

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Biomedical Device Consultants &
Laboratories of Colorado, LLC,

Plaintiff,

v.

ViVitro Labs, Inc.

Defendant.

Case No. 2:23-cv-04291-RGK-E

**DECLARATION OF MICHAEL
GIRARD**

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 action, including infringement and validity (if challenged) of the Patent-in-Suit, 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.

3. I am currently the President of my own consulting firm, Girard Technical Services, Inc. My firm provides research and development, engineering,

1 and technical management consulting services in the medical device industry.

2 4. I have over 42 years of experience in engineering, thirty-two of which
3 are in the medical device industry. I am a named inventor on 52 issued U.S.
4 Patents with additional applications pending.

5 5. My experience includes work with many cardiovascular devices and
6 specifically includes more than 24 years of heart valve experience. I've worked
7 for several medical device companies in the role of development and testing of
8 both surgical and transcatheter delivered prosthetic heart valves. Testing of
9 prosthetic heart valves usually includes durability testing at accelerated rates with
10 equipment like the systems produced by BDC and ViVITro. Therefore, I am very
11 familiar with durability test equipment and the requirements of such testing. My
12 curriculum vitae is attached hereto as **Exhibit A**.

13 **I. TECHNOLOGY OVERVIEW**

14 6. This case concerns equipment used for durability or accelerated wear
15 testing of heart valves. Before any medical device, such as a prosthetic heart
16 valve, is marketed, it must meet certain regulatory standards. International bodies,
17 such as the International Organization for Standardization ("ISO"), set certain
18 standards, such as those for testing the durability of medical devices, including
19 heart valves. The specific standards for heart valves are defined in ISO 5840.

20 7. Prosthetic heart valves must be tested to ensure that they will function
21 for the anticipated life of the patient by opening and closing the valve leaflets
22 under flows and pressures that are present within the human vascular system. The
23 normal human heart beats about 40 million times each year. The test requirements
24 for evaluating prosthetic heart valves according to the above-mentioned standards
25 require that the valves be able to survive and function for hundreds of millions of
26 cycles (*e.g.*, at least 5 years or 200 million cycles). The valves must also be able
27 operate over a specific range of opening and closing pressures that simulate
28 physiological conditions, and therefore testing standards require that a specific

1 pressure differential be generated across the valve when closed for at least 5% of
2 each cycle.

3 8. Testing systems use a test fluid to mimic blood and pressurize the
4 fluid to mimic the blood pressure in the human body. Testing requires fluid flow
5 through the valve and creating a pressure differential across the test valve when
6 closed at a certain minimum pressure for a certain length of the cycle. A “drive
7 mechanism” such as a pump drives the test fluid into the test chamber in order to
8 create the fluid flow and desired pressure conditions. In order to complete
9 hundreds of millions of cycles in a commercially viable timeframe, durability
10 testing is done on an “accelerated” basis. In other words, the speed of the cycles is
11 faster than a normal human heartbeat (a normal beat rate is 70 beats per minute –
12 bpm). Using current technology at accelerated cycling of 800 bpm, testing takes
13 approximately six months to simulate 200 million cycles.

14 **II. PROBLEMS IN PRIOR ART TECHNOLOGY**

15 9. The Patent-in-Suit, attached as **Exhibit B** hereto, identifies several
16 problems with the prior art.

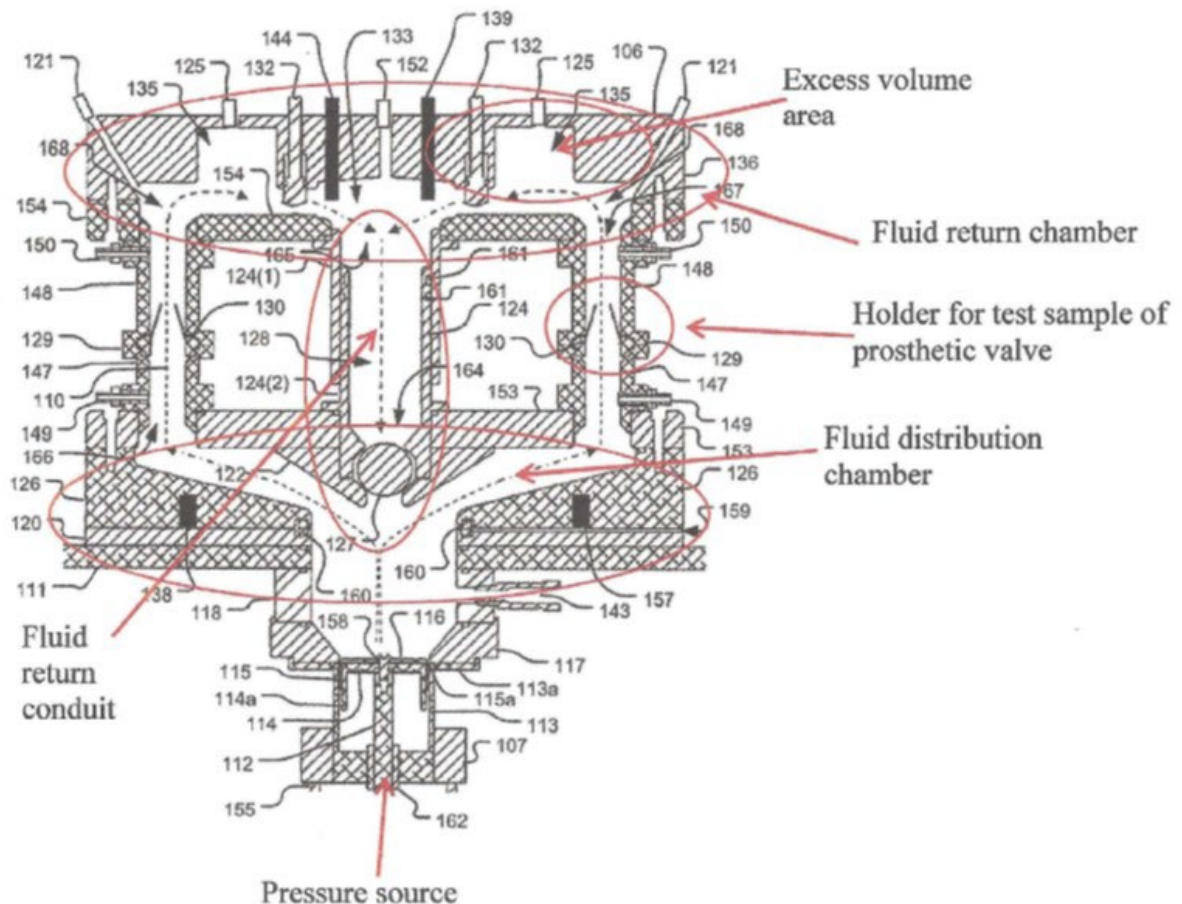
17 10. Driving mechanisms in the prior art had limited control over closing
18 rates and would often produce “pressure spikes” when the systems maintain
19 pressure above the testing threshold for the amount of time required by testing
20 standards. These pressure spikes are undesirable because they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

23 11. According to the Patent-in-Suit, prior art valve testing devices also
24 experienced operational problems. For example, one prior art device used a
25 flexible metallic bellows to pressurize. Ex. B (’935 Patent) at 1:34-36. However,
26 a higher load is required to drive the metallic bellows and can thus, impact the
27 reliability of the test system and increase maintenance requirements which
28 increases the already lengthy durability testing process.

III. OVERVIEW OF THE PATENT-IN-SUIT

12. The Patent-in-Suit proposes to solve these problems in the prior art.

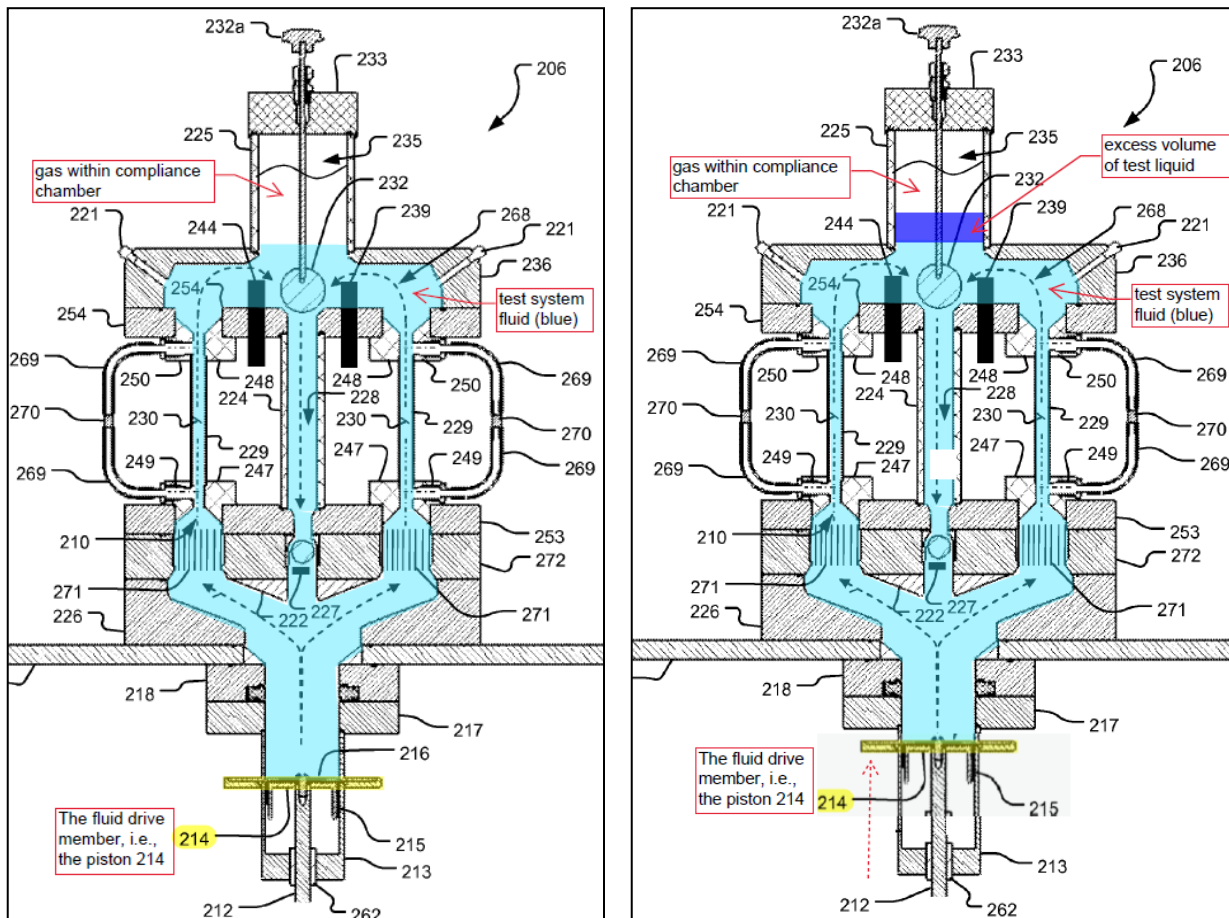
13. The '935 Patent covers a device for accelerated testing of valved prosthetics with several components including a test chamber and an “excess volume area” that is connected to a return chamber. A sample configuration of a test chamber is shown below that illustrates an exemplar excess volume area and return chamber:



14. 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. 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. The excess volume area 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, *i.e.*, recoil, that can negatively impact the durability of the prosthetic test valve.

15. 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:



1 16. Without the excess volume area, the '935 Patented system would not
2 function. In fact, the compressive forces could either cause a break and leakage or
3 cause the motor to become overwhelmed by system pressure and no longer being
4 able to operate.

5 17. The Patent-in-Suit offers potential advantages for heart valve
6 durability testing compared to the prior art. The use of the excess volume area,
7 which reduces pressure spikes, allows the system to better address the rigors of the
8 durability testing standards without exposing the test valves to undesirable, excess,
9 and clinically irrelevant pressures.

10 18. Prior to BDC's invention with an excess volume area, market leaders,
11 including ViVitro, used a different design. However, once BDC identified its new
12 design that allows the system to better mimic the human physiological
13 configuration, through the use of excess volume area, BDC's durability tester
14 became the market leader.

15 **IV. INFRINGEMENT ANALYSIS OF THE ADC HEART VALVE** 16 **DURABILITY TESTER**

17 **A. Claim Construction**

18 19. I understand that claim terms are to be given the ordinary and
19 customary meaning of the term as evaluated from the perspective of one of
20 ordinary skill in the art at the time of the invention. I further understand that the
21 claim term is to be read in context of the claim itself and in the context of the entire
22 patent, including the specification, but that limitations from the specification
23 should not be read into the claims.

24 20. Most of the language used in the relevant claims—claims 1-4, 8-9 and
25 12-13—can be readily understood by a person of ordinary skill in the art without
26 any construction by a court, and the plain and ordinary meaning should suffice.
27 Specifically, the following terms are readily understandable to a person of ordinary
28 skill in the art and should be given their plain and ordinary meaning:

- “pressure source”
- “pressurizable test chamber”
- “fluid distribution chamber”
- “fluid return chamber”
- “excess volume area”
- “under compression”

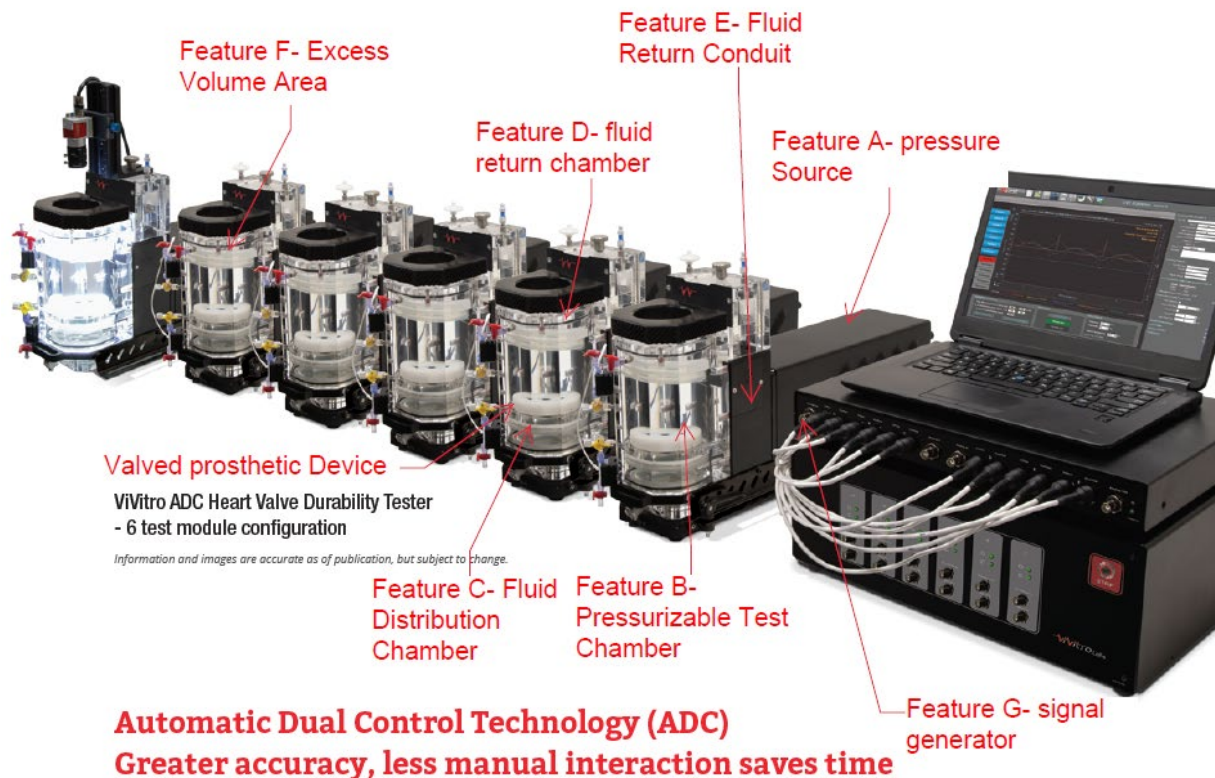
21. Based on context, including both the claims and the specification, the person of ordinary skill would understand that the term “compliance chamber” to mean “a cavity or volume that functions to absorb some of the pressure in the system.” This is explained directly in the specification of the Patent-in-Suit. *See, e.g.,* Ex. B (’935 Patent) at 9:8-16. The specification explains that the chamber or chambers absorb some of the pressure placed upon the fluid in the test chamber and can also impact the recoil. Likewise, the compliance chamber minimizes the effect of rapidly changing pressure gradients associated with accelerated testing. Finally, the compliance chamber is “a cavity or volume” because the specification notes that it may be air or another gas and may directly contact the fluid or may be separated from the fluid by a membrane.

22. The person of ordinary skill would understand that the plain meaning of “under compression” is that compressive forces are being placed on the test system fluid, *i.e.*, it is under pressure. Incompressible liquids cannot be compressed (absent very strong force). However, incompressible liquids can be placed “under compression.” In other words, compressive forces can be placed on liquids. This is the principle behind the field of hydraulics and hydraulic systems: pressure is created and transmitted by placing compressive forces on incompressible fluids. Thus, the plain meaning of “under compression” is “under pressure.”

B. Comparison of Claim Elements to ADC Heart Valve Durability Tester

23. It is my opinion that the ADC Heart Valve Durability Tester infringes at least claims 1-4, 8-9 and 12-13 of the '935 Patent.

24. The ADC Heart Valve Durability Tester includes all the elements of the Patent-in-Suit. A copy of the sales brochure for the ADC Heart Valve Durability Tester, which was available on ViVibro's website as recently as June 26, 2023, is attached as **Exhibit C**.¹ Annotated images of the ADC Heart Valve Durability Tester, taken from that brochure, are shown below and attached as **Exhibit D**. An archived version of ViVibro's website, as of September 26, 2022, is attached as **Exhibit E**.



25. My initial infringement analysis was based upon these publicly-available documents, Exhibits C, D and E. During the course of briefing in the

¹ https://vivitrolabs.com/wp-content/uploads/2022/09/ADC-Heart-Valve-Durability-Tester_Brochure.pdf

1 Colorado case, ViVitro produced a detailed schematic of its system, labeled
 2 VIVITRO 00001-00004, attached as **Exhibit F** *[filed under seal]*. I have reviewed
 3 Exhibit F, and continue to believe the ADC Heart Valve Durability Tester infringes
 4 claims 1-4, 8-9 and 12-13 of the '935 Patent.

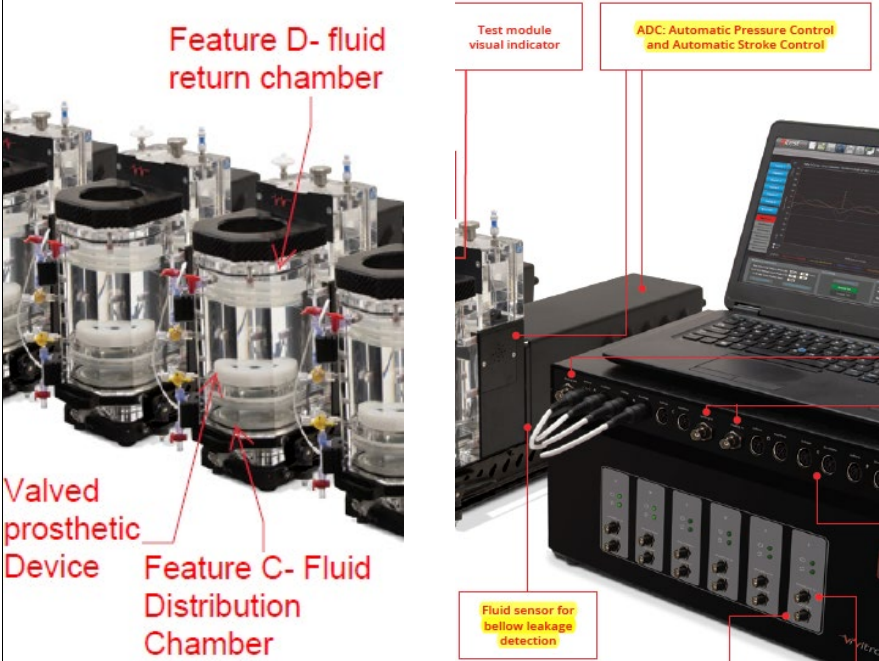
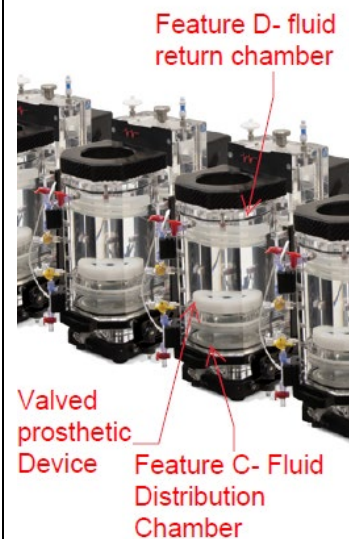
5 26. The ADC Heart Valve Durability Tester has a test chamber with an
 6 excess volume area. The ADC Heart Valve Durability Tester also has a drive
 7 motor that operates the system at an accelerated rate. For example, ViVitro's
 8 website described the ADC Heart Valve Durability Tester as offering
 9 "[a]ccelerated wear testing for replacement heart valves," including a "[d]edicated
 10 linear electromagnetic motor [that] utilizes position feedback for consistent heart
 11 valve opening." *See* Ex. E (Sept. 26, 2022 capture of ViVitro webpage).

12 27. As explained in the following claim charts, it is my opinion that due to
 13 these features, and the other features discussed in the charts, that the ADC Heart
 14 Valve Durability Tester infringes claims of the Patent-in-Suit.

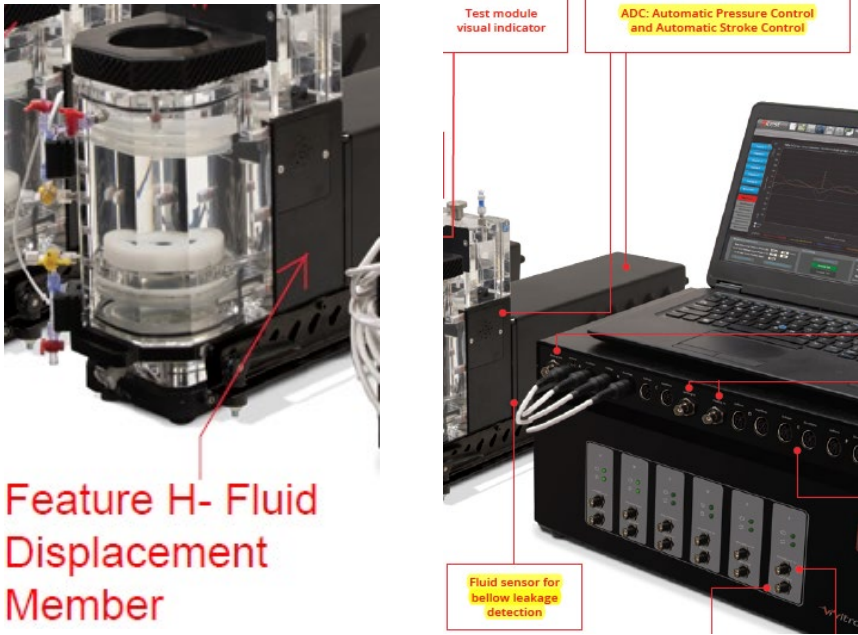
Claim Limitation	Presence of Limitation in ADC Heart Valve Durability Tester System
[preamble] 1. A device for accelerated cyclic testing of a valved prosthetic device comprising	The ADC Heart Valve Durability Tester product is advertised by ViVitro as a "Heart Valve Durability Tester." Ex. C at 1. A prosthetic heart valve is a valved prosthetic device. The ADC Heart Valve Durability Tester product is also touted by ViVitro as a device for "[a]ccelerated wear testing for replacement heart valves." Ex. E (Sept. 26, 2022 ViVitro website) (emphasis added). One touted "feature" is that its "[a]utomatic control system maintains optimum valve loading conditions <i>during accelerated wear or real time testing</i>." Ex. C at 2 (emphasis added). The ViVitro website states that the ADC Heart Valve Durability Tester "meets ISO 5840 AWT, DFM test requirements for all valve types and designs...." Ex. E at 2; Ex. C at 2. This standard requires cyclic testing. Therefore, the ADC Heart Valve Durability Tester is a system for "accelerated cyclic testing of a valved prosthetic device."

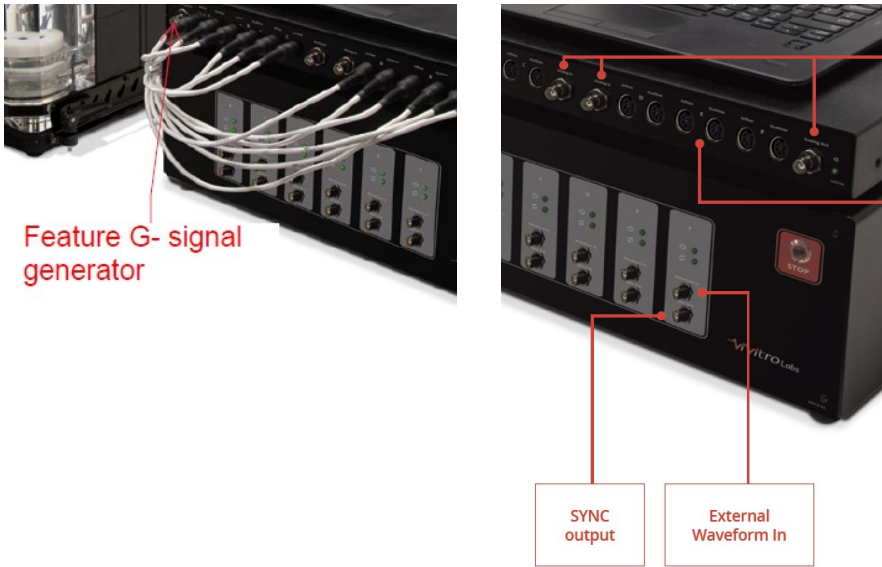
Claim Limitation	Presence of Limitation in ADC Heart Valve Durability Tester System
[1a] a pressure source configured to drive a test system fluid cyclically within the device above a normal physiological rate, at an accelerated pulsed rate of greater than 200 beats per minute within the device; and	Feature A (Ex. D at 1; Ex. C at 3):  The ADC Heart Valve Durability Tester includes a pressure source (contained in the base in the above image). The device operates at a frequency of 1-70 Hz. Ex. C at 4. Hertz (Hz) is a unit of measurement for cycles per second in which 1 Hz corresponds to a rate of 60 beats per minute. Per ISO 5840, accelerated testing is performed at speeds higher than 200 beats per minute (3.33 Hz). Therefore, the ADC Heart Valve Durability Tester is configured to drive a test system fluid at an accelerated pulsed rate.

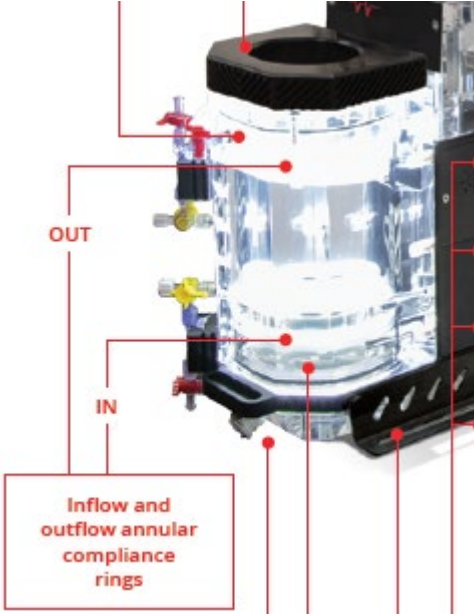
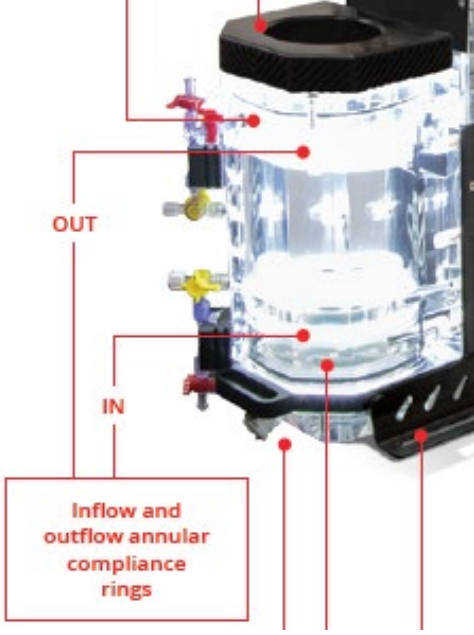
Claim Limitation	Presence of Limitation in ADC Heart Valve Durability Tester System
[1b] a pressurizable test chamber for containing the test system fluid and further comprising	 Feature B- Pressurizable Test Chamber compliance rings optimize differential pressure waveforms.” Ex. C at 2. Feature B (<i>see</i> Ex. D at 1): This picture shows a pressurizable test chamber. The pressurizable test chamber is also clearly noted by the location of the test sample and the inflow and outflow pressure measurement locations shown in Ex. C at 3. The ADC Heart Valve Durability Tester has “[l]arge, customizable test chamber[s]” and “[i]nflow and outflow chamber annular

Claim Limitation	Presence of Limitation in ADC Heart Valve Durability Tester System
[1c] a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source	Feature C (<i>see</i> Ex. D at 1):  This picture shows a fluid distribution chamber positioned underneath (in-flow side) the prosthetic valve being tested. The pressure source (Feature A, Ex. D at 1) is in fluid communication with the fluid distribution chamber at the point indicated by the note above, referencing a leakage sensor. <i>See</i> Ex. C.
[1d] a fluid return chamber positioned on a second side of the valved prosthetic device;	Feature D (<i>see</i> Ex. D at 1):  On the other side of the prosthetic heart valve (out-flow side - the side opposite the fluid distribution chamber), is a fluid return chamber, shown with the red arrow.

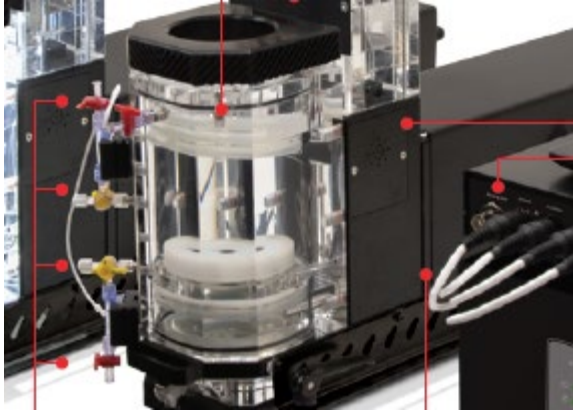
Claim Limitation	Presence of Limitation in ADC Heart Valve Durability Tester System	
[1e] a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and	Feature E- Fluid Return Conduit 	Feature E (<i>see</i> Ex. D at 1): The conduits “both structurally and fluidly” connect the fluid distribution chamber and the fluid return chamber.
[1f] an excess volume area capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid communication with the fluid return chamber providing a volume for storing a volume of a test system fluid when the test system fluid is under compression.	Feature F- Excess Volume Area  moves from the fluid return chamber to the excess volume area. The two are “in fluid communication,” and a portion of this fluid is stored in the excess volume area.	Feature F (<i>see</i> Ex. D at 1): The excess volume area is shown by a red arrow, <i>i.e.</i>, the volume adjacent to the annular compliance ring. As discussed above, the device operates at an accelerated rate. Therefore, the excess volume area is “capable of operating at the accelerated pulsed rate.” Moreover, when the test fluid in this closed system is under compression, it

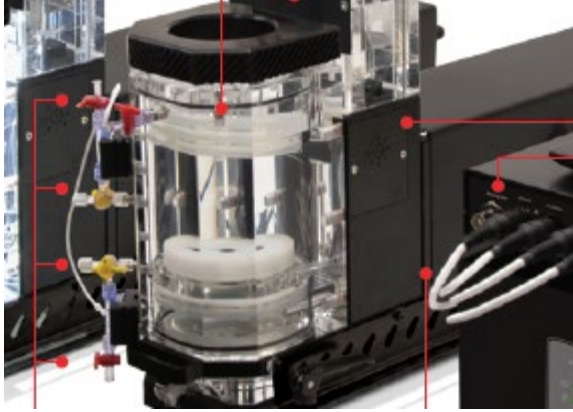
Claim Limitation	Presence of Limitation in ADC Heart Valve Durability Tester System
[2a] 2. The device in claim 1 further comprising a drive motor; and	Feature A- pressure Source  Feature A (<i>see</i> Ex. D at 1). The sales brochure states that the “dedicated linear electromagnetic motor utilizes position feedback for consistent heart valve opening.” Ex. C at 1. Thus, the ADC Heart Valve Durability Tester is driving fluid with linear drive motor.
[2b] a fluid displacement member connected with and driven by the drive motor to provide the pressure source that increases and decreases a pressure on the test system fluid in the test chamber.	Feature H (<i>see</i> Ex. D, Ex. C at 3):  Feature H- Fluid Displacement Member The ADC Heart Valve Durability Tester indicates that this feature has a “[f]luid sensor for bellows leakage detection” and “ADC: Automatic Pressure Control and Automatic Stroke Control.” Ex. C at 3. A person of ordinary skill in the art would understand that this discloses fluid displacement using a bellows system to convert the linear drive motor movements into fluid pressures. The pressure control system would use a pressure source that increases and decreases of pressure that is transmitted to the test chamber (Feature B).

Claim Limitation	Presence of Limitation in ADC Heart Valve Durability Tester System
3. The device of claim 2, wherein the drive motor is configured to operate cyclically, acyclically, or a combination of both, to provide cyclic and acyclic fluid pressures within the test chamber.	Feature G (<i>see</i> Ex. C, Ex. C at 3):  The linear electromagnetic motor drive system of the ADC tester is driven by the signal generator (Feature G). Typically the linear motor would be driven by a programmed cyclical waveform. However, the system has the option for driving the signal by an “External Waveform In.” Ex. C at 3. This indicates that the waveform could not just be cyclical, but acyclical or a combination of both.
4. The device of claim 2, wherein the drive motor comprises a linear motor.	Feature A (<i>see</i> Ex. D at 1).  The sales brochure states that the “dedicated linear electromagnetic motor utilizes position feedback for consistent heart valve opening.” Ex. C at 1. Thus, the ADC Heart Valve Durability Tester is driving fluid with linear drive motor.

Claim Limitation	Presence of Limitation in ADC Heart Valve Durability Tester System
8. The device of claim 1, wherein the excess volume area further contains a volume of a compressible gas that is compressed by the volume of the test system fluid to provide a spring force when the volume of the test system fluid is stored in the excess volume area.	 The ADC Heart Valve Durability Tester has “[l]arge, customizable test chamber[s]” and “[i]nflow and outflow chamber annular compliance rings optimize differential pressure waveforms.” Ex. C at 2. The annular compliance rings optimize differential pressure by allowing gas adjacent to the membrane compress when under pressure. <i>See</i> Ex. C at 3. That compressed gas provides a spring force against the fluid that moves into the excess volume formerly occupied by the compressible gas.
9. The device of claim 1, wherein the excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber.	 The ADC Heart Valve Durability Tester has “[l]arge, customizable test chamber[s]” and “[i]nflow and outflow chamber annular compliance rings optimize differential pressure waveforms.” Ex. C at 2. The compressible cavity defines the compliance chamber. The annular compliance ring on the “outflow” side of the valve is adjacent to the fluid return chamber. <i>See</i> Ex. C at 3.

Claim Limitation	Presence of Limitation in ADC Heart Valve Durability Tester System
12. The device of claim 9, wherein the compliance chamber provides a volume for holding a gas or elastomeric material that compresses under a pressure placed upon the test system fluid in the test chamber and allows the test system fluid in the test chamber to occupy a portion of the volume in the compliance chamber.	The ADC Heart Valve Durability Tester has “[l]arge, customizable test chamber[s]” and “[i]nflow and outflow chamber annular compliance rings optimize differential pressure waveforms.” Ex. C at 2. The annular compliance rings provide compliance by holding a compressible gas adjacent to a membrane that separates the gas from the fluid. The compliance ring on the “outflow” side of the valve defines an interface with the compliance chamber within the fluid return chamber. <i>See</i> Ex. C at 3. When under pressure, the gas compresses, allowing the test fluid to occupy a portion of the volume of that compliance chamber.

Claim Limitation	Presence of Limitation in ADC Heart Valve Durability Tester System
[13a] 13. The device of claim 1, wherein the test chamber defines a first port on a first side of the valved prosthetic device and a second port on a second side of the valved prosthetic device; and	Feature C shows a pressurizable test chamber. <i>See</i> Ex. D at 1. The sales brochure further discloses “[s]ingle inflow, and 3 different heights of outflow pressure measurements,” Ex. C at 2, which are ports for attaching pressure measurement equipment located on the inflow side of the valve (first side) and the outflow side (second side) of the valve. Ex. C at 3.  Single inflow, and 3 different heights of outflow pressure measurements

Claim Limitation	Presence of Limitation in ADC Heart Valve Durability Tester System
[13b] the first port and the second port are configured to receive one or more sensor devices.	Feature C shows a pressurizable test chamber. <i>See</i> Ex. D at 1. The sales brochure further depicts inflow and outflow ports that are 3-way luer lock fittings that are typically are used to attach pressure sensor transducers for the “pressure measurements” as stated. Ex. C at 2.  Single inflow, and 3 different heights of outflow pressure measurements

C. ViVistro’s ADC Durability Tester Has an “Excess Volume Area”

28. I understand that ViVistro has argued that its ADC Heart Valve Durability Tester lacks an “excess volume area.” I disagree.

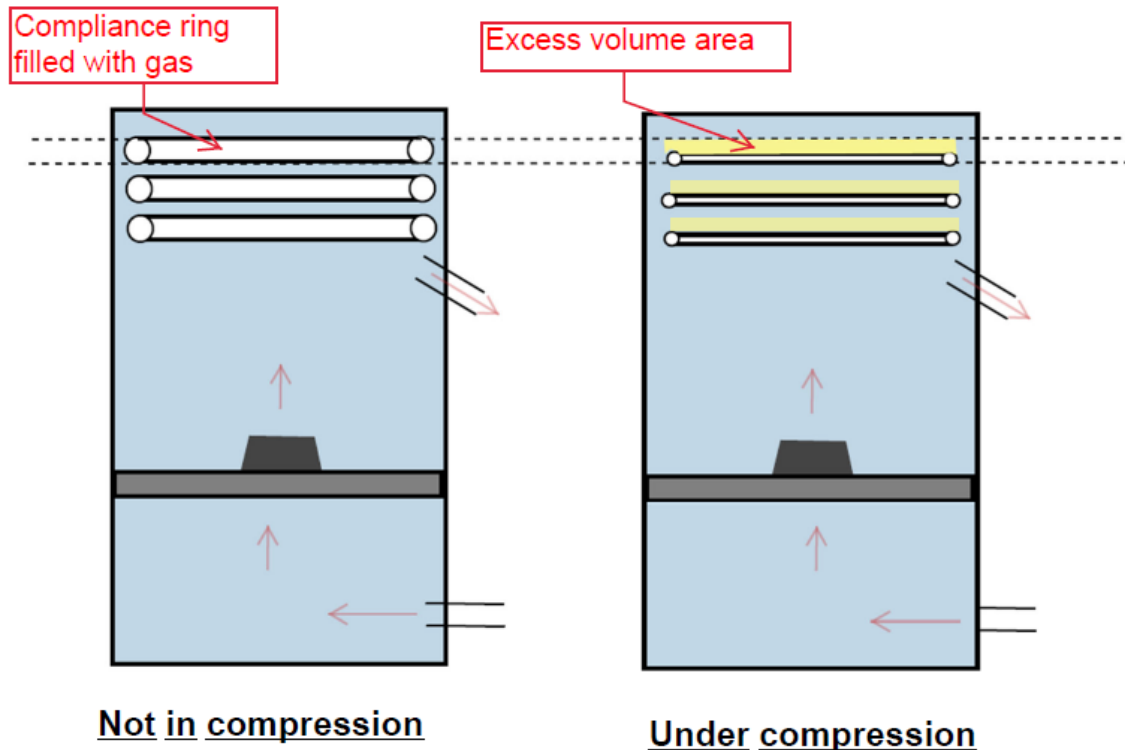
29. The schematic produced by ViVistro, attached as Exhibit F hereto, confirms that the ADC Heart Valve Durability Tester has an excess volume area.

30. These compliance rings are flexible tube structures that must be filled with compressible gas in order to provide compliance to the system when under compression.

31. Similar to the BDC system described in the ’935 Patent, the “excess volume area” is the area within the tubes that is occupied by gas when the system

is not under compression; when the system is under compression and the gas in the tubes is compressed, the compliance rings deform, so that at least some of the area occupied by gas becomes occupied by fluid in the fluid return chamber. The hollow compliance rings themselves contract into a smaller shape, creating additional volume to accommodate the excess volume that exists. Therefore, these compliance rings provide exactly the same excess volume as claimed in the '935 Patent.

32. This principle is illustrated in the figure below, with the yellow portion representing the excess volume area.



33. When the test fluid in this closed system is under compression, it moves from the fluid return chamber to the excess volume area. The two are “in fluid communication,” and a portion of the test fluid—the excess volume—is stored in the excess volume area.

34. A person of ordinary skill in the art would not understand the excess volume area to be a specific structure with rigidly defined boundary locations

1 throughout the pressure cycle of the test system. Rather, a person of ordinary skill
2 in the art would understand the excess volume area, based on the '935 Patent
3 claims and specification, is a location that is occupied by a compressible gas or
4 substantially incompressible fluid, depending on whether the system is not under
5 compression or is under compression by the drive system.

6 **V. VIVITRO'S INVALIDITY ARGUMENT**

7 35. In its opposition to BDC's motion for preliminary injunction in
8 Colorado, ViVitro identified two prior art systems: the Xi system and the Dynatek
9 system. These references, filed by ViVitro, are attached as **Exhibits G and H**.
10 Each of those operates in a completely different manner than the system described
11 in the '935 Patent.

12 36. The '935 Patent claims a system that allows driving fluid through a
13 test sample valve in a manner that better approximates the human physiological
14 state of the heart driving blood through the circulatory system. As I explained
15 above, when the system is driving test fluid through the prosthetic valve, the excess
16 volume area is able to store the excess volume downstream of the prosthetic test
17 valve. This can alleviate some of the system pressure during the drive stroke, and
18 also provides compliance in that it reduces/impacts the resistance and the forward
19 flow pressure gradients across the valve, minimizing unnatural and undesirable
20 pressure noise or spikes. During the reverse stroke of the motor when the valve is
21 closing, the excess volume area and its ability to provide compliance helps to build
22 back pressure on the valve, return the downstream volume to the pump and
23 continue to minimize unnatural and undesirable valve closing pressure spikes, i.e.,
24 recoil, that can negatively impact the durability of the prosthetic test valve. The
25 pressure source within the '935 Patent invention places the test system fluid under
26 compression, which then takes advantage of the excess volume area.

27 37. The Dynatek M6 system from 1993 uses a swashplate design,
28 essentially moving fluid by using a see-saw type mechanism, without impacting

1 the overall system pressure. *See* Ex. H. The Xi system uses a piston to drive the
2 actual heart valve down and then up through the fluid in which the valve is closed
3 during the driving stroke and open during the return. *See* Ex. G. By contrast, the
4 '935 Patent invention keeps the heart valve static and drives fluid through the
5 system using a linear drive motor. Ex. B ('935 Pat.) at 3:66-4:3.

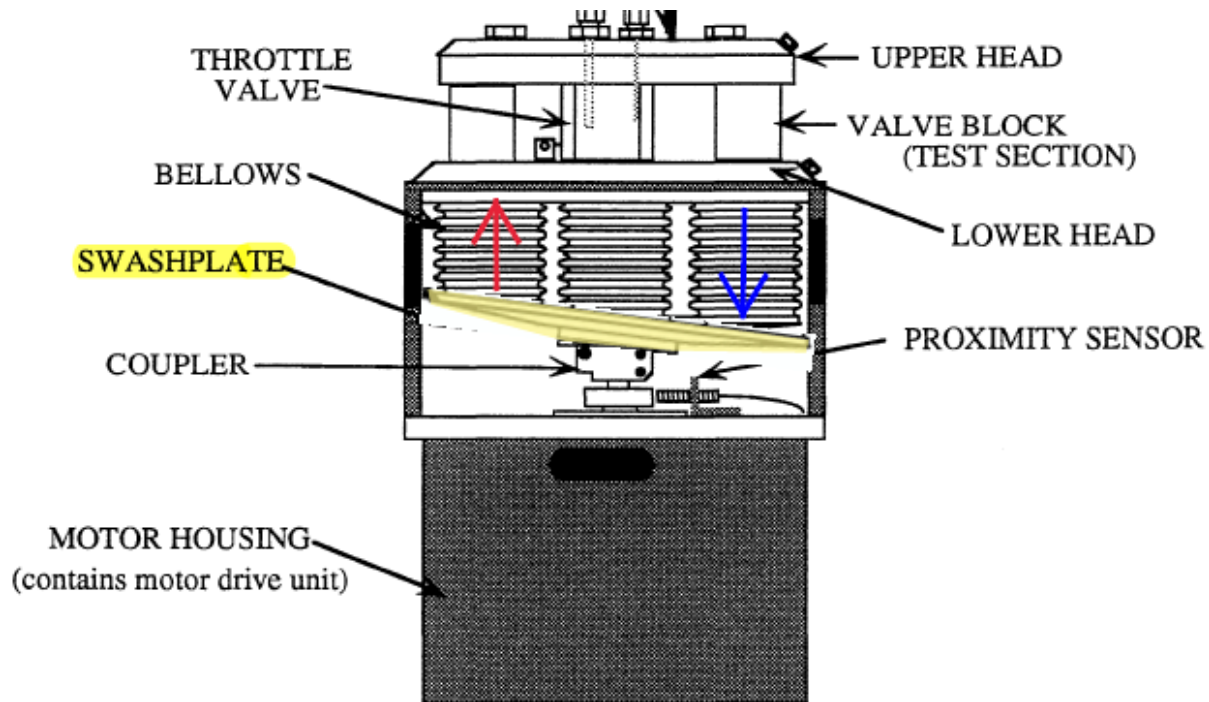
6 38. The '935 Patent claims a system that allows driving fluid through a
7 test sample valve in a manner that more closely approximates the human
8 physiological configuration—the heart driving blood through the valve—than
9 either the sloshing mechanism of the Dynatek M6, or the Xi method that moves the
10 valve up and down through the fluid.

11 **A. The Dynatek M6 1993 Reference**

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

15 40. Simulations of the operation of a swashplate can be found at:
16 [https://en.wikipedia.org/wiki/Swashplate#:~:text=A%20swashplate%2C%20also%](https://en.wikipedia.org/wiki/Swashplate#:~:text=A%20swashplate%2C%20also%20known%20as,reciprocating%20motion%2C%20or%20vice%20versa)
17 [20known%20as,reciprocating%20motion%2C%20or%20vice%20versa; https://w](https://www.youtube.com/watch?v=_VSOgJn-3wo)
18 [ww.youtube.com/watch?v=_VSOgJn-3wo;](https://www.youtube.com/watch?v=_VSOgJn-3wo)
19 <https://www.youtube.com/watch?v=gPlzIJ7maNY> (illustrating Dynatek M6
20 swashplate at minute 1:00-1:27).

41. An annotated and amended version of Figure 1A from Dynatek illustrates this operation. 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. Ex. H.



42. The resulting swashplate action is not putting the test system fluid under net compression 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.

43. While fluid in the test chamber on the upper end of the swashplate is subject to some positive force, the fluid in the test chamber on the lower end of the swashplate is subject to negative force. The overall force in the system is net neutral, and the overall volume does not change.

44. The Dynatek M6 can be likened to sloshing water around in a bowl. While some molecules of water, such as those at the low end, are subject to

1 compressive force, the molecules at the top end are subject to decompressive force.
2 The fluid in the bowl—i.e., the test system fluid—is under exactly the same
3 amount of net pressure at all times; there is no additional compression.

4 45. The Dynatek M6 operates with the valve in the upside-down position
5 (i.e., the inflow side of the valve is the upper portion of the test section). Most of
6 the fluid is moving from the upper head to the lower head and bellows back and
7 forth through the test chamber. The movement of fluid through the valve occurs
8 when the bellows extends and closing of the valve occurs during bellows
9 compression. This is different than the flow path described in the '935 Patent. In
10 the Dynatek M6 system, the bellows compression and elongation move the fluid
11 and pressures from the outflow side of the valve. Whereas, the '935 patent drives
12 the pressures and fluid from the inflow side of the valve.

13 46. The capacitance tank in the diagram has nothing to do with storing
14 fluid when under pressure or otherwise providing an excess volume area for the
15 system under pressure during a drive stroke.

16 47. Per the manual, the capacitance tank is designed to address only
17 “small variations” that occur over a longer period of time—transient leakage and
18 thermal effects—not pressure variations that occur with every cycle—i.e., 200+
19 times per minute. Ex. H at p.19 of 43. The inability of the capacitance tank to
20 handle cyclical pressures is underscored by the size of the tubing: the capacitance
21 tank is connected by 1/8 inch tubing that is 5 feet in length. Ex. H at pp.10, 12 ¶6.
22 This tubing is approximately the same diameter as the charging cord for an iPhone;
23 it is too narrow and too long to allow for passage of fluid during the accelerated
24 cycles performed by the tester.

25 48. This thin, long tube cannot accommodate passage of fluid at a rate of
26 200 times per minute or greater. Indeed, this design actually teaches away from
27 use of a capacitance tank as an excess volume area, as claimed in the '935 Patent,
28 because it teaches use of a structure that, as a matter of ordinary physics, could not

1 accomplish that function. Because the tube would not allow the fluid under
 2 compression to flow to the capacitance tank, that feature cannot be an excess
 3 volume area.

4 49. Also, this capacitance tank is attached to the inflow side of the valve
 5 (e.g., the upper head) and not the outflow side of the valve (e.g., lower head) and
 6 fluid return chamber where high pressures are generated. This capacitance tank
 7 has a different configuration, and more limited function, than the outflow
 8 compliance and excess volume area described by the '935 patent.

9 B. The Xi Reference

10 50. The Xi test system includes a linear motor which drives the movement
 11 of the valve to create pressures and flows. Unlike the '935 Patent invention, which
 12 uses a piston and bellows to drive fluid through the system and the valve, the Xi
 13 system moves the valve through the fluid.

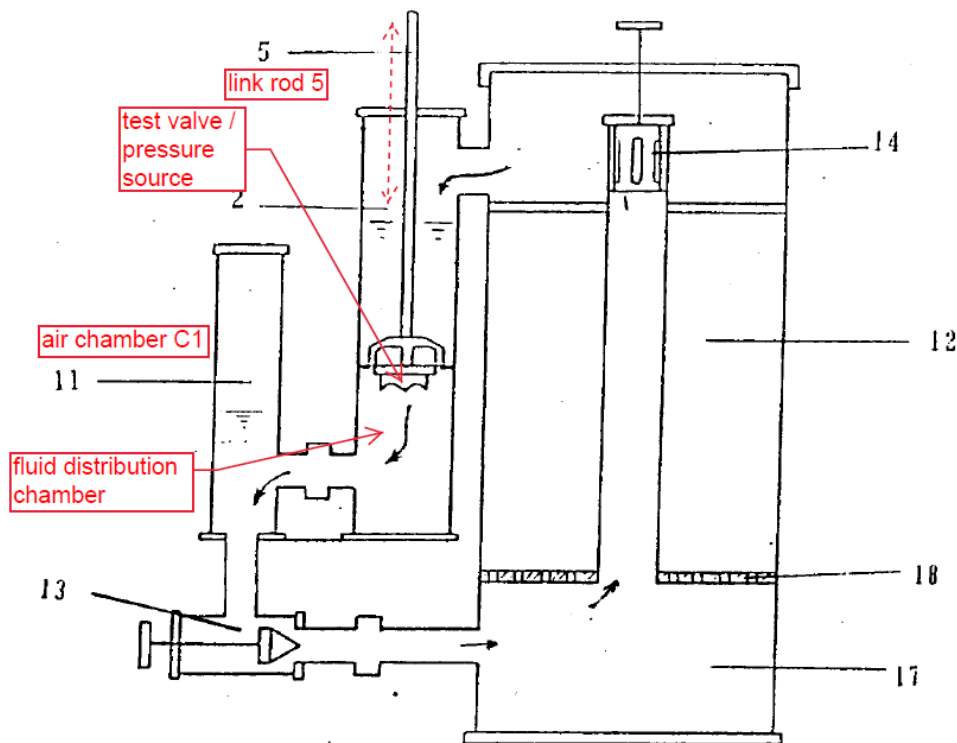


Fig. 4

1 51. Xi does not have limitation 1f: “an excess volume area capable of
2 operating at the accelerated pulsed rate, wherein the excess volume area is in fluid
3 communication with the fluid return chamber providing a volume for storing a
4 volume of a test system fluid when the test system fluid is under compression.”

5 52. The air chamber in the Xi reference serves a different purpose than the
6 excess volume areas in the '935 Patented invention. In Xi, the valve is closed
7 during the drive stroke and the closed valve acts as a pressure source, *i.e.*, the end
8 of the piston. To the extent the air chamber C1 provides some system compliance,
9 it is to prevent the valve from collapsing on itself when the valve is closed. The air
10 chamber is not designed to accept excess volume, because the volume needs to be
11 directed through the Xi system along the path of the arrows. *See* Ex. G. By
12 contrast, the purpose of the excess volume area disclosed in the '935 Patent is to
13 accept the fluid when it is being pushed through the valve into the return chamber
14 when the valve is open.

15 53. The Xi system is an open fluid system, not a closed fluid system like
16 the '935 Patent invention. Thus, it does not require an excess volume area to avoid
17 excessive pressure due to the incompressibility of the fluid.

18 54. Further, the Xi air chamber C1 (11) is not in fluid communication
19 with the fluid return chamber. Air chamber C1 is not in fluid communication with
20 any return chamber—if one exists in Xi—it is in communication with the fluid
21 distribution chamber.

22 55. Even if Xi did disclose an “excess volume area” within the meaning
23 of the '935 Patent, there is no reason why one of ordinary skill would have
24 combined the “air chamber” of Xi with the Dynatek M6 system, when they operate
25 in fundamentally different ways. As described above, Xi uses a piston to drive the
26 valve through fluid, and Dynatek M6 uses a swashplate to move the test liquid
27 around without changing the overall compression of the system. There would be
28 no need to add an in-line air chamber to Dynatek; it does not operate “under

compression.” There is no teaching of where to put it within the Dynatek system in that the Dynatek system would not flow properly with an air chamber. Rather, the Dynatek system requires removing all air from the system. Ex. H at p.9 (“[B]ubble removal is one of the biggest challenges facing a valve tester.”). Thus, the Dynatek manual specifically teaches away from combining it with an air chamber.

56. Additionally, even if such an air chamber were added to Dynatek, it would still not meet the limitations of claim 1, because the Dynatek “pressure source” does not exert compression on the system. Thus, even with the air chamber of Xi, the Dynatek system does not have an “excess volume area,” because the Dynatek system has no net compression, and therefore no “excess volume.” Thus, there is no area to which excess volume flows while under compression in the Dynatek system.

I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on June 26, 2023 in LINO LAKES, Minnesota.

By: Michael Girard
Michael Girard

Exhibit A: Curriculum Vitae

Exhibit B: U.S. Pat. No. 9,237,935

Exhibit C: ViVitro ADC Heart Valve Durability Tester Brochure

Exhibit D: Annotated Images from Brochure

Exhibit E: ViVitro Website as of September 26, 2022

Exhibit F: ViVitro Schematic, produced as VIVITRO 00001-00004 [*under seal*]

Exhibit G: Xi Reference

Exhibit H: Dynatek Reference