliance in a closed system as described in the '935 patent, neither Lu or Xi suggested or attempted to drive the pressures and use a compliance chamber to provide an “excess volume area” for the stroke volume. This was not done in an accelerated tester until BDC developed its patented system. Therefore, I would not conclude that it would be obvious for a POSA to develop a completely closed system as described in the '935 patent based on the teachings of Lu.

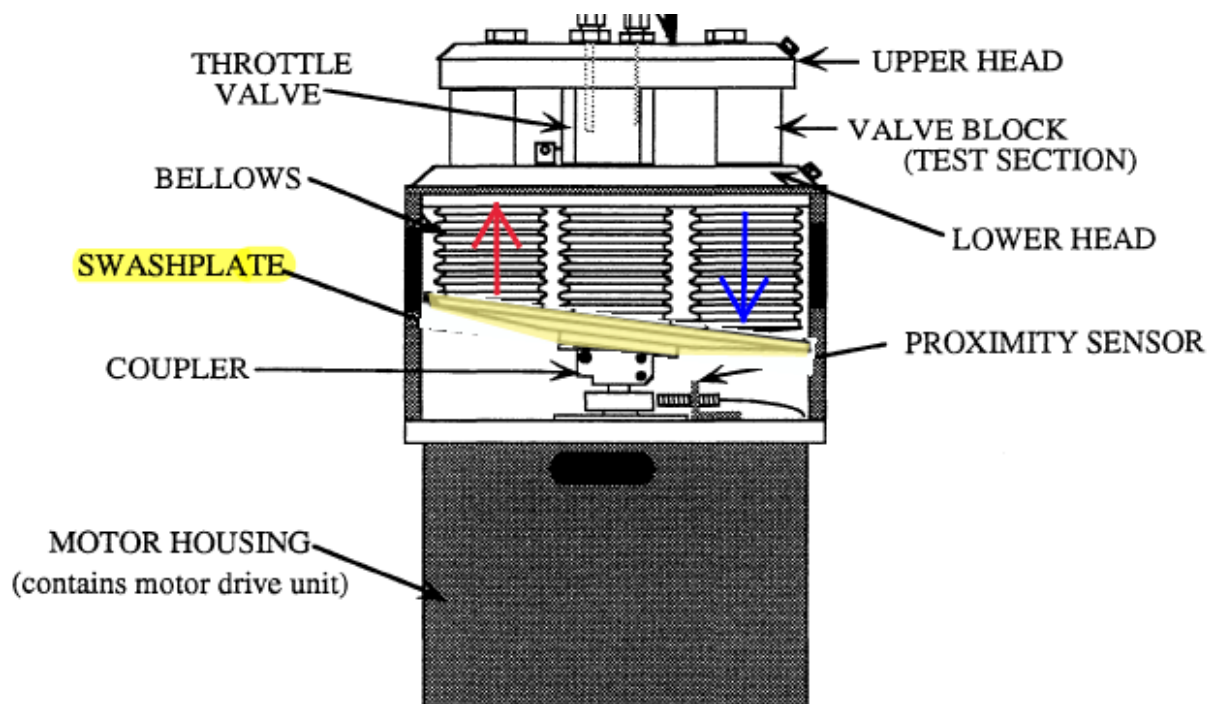
B. Dynatek

88. The Dynatek M6 system from 1993 uses a swashplate design, essentially moving fluid by using a see-saw type mechanism, but not impacting the overall system pressure, *i.e.*, keeping that pressure at a net constant within the system.

89. Simulations of the operation of a swashplate can be found at:
<https://en.wikipedia.org/wiki/Swashplate#:~:text=A%20swashplate%2C%20also%20known%20as,reciprocating%20motion%2C%20or%20vice%20versa;>
https://www.youtube.com/watch?v=_VSOgJn-3wo;

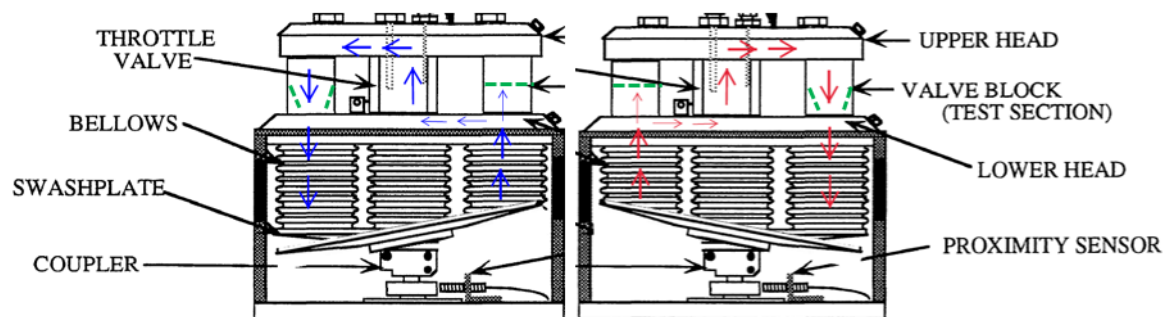
<https://www.youtube.com/watch?v=gP1zIJ7maNY> (illustrating Dynatek M6 swashplate at minute 1:00-1:27).

90. An annotated and amended version of Figure 1A from Dynatek illustrates this operation.⁷ The bellows on the lower end of the swashplate is expanded, creating low pressure for fluid open the valve and go down into the bellows, identified by the blue arrow. The bellows on the upper end of the swashplate is compressed, moving the liquid up toward the top of the test chamber and closing the valve, identified by the red arrow.



⁷ The operation of the swashplate is exaggerated in this annotation to illustrate the method of operation. In practice, the angle of the swashplate and movement of the bellows are small.

91. As the swashplate rotates, the bellows compresses, causing the fluid to reverse direction and move upward to close the test valve. Any additional fluid, in surplus of what is needed to close the test valve, escapes laterally through a bypass port of the lower head into the central reservoir where it then moves to the upper head for another cycle. The annotated figure below illustrates two positions at the beginning and after half of a rotational cycle of the swashplate. In such a system, the associated bellows move fluid from one chamber to another, with flow moving through each “test section” and central channel as it rotates.

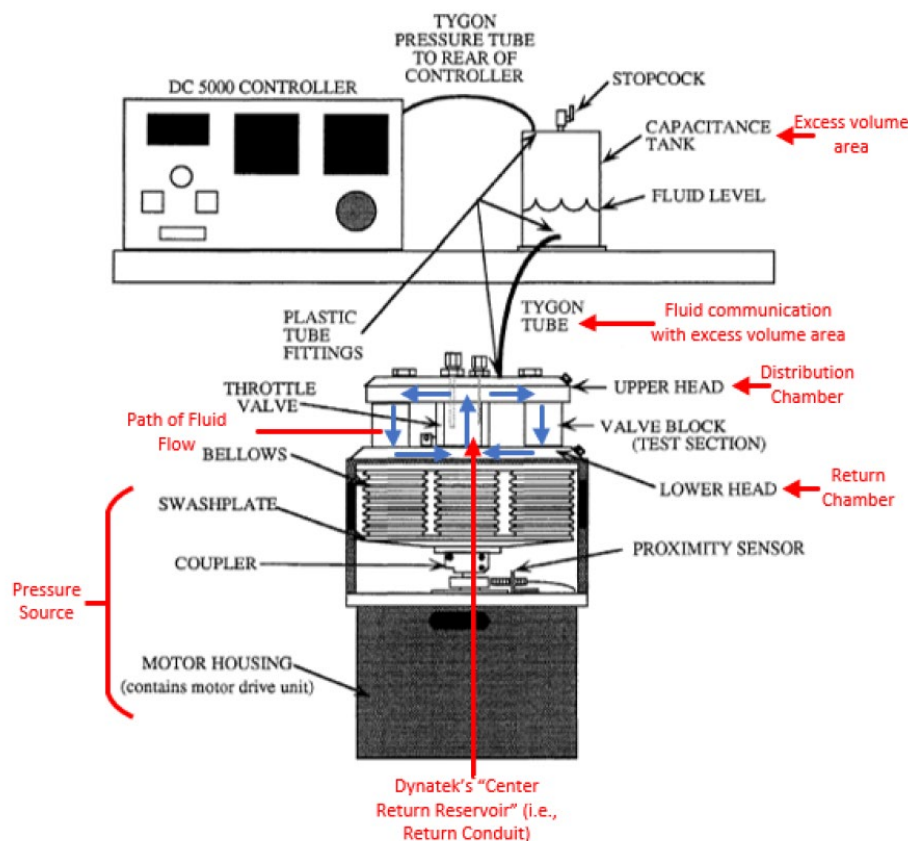


92. The resulting swashplate action is not putting the entire test system fluid under compression at any point in time as the swashplate rotates, but rather the swashplate is moving the system fluid from one bellows to another through the bypass valves to avoid compressing the total system fluid.

93. While fluid in the test chamber on the upper end of the swashplate is subject to some “positive” compressive force to drive flow through the bypass ports, the fluid in the test chamber on the lower end of the swashplate is subject to “negative” force. Because some of the test fluid is under positive pressure and some

is under negative pressure, the fluid would simply move from areas of high pressure to low pressure, rather than flow into an excess volume area. The overall volume within the Dynatek system does not change and thus the system is not under compression, as required in the '935 Patent.

94. The Dynatek M6 operates with the valve in the upside-down position (i.e., the inflow side of the valve is the upper portion of the test section). ViVibro argues that Dynatek's swashplate is the pressure source, the upper head is the distribution chamber, the lower head is the return chamber and the capacitance tank is the excess volume area.



95. As ViVistro's illustration above shows, the alleged pressure source (swashplate) is not in fluid communication with the distribution chamber (upper head) because it is in fluid communication with the return chamber (lower head) and, at certain times in the cycle, the closed test valve prevents any fluid flow from the fluid distribution chamber to the fluid return chamber. In fact, fluid from the bellows must first flow through the return chamber (lower head) and fluid return conduit (center return reservoir) before reaching the distribution chamber (upper head), as illustrated in the figure in paragraph 91 above.

96. The capacitance tank in Dynatek has nothing to do with storing fluid when under compression or otherwise providing an excess volume area for the system under compression during a drive stroke. Instead, it is used to set and buffer System Operating Pressure over time, as described in paragraph 17 above.

97. Specifically, the Dynatek user guide describes the function of the capacitance tank in those very terms. Step 41 of the user guide instructs the user to adjust System Operating Pressure using the capacitance tank:

The systemic operating pressure is displayed on the front panel gauge (G2), and is monitored by a high/low pressure switch which is connected to the capacitance tank. Adjust the systemic pressure by pressurizing the capacitance tank to 2-3 psig as indicated on the pressure gauge. (For more

information about systemic pressure, see section ‘Systemic Pressure Range.’) Attach a syringe or rubber bulb to the stopcock on top of the capacitance tank. Open the stopcock, add air and close the stopcock to refill the syringe with air.

Ex-1006 at 11.

98. Per the manual, the capacitance tank is designed to address only “small variations” that occur over a longer period of time—transient leakage and thermal effects—not pressure variations that occur with every cycle—i.e., 200+ times per minute. Ex-1006 at 15. The inability of the capacitance tank to handle cyclical pressures is underscored by the size of the tubing: the capacitance tank is connected by 1/8 inch tubing that is 5 feet in length. Ex-1006 at pp. 8, 10 ¶¶6, 27. This tubing is approximately the same diameter as the charging cord for an iPhone; it is too narrow and too long to allow for passage of fluid during the accelerated cycles performed by the tester.

99. This thin, long tube cannot accommodate passage of fluid at a rate of 200 times per minute or greater. Indeed, this design actually teaches away from use of a capacitance tank as an excess volume area, as claimed in the ’935 Patent, because it teaches use of a structure that, as a matter of ordinary physics, could not accomplish that function. Because the tube would not allow the fluid under

compression to flow to the capacitance tank, that feature cannot be an excess volume area.

100. The capacitance tank cannot be an excess volume area for another, independent reason: it is connected on the wrong side of the valve. This capacitance tank is attached to the fluid distribution chamber (here, the upper head) and not the fluid return chamber (here, lower head) where high pressures are generated. Fluid would be incapable of rapidly traversing from the lower head, through the throttle valve, through the central return reservoir, and into the upper head before reaching the capacitance tank, as alleged by Petitioner. This capacitance tank has a different configuration, and more limited function, than the outflow compliance and excess volume area described by the '935 patent.

101. The Dynatek user guide makes clear that the air capacitance tank is *not* intended to operate in the same way as air within the test chamber itself. The Dynatek user guide repeatedly instructs the user to remove all gas from the test chamber (debubble) it. This is because the presence of gas in the test chamber is described as problematic. *See* Ex-1006 at 8-10 ¶¶11, 12, 15, 16, 24; *see id.* at 5 (“In our age of high tech testing it's interesting to note that bubble removal is one of the biggest challenges facing a valve tester. It must be stressed, however, that the presence of bubbles in the test fluid can erode both leaflet and occluder type valves.”).

C. Goldstein

102. The Goldstein reference cited by ViVitro (Ex-1007) is a real-time pulse duplicator device that operates in a fundamentally different way from the '935 Patent invention.

103. The Goldstein system is a pulse duplicator intended to study valve function and as a bioreactor for cell seeding of biological valves. This system is a large volume system and would not be able to function at accelerated rates with appropriate flows and pressures across the aortic valve. This is because of inertial mass of the large flow loop volume not being able to maintain the conditions at typical durability test speeds.

104. Closed system pulse duplicators with compliance chambers have been around much longer than the Goldstein patent, which is unique because of the bioreactor aspects of the device. However, it was not obvious to a POSA that operational characteristics of pulse duplicators could be adapted or were capable of running at high speeds for durability testing. This is why durability testers like those described by Iwasaki (Ex-1019) and Dynatek (Ex-1006) were configured quite differently to achieve high speeds while generating acceptable pressure conditions. The '935 patent was the first durability system with these characteristics of pulse duplicators.

D. Reul

105. The durability tester developed by Reul (Ex-1020) and used at HIA is a well-known system that uses a swashplate like the Dynatek system, but each test cell is isolated and flow is driven by a bellows. The Reul durability tester has a bypass adjustment to control pressure and the system is open to atmosphere above the valve. Therefore, any compliance chamber in Reul is not intended to provide an “excess volume area” for the full stroke volume produced by the bellows and swashplate during each cycle. Reul does not describe a case where this is intended because it would require eliminating the by-pass feature.

E. Pickard

106. The Pickard patent '491 (Ex-1018) describes a pulse duplicator system for testing heart valves. The patent describes a closed system with 2 compliance chambers that provide excess volume as a reservoir. Similar to the comments for Goldstein, this system is not capable or intended to run at high speeds required for durability testing.

107. Pickard was cited during prosecution of the '935 Patent, and BDC overcame an objection based upon Pickard. BDC explained, and the Examiner agreed, the existence of compliance in a real-time system did not anticipate or render obvious the specifically-claimed excess volume area of the '935 Patented invention.

VI. THERE IS NO MOTIVATION TO COMBINE

108. I have been informed that the '935 Patent claims priority to a provisional application that was filed on March 6, 2009. I have been further informed that question is whether a person of ordinary skill in the art would have been motivated to combine the cited prior art references in March 2009.

109. In 2009, I was working for a cardiovascular medical device company developing transcatheter delivered heart valve replacement devices. By that point, I had spent over 18 years working in product design, research & development and testing of cardiovascular medical devices, including as a Vice President of Research & Development at Impres Medical, Inc., and as a Senior Director of Research & Development at St. Jude Medical, Inc. (now part of Abbott Laboratories). I had substantial experience with the available testing systems and was intimately familiar with the state of the art. In the course of this proceeding and the related litigation, I have reviewed art references from that period of time, and can confidently say that I can place myself in the shoes of a POSA as of March 2009.

110. Prior to disclosure of the '935 Patented invention, there was no accelerated durability tester that could operate in a manner similar to a real-time pulse duplicator. If it were possible to turn a real-time pulse duplicator tester into an accelerated durability tester by simply speeding it up, everyone would have done this decades ago. They would not have come up with different ways to operate an

accelerated tester, such as using a swashplate or using the valve as pressure source. The '935 Patent disclosed an innovative solution.

111. I have reviewed Dr. Dasi's declaration, and I strongly disagree with his suggestion that a POSA would have had a motivation to combine the various art references Dr. Dasi describes.

112. As I mentioned, the existing durability testers could not operate at an accelerated rate using the pulse duplicator methodology. As I have explained above at paragraphs 18-19, the operational limitations of pulse duplicator systems prevented them from being effective when sped up to accelerated rates. Therefore, I strongly disagree with Dr. Dasi's assumption that it would be obvious—and possible—to simply speed up prior systems, such as Goldstein, to achieve an accelerated system. *See* Dasi Decl. ¶¶ 203-05. The fact that more than 20 years lapsed between publication of the Pickard patent for a real-time tester (1987) and development of the '935 Patented accelerated tester (2009) is compelling evidence that it was **not** an “obvious” modification of simply adjusting the settings.

113. In fact, the Krynauw thesis (Ex-1015)—which ViVitro relies upon even though it *post-dates* the '935 Patent priority date⁸—demonstrates that the prior systems experienced operational problems when an attempt was made to operate them as accelerated testers. Krynauw describes a closed system similar to the pulse duplicators intended to run at physiological conditions and not accelerated conditions required for durability testing. In Section 5.2, Krynauw summarizes his conclusions including that the system could only run at speeds up to 230 bpm—just barely above the high end of the normal range 30-200bpm, and far lower than the typical accelerated testing rates of 600-1200 bpm. Based on the Krynauw thesis describing the attempted development of a workable high speed durability test system (after the '935 Patent priority date), Krynauw's failed efforts demonstrate that it was *not* obvious even to a sophisticated POSA to successfully design an accelerated durability tester as described in the '935 patent.

⁸ I understand that Hugo Krynauw has submitted a declaration stating that, while the cover page of his thesis says "May 2008," it was in fact submitted in May 2009, after the bar date. Ex-1016; *see also* Ex-1016, ¶ 5 ("I did not submit my thesis until shortly before my graduation date, which is 12 June 2009. The Declaration page of my thesis (page ii) reflects my signature dated 8 May 2009.").

114. In my opinion, a POSA would not have been motivated to combine Dynatek and Xi. There is no reason why one of ordinary skill would have combined the “air chamber” of Xi with the Dynatek M6 system, when the systems operate in fundamentally different ways. As described above, Xi uses a piston to drive the valve through fluid, and Dynatek M6 uses a swashplate to move the test liquid around and neither changes the overall test system volume or has test fluid under compression as claimed in the ’935 Patent. There is no explanation of how one could have combined these or why one would even think to do so. For example, the following (unanswered) questions arise:

- a. Where would one place, in the Dynatek system, the large tube in Xi that contains the air chamber? Adding an air chamber to the location of connection of the capacitance tank would not have worked, because it would be on the inflow side of the valve, *see* paragraphs 96-100 above.
- b. Why would one expect that adding an air chamber to the Dynatek test chamber would make it better? The Dynatek user manual repeatedly instructs users to remove air from the test chamber.

115. The Dynatek system does not reduce the overall volume of the test loop when driving the fluid through the valve with the swashplate. Therefore, adding an air chamber anywhere in the system to absorb fluid volume was not required and would not provide any benefit based on the way the Dynatek system operates.

116. In fact, the Dynatek system teaches away from use of gas within the test chamber; the Dynatek user guide requires removing all air from the test chamber. Ex-1006 at p. 9 (“[B]ubble removal is one of the biggest challenges facing a valve tester. It must be stressed, however, that the presence of bubbles in the test fluid can erode both leaflet and occluder type valves.”).

117. Neither Dynatek nor Xi involve a change in the overall volume of the test system through the test cycle, and thus the use of “compliance” chambers in either system would not act as an excess volume area as described in the ’935 Patent.

118. As previously mentioned, my opinion is that combining Goldstein (common normal speed closed pulse duplicator operation) with Lu (high speed open durability test operation) is not obvious. Closed system pulse duplicators with compliance chambers were common prior to durability testers like those described by Iwasaki (Ex-1019) and Dynatek (Ex-1006) were developed. Any obvious efforts to adapt pulse duplicators to higher speed durability testing was not successful, so systems that were configured differently like Reul (Ex-1020), Iwasaki, and Dynatek were developed to meet pressure conditions at higher speeds. The failed efforts of Krynauw (Ex-1015) further confirms that the system elements described and claimed in the ’935 patent were not successfully anticipated by prior art.

119. I disagree with Dr. Dasi’s view that it would have been obvious to combine Goldstein (Ex-1007) and Lu (Ex-1005) to render obvious the system of the

'935 patent. Goldstein is a closed pulse duplicator system that runs at physiological rates and not accelerated rates, similar to other pulse duplicators in prior art. Goldstein was not capable of running at accelerated durability rates. The teachings of Lu provided mathematical principals of compliance, but the system for accelerated durability testing were not closed systems requiring an “excess volume area” for the full stroke volume. And Krynauw (Ex-1015) was not successful in running at accelerated rates for durability testing. So, Dr. Dasi’s assertion that a POSA could combine these or other prior art to produce a system as described by the '935 patent was not demonstrated and in my opinion a POSA would not have been motivated to combine these references, nor would a POSA expect this result.

VII. CONCLUSION

120. For the reasons described above, it is my opinion that claims 1-4, 7-10 and 12-13 of the '935 Patent are not anticipated or rendered obvious by any of the prior art cited by ViVitro.

I declare under the penalty of perjury of the laws of the United States that the foregoing is true and correct. Executed on May 7, 2024.

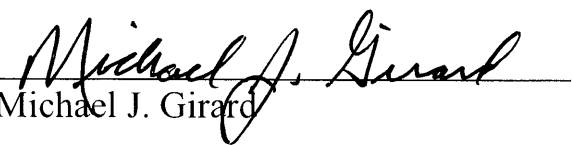

Michael J. Girard

Exhibit A

PROFESSIONAL PROFILE:

Technical business leader with 44 years of engineering and leadership experience, including the last 33 years in the medical device industry. Proven track record of developing products and technologies to drive business growth for US based and international organizations from start-up level to industry leaders. Demonstrated ability for creating technical strategic vision, implementing plans and building technical teams to support the strategy. Provided leadership and development for R&D groups of up to 25 people in highly cross-functional environments.

PROFESSIONAL EXPERIENCE:

April 2017 to Present **Girard Technical Services, Inc. – Lino Lakes MN**
President - Consultant

Independent consulting services for R&D, engineering and technical management focusing on the medical device industry. Expert medical device witness experience supporting litigation issues.

January 2015 to April 2017 **HLT, Inc. – Bracco Group, Maple Grove MN**

Vice President, Research & Development – Reporting to General Manager

HLT is a medical device company owned by the Bracco Group in Milan Italy that is developing products for Transcatheter Aortic Valve Implantation (TAVI). The company experienced deployment issues and halted a clinical feasibility study in late 2014 just prior to joining HLT. Initial responsibilities involved leading the redesign and development of the delivery system, but then took over the entire R&D group in mid-2015. Reorganized and developed the R&D department into a strong team of 20 engineers and technicians. Both the valve and delivery system were redesigned and design verification testing completed to demonstrate significant improvement in performance from the system that failed in 2014. The redesigned system resumed use in a clinical trial in late 2016 and now has successfully implanted valves in five patients. In addition to leading the R&D efforts, the Product Development Process (PDP) was overhauled to be more effective, a short and long-term product development strategy was created and the patent portfolio was managed and expanded to protect the technology. The development strategy drove the initiation of several successful projects to fill the product pipeline with further improvements and a next generation system.

April 2009 to January 2015 **JVT R&D Corporation/JenaValve, Irvine CA**
JenaValve Technology GmbH, Munich Germany

Head of Valve Development – Reported to VP of R&D (11/12 to 1/15), Reported to CEO (4/09 to 11/12)

JenaValve is a company developing and marketing products intended for the treatment of aortic valve disease based on catheter delivered prosthetic heart valve technologies. Started with the company at the early start-up stage providing technical expertise and leadership. Responsible for all valve engineering, development and manufacturing activities as the company grew from initial prototypes through the clinical trial and commercialization with two implantable valve product lines. Included extensive international travel to manage activities and interact with company personnel, outside development and contract manufacturing partners in multiple countries. Key responsibilities and accomplishments included the following:

- Porcine root heart valve for the 32F transapical delivery approach:
 - Finalized the development and manufacturing processes
 - Coordinated *in vitro* valve testing and manufacturing of the prostheses to support First-In-Man (FIM) clinical studies started in 10/09
 - Coordinated all *in vitro* valve testing for Regulatory Submissions to obtain a 9/12 CE Mark approval
 - Managed valve manufacturing and production activities with a UK based manufacturing partner through the commercial launch of the product in Europe.
 - Transferred manufacturing processes for the porcine root prosthesis to a 2nd source manufacturing partner in Canada to increase output and minimize production risks.
 - Implemented manufacturing improvements to double manufacturing yields from 30% to over 60%

- Pericardial heart valve for the 22F transapical and 18F transfemoral delivery approaches:
 - Performed directly and/or managed all design, engineering and development for the unique 2nd generation prostheses product line
 - Coordinated all *in vitro* valve testing and manufacturing of the prostheses to support FIM clinical studies started in 12/13 and Regulatory Submissions to initiate CE Mark clinical studies in 2014
 - Managed valve manufacturing of the pericardial valve prosthesis with a Canada based development and manufacturing partner
 - Transitioned manufacturing management activities to a new JenaValve manufacturing team based in Irvine
- Inventor on several key US and International patent applications to protect unique prosthesis design features.
- Led the establishment of a valve R&D group in Irvine, CA.

May 2008 to
April 2009

ATS Medical, Inc., Maple Grove MN (now part of Medtronic, Inc.)

Consultant – Reported to VP of R&D

ATS Medical was a surgical cardiovascular medical device company. Provided expertise and services to support engineering and development activities. Responsibilities included cryogenic ablation product development and improvements for the surgical based Atrial Fibrillation (AF) treatment product line. Coordinated and led less experienced engineers with design, testing and implementation activities. Investigated new cryogenic technologies for a 2nd generation AF treatment product platform.

April 2005 to
April 2008

St. Jude Medical, Inc., St. Paul MN (now part of Abbott Laboratories)

Senior Director, Research & Development – Reported to VP of R&D, Cardiovascular Division (9/06 to 4/08), Reported to Division President, Cardiac Surgery Division (4/05 to 9/06)

Responsible for the management and leadership of all research and development activities for the cardiac surgery business. This included a department of 25 engineers, scientists and technicians with an annual expense budget of approximately \$6M. Some of the key individual and group accomplishments and activities include the following:

- Responsible for developing business portfolio technology strategy.
- Prepared and presented yearly operational plans and 5 year strategic plans to upper management for the cardiac surgery business.
- Launch of new products and line extensions of existing products within the cardiac surgery product portfolio. Products launched from 4/05 to 4/08 are expected to generate approximately 20% of Division revenue in 2008 (\$60M).
- Completed development and gained approval to start an IDE clinical trial for a completely new aortic tissue valve platform.
- Developed technical strategy, negotiated outside collaborative partnerships and initiated development programs on two key future product platforms:
 - Transcatheter beating heart aortic valve replacement
 - Polymer valve
- Worked with legal department and outside attorneys to manage extensive IP portfolio, including filing more than 20 key new patent applications for novel technologies.
- Primary technical interface for evaluation of new technologies and business opportunities with physicians and other outside organizations.
- Provided materials and analytical chemistry testing for entire Division

October 2003 to
April 2005

Impres Medical, Inc., Edina MN

Vice President, Research & Development – Reported to Chief Executive Officer

Impres Medical was a small start-up company developing technologies in the area of gynecology. Responsibilities included directing all research and development strategies and activities focused on demonstrating concept feasibility and the development of an intrauterine implant device and delivery system to treat abnormal uterine bleeding. Coordinated the device design, manufacture and pathological evaluations of biological tissue response of the device in preclinical and clinical studies. Filed several key pieces of IP based on very unique device tissue response and performance. In addition, key support was provided to the CEO to help company fund raising activities.

May 1998 to
October 2003

Acorn Cardiovascular, Inc., St. Paul MN

Director, Product Development – Reported to Chief Technology Officer (11/98 to 10/03), Reported to President/CEO (5/98 to 11/98)

Acorn Cardiovascular was a start-up company developing a Class III implanted Cardiac Support Device (CSD) that provided mechanical support for the ventricular portion of the heart to treat congestive heart failure. Responsibilities included the overall management and leadership for all product development activities. Was the second hired employee in an instrumental role helping to build the staff, infrastructure and lead development efforts required to take the CSD from concept to a clinical and commercial product. This included defining and implementing the product development procedure framework to assure satisfying all QSR requirements.

The CSD, packaging and accessories for implantation were developed and ready for first clinical use in only 12 months, which exceeded initial company expectations. Key responsibilities, activities and challenges that were met included the following:

- Hired staff to support product development and other operational functions.
- Planned and helped coordinate build-out and equipment set-up for lab, prototype shop and pilot manufacturing in a new facility.
- Created Product Development Protocol (PDP) and Intellectual Property (IP) Procedures, and supported development of numerous other procedures/policies for a Quality System (QS) that meets ISO requirements.
- Led all product development efforts.
- Directly supervised a department of 5 engineers/technicians.
- Set-up outside supply and development agreements for key materials and components.
- Coordinated preparation of drawings, specifications, manufacturing procedures, test protocols, reports and execution of all product bench testing.
- Coordinated preparation of design verification protocols, testing and reports.
- Wrote all engineering sections for CE Mark and FDA regulatory submissions.
- Key product development milestones starting from time of hire and product concept (5/98):
 - First clinical implant in Europe – 12 months
 - FDA IDE approval - 19 months
 - ISO 9001/EN46001 facility approval - 25 months
 - CE Mark approval to sell in Europe - 29 months
 - US clinical trials and approval for the CSD continued beyond 10/03

October 1990 to
May 1998

St. Jude Medical, Inc., St. Paul MN (now part of Abbott Laboratories)

Manager, Product Design and Evaluation Center (12/96 to 5/98) - Reported to Director of QS

Responsible for leading a department of ten employees performing design, computer modeling, analyses, engineering testing, rapid prototyping and machine shop prototyping for both mechanical and tissue valve R&D programs. This position also provided input to define the strategic direction and annual operating plans for Divisional R&D. The department managed had an annual expense budget of \$1.8 million.

Led all structural/mechanical Finite Element Analysis (FEA) and Computational Fluid Dynamics (CFD) activities required to evaluate new and existing designs for the Division. These analyses supported project needs in the areas of engineering design, regulatory agency submissions, marketing and manufacturing.

Responsibilities also included the development of new testing methods and the coordination of existing tests to evaluate new and existing components and products for durability and hydrodynamic performance. New technologies such as particle image velocimetry (PIV) were implemented to enhance the flow testing capabilities of the department. Coordinated all R&D prototyping and manufacturing fixture development activities using departmental CNC lathe, CNC milling and stereolithography capabilities.

Provided input to help guide IP protection decisions as part of a six-member Divisional panel that reviewed all new ideas and technologies.

Project Manager (9/95 to 12/96) - Reported to Director of Mechanical Development Programs

Responsible for project leadership of the minimally invasive surgery (MIS) product line. This position helped shape the strategic direction for St. Jude's involvement in MIS for heart valves. Coordinated the development of

components to enable valve repair and replacement using new surgical techniques. This included coordination of a relationship with an outside business partner who pioneered a new surgical approach. In addition, activities involved directing an in-house cross functional project team in designing, testing, documenting, manufacturing, obtaining regulatory approval and launching a new valve delivery system into the market. Obtained regulatory approvals and commercially launched the first MIS valve system for mitral valve replacement in October of 1996. Coordinated the preparation of a detailed business plan to support the market launch.

Manager, Mechanical Valve Technologies (12/93 to 9/95) - Reported to Vice President of Technology

Responsible for leading a department of nine engineers and technicians performing R&D projects to advance the mechanical heart valve product line. As head of this department, provided input to define the strategic direction and annual operating plans for mechanical valve R&D. Was directly responsible for managing departmental expenses with an annual budget of \$1.6 million.

The department provided support for various projects, product regulatory submissions/approvals, transition of product and process to manufacturing, and technical support for marketing. The capabilities of this department included design, analysis and testing to support both mechanical and tissue R&D programs. The design and analyses included 3D computer modeling and further utilization and expansion of the FEA and CFD capabilities that were previously established in-house. Testing services performed included *in vitro* accelerated life, steady flow, and pulsatile flow that simulate *in vivo* blood flow conditions. New testing methods were developed as needed to evaluate new products and components, including *in vitro* testing to directly evaluate blood damage resulting from prosthetic heart valve mechanics. This testing provided a new method for comparing and assessing blood interactions for new valve designs.

Also served as the project leader for several R&D projects such as a large cross-functional (12 to 15 core team members) project to develop a rotatable valve product line from conceptual design through market launch in 15 months.

Principle Design Engineer (3/93 to 12/93) - Reported to Product Development Manager
Senior Design Engineer (10/90 to 3/93) - Reported to Product Development Manager

Performed structural/mechanical design and analyses of heart valves and components to support R&D projects. Analyses included coordinating computer simulation using ANSYS structural/mechanical finite element analysis (FEA). Initially, coordinated FEA performed by outside consultants, but within 5 months brought capabilities for FEA in-house to save \$300k/year in outside service expenses.

Expanded responsibilities to lead both structural mechanical computer analyses as well as simulation of blood flow using FIDAP computational fluid dynamics (CFD). Hired and supervised two engineers to help provide design and computer analyses for numerous R&D projects. Also was responsible for preparing design drawings, specifications, reports and coordination of work with outside vendors for fabrication of injection molded components, software vendors, hardware vendors and engineering consulting firms.

March 1986 to
October 1990

FluiDyne Engineering Corp., Minneapolis MN (now part of Aero Systems Engineering, Inc.)

Structural/Mechanical Engineer (3/86 to 10/90) - Reported to Manager of Facility Engineering

FluiDyne provided engineering consulting, testing and development of turnkey test facilities such as wind tunnels. Primary customers for these services and facilities were the U.S. Air Force, NASA and other aviation and space agencies throughout the world. Responsibilities included design, analysis and fabrication support for the development of advanced aerodynamic test facility component and system assemblies. Performed design and analysis of structural and pressure vessel components for both static and dynamic loadings using both manual calculations and ANSYS finite element computer methods. Utilized technical codes such as AISC, ASME, ANSI, UBC and foreign pressure vessel codes extensively to evaluate loads, stresses and fatigue life.

Prepared engineering documents, including calculation packages, specifications, reports and design drawings. As Lead Engineer on several projects, directed less experienced engineers, tracked project budgets/schedules and reported status to management. Also, prepared cost estimates for large-scale project design feasibility studies, interfaced with clients, regulatory agencies, subcontractors and vendors on various projects.

June 1980 to
March 1986

NUTECH Engineers, Minneapolis MN (1/83 to 3/86)
NUTECH Engineers, San Jose CA (6/80 to 1/83)

Project Engineer (1/83 to 3/86) - Reported to Engineering Manager

Design Engineer/Lead Engineer (6/80 to 6/81) - Reported to Unit Supervisor of the Structural Mechanics Group

NUTECH provided consulting services to the nuclear power industry. Responsible for design, analysis and implementation of various structural and mechanical system modifications at several nuclear power plant facilities. Provided technical and project leadership for a number of plant modification projects. This included preparing loading and analysis calculations, design specifications, drawings, design reports and safety evaluations to support Nuclear Regulatory Commission (NRC) requirements. Design and analysis activities utilized both manual calculations and computer methods for static and dynamic mechanical loads, as well as thermal conditions. Structural and mechanical engineering codes such as AISC, ASME and ANSI were used extensively to design and evaluate modifications. In addition to technical tasks, project budgets and schedules were managed and reported to upper management and customers.

EDUCATION: University of St. Thomas, Minneapolis, MN, M.B.A., December 1996
University of Illinois, Urbana, IL, B.S. Civil (Structural) Engineering, May 1980

PREVIOUS PROFESSIONAL REGISTRATIONS:

Professional Engineer in the State of Minnesota, Registration No. 017035 4
Professional Engineer in the State of California, Registration No. C 043378

PATENTS: Inventor for 52 issued US patents, with other patent applications pending. See Appendix A for a list of US issued patents.

APPENDIX A: Issued US Patents – Michael J. Girard Inventor

<u>Patent No.</u>	<u>Issue Date</u>	<u>Assignee</u>	<u>Title</u>
11,589,981*	2/28/23	JVT	Prosthetic heart valve and transcatheter delivered endoprosthesis comprising a prosthetic heart valve and a stent
11,185,405*	11/30/21	JVT	Radially collapsible frame for a prosthetic valve and method for manufacturing such a frame
11,154,398	10/26/21	JVT	Stent for the positioning and anchoring of a valvular prosthesis in an implantation site in the heart of a patient
10,993,805	5/4/21	JVT	Stent for the positioning and anchoring of a valvular prosthesis in an implantation site in the heart of a patient
10,702,382	7/7/20	JVT	Stent for the positioning and anchoring of a valvular prosthesis in an implantation site in the heart of a patient
10,603,164*	3/31/20	JVT	Prosthetic heart valve and endoprosthesis comprising a prosthetic heart valve and a stent
10,433,954*	10/8/19	JVT	Radially collapsible frame for a prosthetic valve and method for manufacturing such a frame
10,405,973	9/10/19	SJM	Collapsible expandable prosthetic heart valves with native calcified leaflet retention features
10,154,901	12/18/18	JVT	Stent for the positioning and anchoring of a valvular prosthesis in an implantation site in the heart of a patient
9,987,133	6/5/18	JVT	Stent for the positioning and anchoring of a valvular prosthesis in an implantation site in the heart of a patient
9,867,699	1/16/18	JVT	Endoprosthesis for implantation in the heart of a patient
9,867,694*	1/16/18	JVT	Radially collapsible frame for a prosthetic valve and method for manufacturing such a frame
9,744,031*	8/29/17	JVT	Prosthetic heart valve and endoprosthesis comprising a prosthetic heart valve and a stent
9,615,921	4/11/17	SJM	Collapsible/expandable prosthetic Heart Valves with Native Calcified Leaflet Retention Features
9,439,759	9/13/16	JVT	Endoprosthesis for implantation in the heart of a patient
9,364,321	6/14/16	SJM	Collapsible/Expandable prosthetic Heart Valves with Native Calcified Leaflet Retention Features
9,289,290	3/22/16	SJM	Collapsible/expandable prosthetic Heart Valves with Native Calcified Leaflet Retention Features
8,801,598*	8/12/14	Mardil	Cardiac support device
8,790,395	7/29/14	JVT	Stent for the positioning and anchoring of a valvular prosthesis in an implantation site in the heart of a patient
8,784,481	7/22/14	SJM	Collapsible/expandable prosthetic heart valves with native calcified leaflet retention features
8,468,667	6/25/13	JVT	Device for compressing a stent
8,465,540	6/18/13	JVT	Stent for the positioning and anchoring of a valvular prosthesis
8,398,704	3/19/13	JVT	Stent for the positioning and anchoring of a valvular prosthesis in an implantation site in the heart of a patient
8,109,868*	2/7/12	Mardil	Cardiac support device
8,100,821	1/24/12	Mardil	Low friction delivery tool for a cardiac support device
7,326,174	2/5/08	Acorn	Cardiac disease treatment and device
7,214,181	5/8/07	Acorn	Septum attached ventricular support
6,951,534*	10/4/05	Acorn	Cardiac support device
6,902,524	6/7/05	Acorn	Cardiac disease treatment and device
6,730,016	5/4/04	Acorn	Cardiac disease treatment and device
6,682,476	1/27/04	Acorn	Cardiac disease treatment and device
6,682,475	1/27/04	Acorn	Tension indicator for cardiac support device and method therefore
6,572,533	6/3/03	Acorn	Cardiac disease treatment and device
6,564,094	5/13/03	Acorn	Cardiac disease treatment and device
6,482,146	11/19/02	Acorn	Cardiac disease treatment and device
6,358,278	3/19/02	SJM	Heart valve prosthesis with rotatable cuff

6,176,877	1/23/01	SJM	Two-piece prosthetic heart valve
6,176,876	1/23/01	SJM	Leaflet positioning for a mechanical heart valve
6,174,279**	1/16/01	Acorn	Cardiac constraint with tension indicator
6,155,972	12/5/00	Acorn	Cardiac constraint jacket construction
5,984,973*	11/16/99	SJM	Integral supporting structure for bioprosthetic heart valve
5,984,958**	11/16/99	SJM	Heart valve prosthesis with wear reducing edges
5,910,170	6/8/99	SJM	Prosthetic heart valve stent utilizing mounting clips
5,876,436	3/2/99	SJM	Rotatable cuff assembly for a heart valve prosthesis
5,843,179	12/1/98	SJM	Suture guard for prosthetic heart valve
5,843,178	12/1/98	SJM	Suture guard for annuloplasty ring
5,814,101	9/29/98	SJM	Holder for heart valve prosthesis
5,788,689	8/4/98	SJM	Prosthetic heart valve rotator tool
5,776,187	7/7/98	SJM	Combined holder tool and rotator for a prosthetic heart valve
5,735,842	4/7/98	SJM	Low profile manipulators for heart valve prostheses
5,716,417*	2/10/98	SJM	Integral supporting structure for bioprosthetic heart valve
5,571,175	11/5/96	SJM	Suture guard for prosthetic heart valve

Note: * Lead inventor, ** Sole inventor