

No. 2023-2393

IN THE
United States Court Of Appeals
FOR THE FEDERAL CIRCUIT

BIOMEDICAL DEVICE CONSULTANTS & LABORATORIES OF
COLORADO, LLC,

Plaintiff-Appellant,

v.

VIVITRO LABS, INC.,

Defendant-Appellee.

**APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE
CENTRAL DISTRICT OF CALIFORNIA**

Case No. 2:23-cv-04291-HDV

APPELLANT'S CORRECTED OPENING BRIEF AND ADDENDUM

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October 24, 2023

Petitioner's Exhibit 1022
VIVITRO v. BDC
IPR2024-00320

EXEMPLAR CLAIM OF U.S. PATENT NO. 9,237,935

1. 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.

CERTIFICATE OF INTEREST

Counsel for Plaintiff-Appellant Biomedical Device Consultants & Laboratories of Colorado, LLC certifies the following:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

Biomedical Device Consultants & Laboratories of Colorado, LLC.

2. **Real Party in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

None.

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

Tentamus North America.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

Dorsey & Whitney LLP: Maral Shoaee; Kent Schmidt (for Appellant)

5. **Related Cases.** Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5).

None.

6. **Organizational Victims and Bankruptcy Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not Applicable.

I certify that the foregoing information is true and correct to the best of my knowledge.

Dated: October 24, 2023

By: /s/ Gregory S. Tamkin
Gregory S. Tamkin

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STATEMENT OF RELATED CASES

This appeal arises from a pending civil action in the United States District Court for the Central District of California. *See Biomedical Device Consultants & Laboratories of Colorado, LLC v. ViVitro Labs, Inc.*, No. 2:23-CV-04291-HDV (C.D. Cal.). Pursuant to Federal Circuit Rule 47.5(b), Appellant states that this is the only appeal from the foregoing civil action. No other appeal from that action has previously arisen in this Court or in any other appellate court.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. § 1331 because this civil action alleges patent infringement under the federal patent statutes, 35 U.S.C. § 271 *et seq.* This Court has jurisdiction under 28 U.S.C. § 1292(c)(1) to hear this appeal of an order denying an injunction in this civil action arising under an Act of Congress relating to patents. 28 U.S.C. § 1292(a)(1) (appellate jurisdiction over orders “refusing ... injunctions”); 28 U.S.C. § 1295(a)(1) (Court of Appeals for the Federal Circuit has jurisdiction over patent cases). The United States District Court for the Central District of California entered an order denying a preliminary injunction on August 29, 2023. APPX0001. A timely notice of appeal was filed on September 11, 2023. 28 U.S.C. § 2107(a); Fed. R. App. P. 4(a)(1)(A).

STATEMENT OF THE ISSUES

1. Whether the district court erred as a matter of law in construing the term “excess volume area” in a way that incorporates a limitation from the specification into the claims, disregards the specific claim language and ascribes the same meaning to two different claim terms?
2. Whether the district court erred as a matter of law in finding that Appellees raised “substantial questions” of infringement, where it applied misconstrued claim terms to the undisputed facts concerning the Accused Product?
3. Whether the district court erred as a matter of law in concluding that Appellees raised a “substantial question” of invalidity when the Dynatek reference fails to disclose multiple elements of the Patent-in-Suit and where the district court recognized that Appellee presented insufficient evidence of a motivation to combine Dynatek with Xi?

STATEMENT OF THE CASE AND FACTS

BDC has revolutionized the market for heart valve durability testers, and has protected its invention and investment through patents. BDC’s best-selling system, the VDT-3600i, is used for testing the durability of prosthetic heart valves and is covered by a family of patents including U.S. Patent No. 9,237,935 (“the ’935 Patent,” attached starting at APPX00013). The technology behind the VDT-3600i made it the market standard, rendering prior products obsolete—including Defendant/Appellee ViVidro Labs Inc.’s (“ViVidro”) then-offered tester—and earning BDC the dominant market position and a reputation for innovation.

Attempting to capitalize on this technology pioneered by BDC, ViVidro is now offering an infringing test system known as the ViVidro ADC™ Heart Valve Durability Tester. With respect to infringement, the dispute centers on a single limitation of the sole independent claim: whether ViVidro’s product has an excess volume area in fluid communication with the fluid return chamber. In this case, ViVidro has inserted gas-filled annular compliance rings into its fluid return chamber. These rings create an excess volume area in the chamber as, when under compression, the test fluid moves into the volume previously occupied by the uncompressed gas. That excess volume area is in fluid communication with the return chamber as the excess volume is flowing into that area from the return chamber.

BDC filed this lawsuit only after trying unsuccessfully for months to persuade ViVistro to stop its commercialization of the infringing ADC Heart Valve Durability Tester without court intervention. ViVistro repeatedly rejected those efforts, continuing to market its soon-to-be-launched product at trade shows. To the best of BDC's knowledge, ViVistro intended to begin shipping its infringing product in fall 2023—meaning that the distribution process has likely begun. If ViVistro is allowed to continue its infringing activities, BDC will suffer an irreparable and irretrievable loss of market position, loss of business opportunities, harm to business relationships, and damage to its reputation as an industry-leading innovator in equipment for the durability testing of heart valves.

BDC sought a preliminary injunction at the district court level over the last few months. On August 29, 2023, District Court Judge Hernan D. Vera issued an order denying BDC's request, which can be found at APPX0001. BDC hereby appeals that denial. Judge Vera found that BDC failed to show a likelihood of success. In fact, that ruling was based on the application of a faulty claim construction and a flawed understanding of a reference that was not even asserted against all the claims in question. This Court should reverse, instruct the district court that BDC has made a strong showing of a likelihood of success and remand for consideration of the other preliminary injunction factors.

FACTUAL BACKGROUND

A. Field of Technology and BDC's Role

Prosthetic heart valves must be tested to ensure that they will function for the anticipated life of a patient by opening and closing under the flows and pressures present within the human vascular system. APPX0907 at ¶6. The International Organization for Standardization (“ISO”), and other international bodies, set the standards for testing the durability of heart valves. *Id.* Testing standards require that prosthetic valves be able to withstand a certain number of cycles of opening and closing of the valve leaflets, usually in the hundreds of millions (representing years of service in a human body), and that a specific pressure differential be generated across the valve when closed. APPX0907-0908 ¶7. In order to complete hundreds of millions of cycles in a commercially viable timeframe, durability testing is done on an “accelerated” basis. In other words, the speed of the cycles is faster than a normal human heartbeat (a normal beat rate is 70 beats per minute (“bpm”)). Using current technology at accelerated cycling of up to 800 bpm (though anything over 200 bpm is considered “accelerated”), testing takes approximately six months. APPX0907 ¶8.

B. The Patented Invention with an Excess Volume Area

BDC developed a new system that would drive fluid through the accelerated testing system in a circulatory manner—more closely approximating human physiology than other prior art systems—without subjecting the valve to undue

pressure. Providing fluid flow through the test valve and pressure across it requires a “drive mechanism” such as a pump that drives fluid into a test chamber. APPX0909-0911 ¶¶13-16. Before commercialization of the technology of the Patent-in-Suit, durability testing equipment used drive mechanisms that had limited control over the closing rate of the valve and often produced “pressure spikes” when maintaining 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 in the human body, causing erroneous test failures. APPX0911 ¶¶17-18.

To better manage the valve closing dynamics and differential pressure spikes, and thus better comply with durability testing standards, BDC developed a novel accelerated test system that, among other things, placed an “excess volume area” on the outflow side of a sample test valve. APPX0867-0868 ¶5. BDC employees also developed a method of operating the test system using this excess volume area that helps control differential pressure spikes. This excess volume area improves the test environment by minimizing unnatural and undesirable pressure spikes, and provides advantages of speed and longevity in the drive system. APPX0869 ¶9. Specifically, the excess volume area can alleviate some of the system pressure during the drive phase. APPX0868 ¶7. The excess volume area also reduces pressure recoil by releasing fluid downstream of the valve during the return phase (when pressure is

released) that helps build pressure back up on that side of the valve. *Id.* Claim 1 claims the following excess volume area:

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.

APPX0032 at 17:29-50.

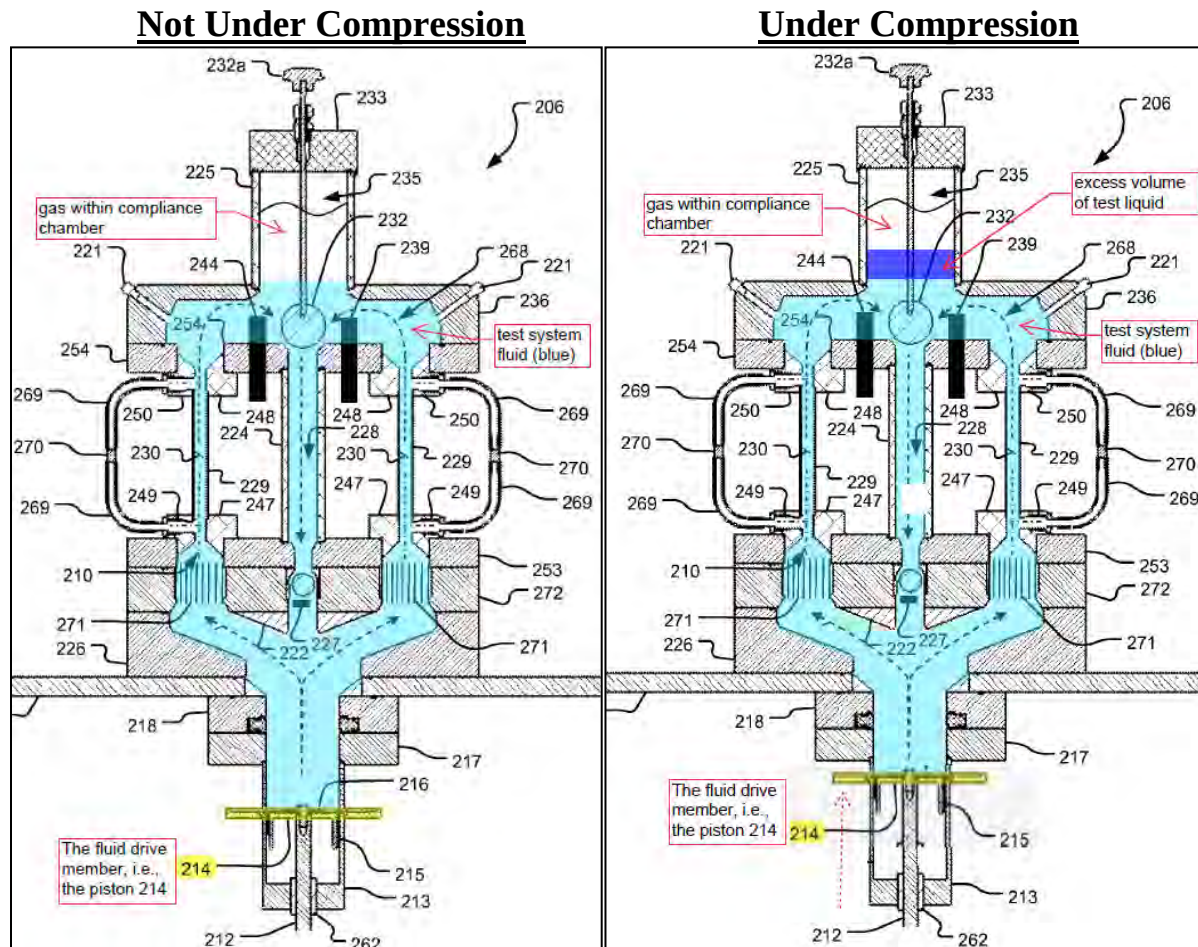
The only limitation at issue in this appeal is the “excess volume area” element. As relevant here, the “excess volume area” is an area that (1) provides a “volume for storing a volume of a test system fluid when the test system fluid is under compression,” (2) is “in fluid communication with the fluid return chamber” and (3) is “capable of operating at the accelerated pulsed rate.” APPX0032 at 17:45-50.

1. A Volume for Storing Test Fluid When the System is Under Compression

The excess volume area is the **area** that can be filled with fluid when under compression during the drive stroke, and can be filled with gas when the system is not under compression. APPX0029 at 12:4-39. In other words, the excess volume area is a three-dimensional **space** that is alternately occupied by gas or by fluid, depending upon whether the system is under compression.

A portion of Figure 6 of the '935 Patent is depicted below, with the test fluid in light blue, and the excess volume—*i.e.*, that additional portion of test fluid that

enters the excess volume area during compression—in darker blue. During the drive stroke, the gas in the compliance chamber (235) is compressed, and there is a larger volume of fluid than when the piston is in a decompression stroke. APPX0029 at 12:4-39; APPX0909-0910 ¶14.



Using one (or more) compliance chambers adjacent to the fluid return chamber is one way to provide an excess volume area, but it is not the only way. In describing Figure 4, the specification states:

The compliance chambers 135 provide **excess volume area** for fluid to move into when the piston performs a compression stroke. As the pressure of the gas in the

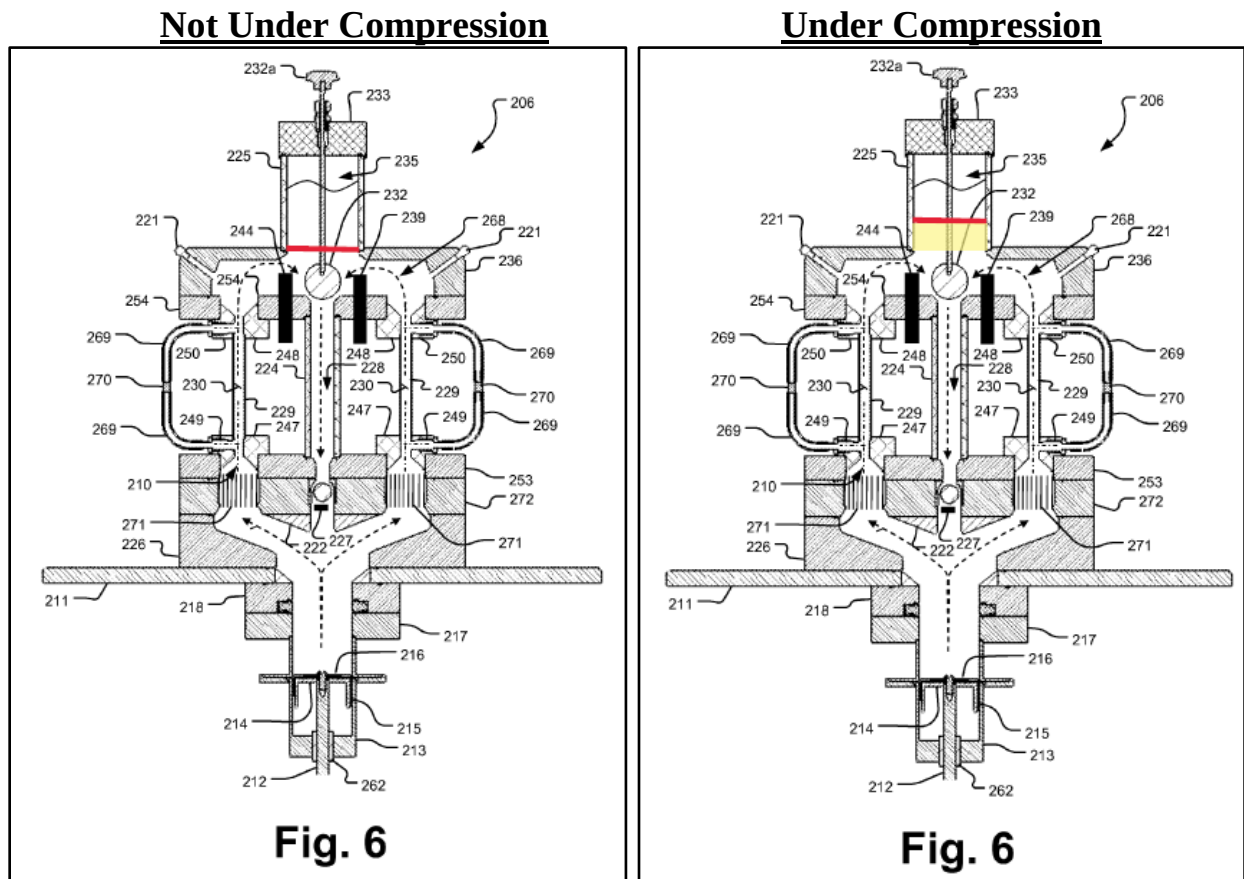
compliance chamber 135 increases, the volume occupied by the gas decreases *to provide additional volume* for displacement of the liquid working fluid within the test chamber 106.

APPX0029 at 12:4-9 (emphasis added). Dependent Claim 9 claims the narrow example of one preferred embodiment: it provides for the device of Claim 1 “wherein the excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber.” APPX0032 at 18:29-31.

2. In Fluid Communication with the Fluid Return Chamber

The excess volume area must be “in fluid communication with the fluid return chamber.” APPX0032 at 17:28-50. As described above, the excess volume area is a space that alternately holds test fluid or gas,¹ depending upon whether the system is under compression. The excess volume area is “in fluid communication” with the return chamber, which is illustrated by the fact that the test fluid from the return chamber moves into that volume when the system is under compression. The ’935 Patent expressly states, however, that the gas and the fluid need not be touching—they may be separated by a membrane—and the return chamber will still be in fluid communication with the excess volume area. APPX0028 at 9:20-28. A further annotated version of Figure 6 illustrates this principle:

¹ Both experts treat the terms “test fluid” or “fluid” to mean something in liquid form, and exclude “gas” or “air” from the term “fluid” for these purposes. See, e.g., APPX1175 at ¶21 (ViVitro expert); APPX0910 at ¶15.



The membrane (red) separates the gas (above) from the fluid (below) at all times during the cycle. When the system is in the drive stroke (right), the gas compresses and fluid flows into the excess volume area (yellow). The excess volume area is “in fluid communication with” the return chamber (268)—because fluid can flow directly into and out of the excess volume area to the return chamber—even if the gas and fluid are separated by a membrane. Even with a separating membrane, the locations remain in fluid communications, as claimed.

3. Capable of Operating at an Accelerated Rate

The excess volume area must be capable of operating at an accelerated rate.

APPX0032 at 17:45-46; APPX0029 at 12:4-39. While the concept of compliance in

other types of systems was known, the novel aspect of the '935 Patent was its use of an excess volume area in an accelerated-rate tester to provide an excess volume area to store the stroke volume in a closed system running at accelerated rates (*i.e.*, >200 bpm). *See* APPX1175-1176 ¶¶21-22 (ViVitro's expert explaining well-known water hammer arrestor); APPX0909-0911 ¶¶12-18 (BDC's expert explaining novelty of excess volume area); APPX0868-0869 ¶8 (BDC's CTO explaining the same).

C. BDC's Heart Valve Durability Test Equipment Dominated the Market

BDC's VDT-3600i heart valve durability tester, which practices the '935 Patent, has become a core component of BDC's overall business and is BDC's best-selling medical device test system. APPX0869-0871 ¶¶9-16, 20. The specialized nature of heart valve durability systems means that there are a limited number of competitors in the marketplace. APPX0870-0871 ¶¶17-19. There are currently only three: Defendant/Appellee ViVitro (which until recently was promoting its obsolete technology), TA Instruments-Waters LLC ("TAI"), and Dynatek Labs. APPX0870 ¶15; APPX0873 ¶25. The superior performance of the VDT-3600i has made it the industry standard for heart valve durability testing, with an estimated 70-75% worldwide market share. APPX0870 ¶16.

Market share in the heart valve durability testing equipment market is important due to incumbency effects. APPX0870-0871 ¶17. A single testing system can only test a few devices at a time. *Id.* To bring a new prosthetic valve device to

market, however, medical device manufacturers need testing data from many, often dozens, of sample devices, and need multiple testers. *Id.* Customers generally do not use testing equipment from multiple sources in one testing program, in order to avoid introducing additional testing variables (*i.e.*, differences between testing machines from different suppliers) into the test data—data that is submitted to the FDA, or to other international regulatory agencies. APPX0871 at ¶18. The lifespan of valve durability testing equipment is generally ten to fifteen years. Once a customer has decided which testing equipment to use, it will likely be many years before a competitor has the opportunity to usurp the place of an incumbent. *Id.*

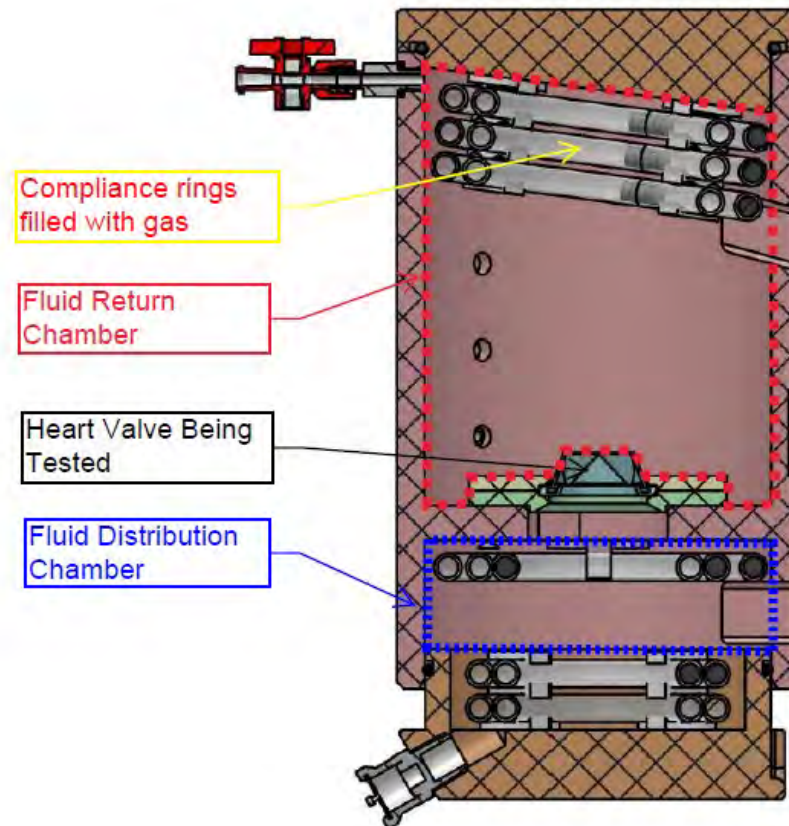
Both parties agree that, prior to the launch of BDC’s VDT-3600i tester, ViVidro was a market leader in accelerated test systems, gaining a stellar reputation. APPX1156-1157 ¶11 (Declaration of ViVidro’s President); APPX0869 ¶11 (Declaration of BDC’s CTO). ViVidro confirms that BDC’s VDT-3600i durability tester achieved commercial success and supplanted ViVidro’s HiCycle tester as the market leader. APPX1158-1159 ¶16; APPX0870 ¶¶14, 16 (BDC currently has 80-85% share of U.S. market). Per ViVidro’s CEO and confirmed by BDC’s Chief Technical Officer, in this industry, a “reputation for reliability and innovation is essential to [] customer relationships and business.” APPX1164 ¶33; APPX0871-0872 ¶21. And in this industry, the “negative impact” from reputational harm is “severe” and “is difficult, if not impossible, to measure accurately.” APPX1164 ¶36.

D. ViVitro's ADC Heart Valve Durability Tester Infringes the '935 Patent and Competes Against BDC's VDT-3600i

Years after BDC's invention supplanted ViVitro's prior technology, ViVitro developed an infringing product and began a worldwide campaign to launch it.

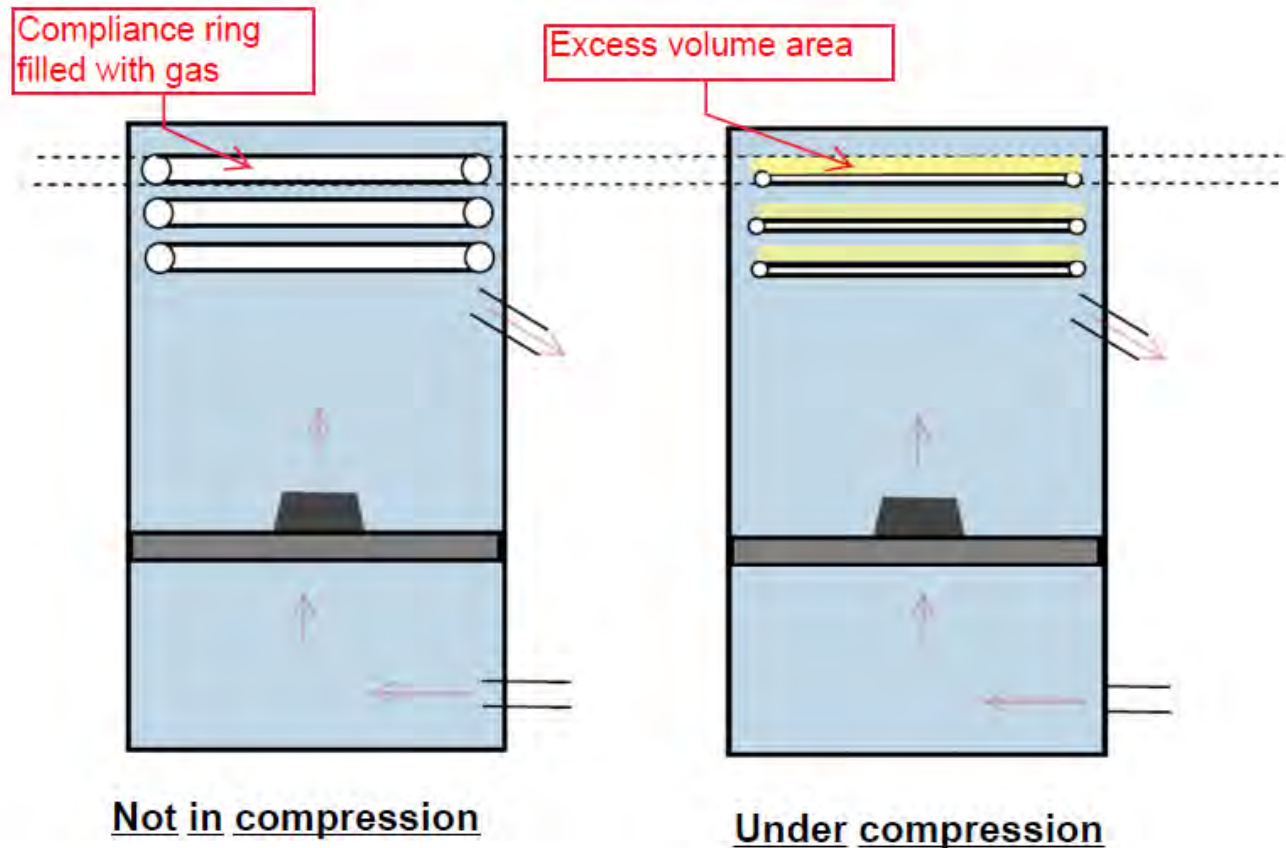
ViVitro's infringing ADC Heart Valve Durability Tester is marketed as a device for accelerated cyclic testing of a valved prosthetic device comprising (1) a pressure source that drives the test system at an accelerated rate above 200 beats per minute, (2) the claimed pressure chambers on each side of the valve, (3) a fluid conduit structurally and fluidly connecting the chambers, and (4) the claimed excess volume area for storing fluid when the fluid is under compression. APPX0913-APPX0924 ¶¶23-27.

The Accused Product has three hollow compliance rings within the fluid return chamber. These compliance rings are flexible tube structures that are filled with compressible gas in order to provide compliance to the system when under compression. APPX0924-0926 at ¶¶28-34; APPX1606.



When the system is under compression, the gas within those compliance rings contracts, creating additional volume to accommodate the excess volume of fluid that is created by the drive mechanism. APPX0924 ¶30. The displacement of the compliance rings when the outflow fluid is under compression results in *fluid* occupying the excess volume area that was previously occupied by the compliance rings and gas. APPX0924-0925 ¶¶31-32. Simplified images of the Accused Product,

below, demonstrate this principle:



These compliance rings provide the same excess volume area and compliance function as described in Claim 1 of the '935 patent. *Id.*; APPX0028 at 17:28-50.

E. BDC Attempts to Stop the Irreparable Harm Through Negotiation, But is Unsuccessful

Last summer, BDC learned that ViVitro was distributing marketing materials for a new tester: the ADC Heart Valve Durability Tester (the “Accused Product”). APPX0870 ¶15. In August 2022, BDC sent a letter notifying ViVitro of its infringement of the '935 Patent and other BDC patents. APPX0876 ¶36. Instead of arguing that it did not infringe BDC’s patent, ViVitro claimed that one of BDC’s annotations pointed to the wrong feature. APPX0876 ¶37. BDC gathered additional

information about the Accused Product, including observing it in operation at a conference in Boston and speaking with ViVistro’s President, Karim Mouneimné. APPX0877 ¶39. BDC sent another letter warning ViVistro of its infringement. APPX0877 ¶41. ViVistro failed to respond to that communication, and BDC had to follow up multiple times to secure a response. APPX0877 ¶42. After granting itself multiple extensions, ViVistro provided its substantive response in early 2023. *Id.* Again, ViVistro did not attempt to argue that the Accused Product did not meet the limitations of the independent claim of the Patent-in-Suit. Instead, ViVistro declared that it did not infringe any “valid” claims, and provided copies of clearly different and unrelated prior art. *Id.* ViVistro provided no chart nor any other indication as to why any particular prior art was invalidating.

Meanwhile, ViVistro continues to actively market and sell the Accused Product, and has expressed an intention to begin distribution in fall 2023. APPX0878 ¶44. The harm faced by BDC absent an injunction has only become more acute.

On April 7, 2023, BDC filed this lawsuit, and days later filed a motion for preliminary injunction. APPX0034-0035 (Dkts. 1, 8).

F. In Response to the Preliminary Injunction Motion, ViVistro for the First Time Puts Forth Non-Infringement and Invalidity Defenses

For the first time, ViVistro claimed in its preliminary injunction response it did not infringe the ’935 Patent. ViVistro claimed that (1) an “excess volume area” must be a physical structure and should be construed to be the same as the “compliance

chamber,” and (2) it has no such structure that is “in fluid communication with the fluid return chamber because (a) the identified area is *inside* the fluid return chamber, and (b) a membrane separates the gas within the compliance rings from the test fluid outside those rings. APPX0343; APPX0036 (Dkt. 24). In response, BDC pointed out that all three of these arguments rely upon a faulty and improperly narrow construction of the claim.

ViVitro also provided an invalidity argument. **First**, ViVitro argued that the ’935 Patent is anticipated by a manual from a competitor, Dynatek. APPX0324-0325 ¶45; APPX0036 (Dkt. 24). In response, BDC pointed out that the Dynatek system lacks three necessary elements: it lacks an excess volume area because the system is not “under compression,” the supposed “excess volume area” is connected on the wrong side of the valve (as even ViVitro’s expert admits), and the supposed “excess volume area” cannot possibly operate at an accelerated rate. Moreover, ViVitro’s anticipation defense applies to only four of the eight asserted claims; the other four retain their presumptive validity. APPX0928-0930 ¶¶42-49.

Second, ViVitro argued that the ’935 Patent is obvious over Dyantek in view of Xi. APPX0324-0325 ¶45. ViVitro did not attempt to map Xi onto the patented claims; instead, it argued that the “air chamber” of Xi could be combined with the device of Dynatek to supply the missing “excess volume area” element. *Id.* BDC pointed out that Xi is not even close to invalidating. Like Dynatek, the supposed

“excess volume area” in Xi is connected to the wrong side of the valve. Even if ViVitro could identify the missing element in Xi, it failed to provide any motivation to combine Xi and Dynatek, which operate in fundamentally different ways. In fact, Dynatek teaches away from this combination; it repeatedly warns the user not to add air to the test chamber. Even assuming a person of ordinary skill in the art (“POSITA”) were motivated to combine the Xi air chamber with Dynatek, it would still not be an “excess volume area” when the air chamber is added to the Dynatek device because Dynatek is not under compression, a required element of each of the claims. APPX0931-0932 at ¶51-56.

G. BDC’s Motion Is Ultimately Heard, and Denied

BDC diligently sought to have its motion heard promptly. BDC moved for a preliminary injunction only days after it filed this lawsuit in the District of Colorado. *See* APPX0034-0035 (Dkts. 1, 8). A hearing was tentatively set for April 20, then reset for June 6-7. One week before the hearing, the District of Colorado transferred the case to the Central District of California, after finding sufficient contacts with that jurisdiction. *See* APPX0036 (Dkt. 28). The case was docketed on June 7, and assigned to Judge R. Gary Klausner. The parties jointly requested that the judge hear the motion based upon the already-briefed papers in the District of Colorado. *See* APPX0037 (Dkt. 52). The district court denied the request and ordered the parties to re-brief the motion in compliance with local requirements. *See id.* (Dkt. 53). The

next business day, June 26, BDC filed a renewed motion for preliminary injunction, and noticed a hearing for July 24. *See* APPX0038 (Dkt. 59). The following day, the case was transferred to District Judge Hernan D. Vera, who had just been sworn in as a newly-appointed Article III judge in the Central District of California. Although Judge Vera postponed all then-scheduling hearings until October 2023, BDC sought (and received) an expedited hearing. APPX1098-1100.

The August 17 hearing was comprised solely of attorney argument; the parties were not permitted to offer evidence or call witnesses, either fact or expert. As this was the district court's first hearing in a patent case, counsel for both parties provided significant background on U.S. patent law. *See, e.g.*, APPX1653 ("Let me stop you there. I wasn't a patent lawyer in private practice. I was a business litigator. I appreciate what you're saying, but I will have some questions. So when you say one of two preferred embodiments, tell me a little bit more about that. What is the legal effect of that?"); APPX1653-1654 (describing preferred embodiments); APPX1668-1669 (describing the scope of patent coverage); APPX1710-1712 (describing POSITA); APPX1743 (prior art references).

On August 29, the district court entered an order denying the request for an injunction. Based upon the district court's construction of "excess volume area," the district court ruled that there was a "substantial question" as to infringement, for four reasons. **First**, the district court held that Claim 1 was not infringed because:

the specification outlined in the '935 Patent teaches that to make the system shown in Figs 1–5B of the '935 Patent, the system needs a “compliance chamber” to hold the excess volume. This suggests that it would be at least a *separate space, if not a separate structure altogether....* As ViVitro’s system is all connected, it would be inconsistent with the specification.

APPX0006-0007 (emphasis added). **Second**, the district court stated that “BDC takes the position that material deformation that provides compliance is *not* a space for fluid to flow into,” and thus the Accused Product lacks an excess volume area since the compliance rings are deformed by the compression of the gas inside. APPX0008 (emphasis in original). **Third**, the district court ruled that the Accused Product lacks an “excess volume area” because the identified portion “only exists when under compression but becomes non-existent when not in compression.” APPX0009. **Fourth**, the district court ruled that the excess volume area in Claim 1 must be *outside* the return chamber, because dependent Claim 9—which claims a compliance chamber located *within* the return chamber—would otherwise be superfluous. APPX0009.

The district court also determined ViVitro raised “substantial questions” about validity. The district court stated conclusorily that ViVitro’s expert “declaration supports the view that Dynatek ... anticipates Claim 1 and other dependent claims,” APPX0011, but provided no analysis for this conclusion. The district court ignored that ViVitro’s anticipation challenge targeted only four of the eight asserted claims. In commenting on ViVitro’s obviousness challenge, the district court stated:

Similar doubts remain for the concept of obviousness, and the Court will benefit from further briefing to determine whether the teachings of Xi, Dynatek, and Lu could have been combined.

APPX0011-12. The district court did not address any of the other preliminary injunction factors, such as irreparable harm, balance of the harms, public interest or bond.

BDC filed its notice of appeal on September 11, 2023.

SUMMARY OF ARGUMENT

In denying BDC’s motion for a preliminary injunction, the district court committed several legal errors, and abused its discretion.

The district court erred as a matter of law in its claim construction. Although it claimed to apply only the “plain and ordinary meaning” to the term “excess volume area,” in reality it applied a construction that runs contrary to several foundational principles of claim construction. The district court ruled that the “excess volume area” of Claim 1 “is a compliance chamber that is *separate and needs to be fluidly connected*” to the fluid return chamber. APPX0010 (emphasis in original). This construction is incorrect for four reasons. **First**, in equating the “excess volume area” claimed in independent Claim 1 with the “compliance chamber” of the preferred embodiment and dependent Claim 9, the district court improperly imported a limitation from the preferred embodiment into the claims and ignored the doctrine of claim differentiation. **Second**, the district court erroneously determined that the “excess volume area” was not “in fluid communication with” the fluid return chamber as the test fluid was separated from the gas by a membrane. APPX0008 (“[T]he area within the tubes’ is a closed chamber. No ‘fluid communication’ exists between the tubes and any other part of the device.”) (citation omitted). This construction of fluid communication is at odds with the specification, which specifically explains that “a membrane may be provided ... to separate the air or gas

from the working fluid.” APPX0028 at 9:20-28; *see Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1304 (Fed. Cir. 2007) (rejecting claim construction that “would exclude several examples in the specification”). **Third**, the district court erred in concluding that, because the excess volume area of dependent Claim 9 is “within” the return chamber, the excess volume area of independent Claim 1 must therefore be “outside” or “separate” from the return chamber. APPX0009. This result is contrary to logic and to law, because the dependent claim must at least include all the elements of the independent claims. **Fourth**, the district court erred by holding that an excess volume area that involves material deformation is outside of the claim scope, misconstruing a statement in an abandoned IPR involving a different patent and different prior art, and then improperly applying it as a limitation. APPX0009. A proper understanding of the statement shows that it is not relevant, but in any event, it does not qualify as prosecution disclaimer.

By applying these legally erroneous claim constructions to its infringement analysis, the district court committed legal error and abused its discretion. *See Trebro Mfg. v. FireFly Equip., LLC*, 748 F.3d 1159, 1166-68 (Fed. Cir. 2014) (holding district court abused its discretion when it applied incorrect claim construction to deny injunction). The sole infringement question is whether the Accused Product has the claimed excess volume area in fluid communication with the return chamber. It does; the gas-filled compliance rings in the ViVibro device

compress to accommodate the excess volume of fluid during the drive stroke, falling within the properly interpreted scope of “excess volume area” as described in Claim 1, and the entire area is in direct communication with the stated chamber.

The district court also committed error and abused its discretion in finding a “substantial question” as to validity. APPX0010-0012. The sole reference ViVitro raises for anticipation—the Dynatek M6 tester—lacks the excess volume area claimed in the ’935 Patent. **First**, ViVitro’s own annotation shows that the supposed “excess volume area” in Dynatek is on the wrong side of the valve; it is “in fluid communication with” the **distribution** chamber, **not** the **return** chamber as required in Claim 1. APPX1187-1188 ¶59. **Second**, Dynatek does not disclose “an excess volume area ... providing a volume for storing a volume of test system fluid when the test system fluid is under compression.” Quite simply, the Dynatek system is not under compression, thus it has no “excess volume area” that is used when under compression, as required by the claims. **Third**, the Dynatek capacitance tank is incapable of “operating at an accelerated rate”—*i.e.*, providing compliance at the accelerated rate of 200-800 beats per minute. The capacitance tank is connected to the test chamber by a tube 1/8 wide and 5 feet long; as a matter of ordinary physics, the fluid cannot adequately transmit flow back and forth through that tube hundreds of times per minute. **Finally**, irrespective of the reference, ViVitro only posited that it anticipated four of the eight asserted claims, leaving four valid infringed claims.

ViVistro's obviousness claim—based upon the addition of Xi to supply an “excess volume area”—also fails. While the district court did not appear to base its ruling on Xi, it suggested that it would “benefit from further briefing” concerning Xi. APPX0011-0012. Xi does not have an excess volume area within the meaning of the '935 Patent. And ViVistro has not provided any evidence or explanation as to why a POSITA would add the air chamber of Xi to Dynatek, particularly when Dynatek teaches away from that by *repeatedly* warning that all air must be removed from the test chamber. Dynatek is a working system without an added air chamber, and there is no reason to believe adding Xi to Dyntek would be an improvement, since the air chamber is unnecessary.

Accordingly, BDC has made an extremely strong showing of infringement and ViVistro has not raised substantial questions of invalidity. As a result, this matter should be remanded to the district court for consideration of the remaining preliminary injunction factors, which were not addressed by the district court.

STANDARD OF REVIEW

Because a court’s decision on a motion for preliminary injunction “is not unique to patent law,” the Federal Circuit “applies the law of the regional circuit when reviewing and interpreting such a decision.” *Aevoe Corp. v. AE Tech Co.*, 727 F.3d 1375, 1381 (Fed. Cir. 2013). “However, the Federal Circuit has itself built a body of precedent applying the general preliminary injunction considerations to a large number of factually variant patent cases, and gives dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues.” *Trebro Mfg.*, 748 F.3d at 1165 (cleaned up).

The Ninth Circuit “review[s] the district court’s grant of a preliminary injunction for abuse of discretion.” *Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1014 (9th Cir. 2013); *see also Trebro*, 748 F.3d at 1165 (the same). An abuse of discretion occurs when a district court either makes a decision relying upon an error of law, or makes a factual finding that is “illogical, implausible, or without support.” *Trebro*, 748 F.3d at 1166 (quoting *Valle del Sol*, 732 F.3d at 1014). “As a necessary corollary to this standard of review, ‘to the extent that a district court’s decision to grant [or deny] a preliminary injunction ***hinges on questions of law, [our] review is de novo.***’” *Nat’l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1325 (Fed. Cir. 2004) (quoting *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1329 (Fed. Cir. 2001)) (emphasis added).

This Court reviews *de novo* a district court’s claim construction, *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc), and also reviews “*de novo* the district court’s findings based on evidence ‘intrinsic to the patent,’ which is all that it at issue here,” *Power Probe Grp. v. Innova Elecs. Corp.*, No. 2021-2354, 2022 U.S. App. LEXIS 9717, at *4-5 (Fed. Cir. Apr. 12, 2022) (reversing denial of preliminary injunction based upon erroneous claim construction). Whether a movant has shown a likelihood of success for infringement, and whether the patent challenger has raised a substantial question of validity are factual issues reviewed for clear error. *BlephEx, LLC v. Myco Indus.*, 24 F.4th 1391, 1400 (Fed. Cir. 2022). In this case, any factual determinations are based solely upon the written record, because there was no evidentiary proceeding.

ARGUMENT

To obtain a preliminary injunction, a patentee must show that (1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in its favor; and (4) an injunction would be in the public interest. *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1363 (Fed. Cir. 2017) (citing *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1352 (Fed. Cir. 2016)). In the Ninth Circuit, these factors “may be evaluated on a sliding scale” in the “‘serious questions’ test,” wherein “the elements of the preliminary injunction test are balanced, so that a stronger showing of one element may offset a weaker showing of another.” *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131, 1134-35 (9th Cir. 2011) (citing *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). The district court addressed only one of the four factors—likelihood of success—which is the sole focus of this appeal.

I. THE DISTRICT COURT ERRONEOUSLY CONSTRUED THE CLAIMS

“An infringement analysis proceeds first to claim construction to determine the scope and meaning of the asserted claims, and second to a comparison of the properly construed claims with the allegedly infringing product to determine whether the product embodies every limitation of the claims.” *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1301 (Fed. Cir. 2005).

Claim construction begins with the words of the claims, which “are generally

given their ordinary and customary meaning.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-14 (Fed. Cir. 2015) (cleaned up). No construction is necessary when “the ordinary meaning of claim language as understood by a person of skill in the art [is] readily apparent even to lay judges.” *Id.* at 1314; *see also* APPX0911-0912 at ¶¶19-22.

The district court stated that it was applying the plain and ordinary meaning, but then set forth a specific and contrary construction to the term “excess volume area.” The district court stated that “[t]he plain and ordinary meaning of ‘excess volume area’ as used in Claim 1 and as supported by the teachings of the specification, is a *compliance chamber* that is *separate* and *needs to be fluidly connected*” to the fluid return chamber. APPX0010 (emphasis added to “compliance chamber”; remaining emphasis in original). The plain and ordinary meaning of an area is not a separate structural chamber. The district court further construed “in fluid communication with” the fluid return chamber to mean that there cannot be a membrane or separation between the fluid and the gas of the excess volume area. APPX0008 (“[T]he area within the tubes’ is a closed chamber. No ‘fluid communication’ exists between the tubes and any other part of the device.”) (citation omitted). These erroneous constructions, which are an issue of law reviewed *de novo*, formed the basis for the district court’s infringement decision.

A. The “Excess Volume Area” is an Area, and Is Not Interchangeable

with the Separately-Claimed “Compliance Chamber”

The district court erroneously construed the claimed “excess volume area” as a “compliance chamber,” thereby importing a limitation from the specification—or at least the figures of the specification—and assigning identical meaning to two separate claim terms. See APPX0032 at 17:29-50 (Claim 1, “excess volume area”), 18:29-32 (Claim 9, “wherein the excess volume area comprises a compliance chamber”). As this Court made clear in *Phillips v. AWH Corporation*, the analysis of a claim term should look first to **intrinsic evidence**: the claims followed by the patent specification. 415 F.3d at 1313-17.

Claim 1 itself provides a description of “excess volume area,” stating that it is an area “capable of operating at the accelerated pulsed rate” and that it provides a “volume for storing a volume of a test system fluid when the test system fluid is under compression.” APPX0032 at 17:45-50. Unlike other limitations, which describe structures such as “chambers” and “conduits,” the excess volume area is described using spatial terms: it is an **area** or, in three-dimensional terms, a **volume**.

The specification makes clear that an “excess volume area” is exactly what it says: an **area** in which excess volume can be stored. APPX0025 at 3:14-16 (“excess volume area” is an area in which a “volume of test system fluid is stored ... during a system driving stroke that opens the valved prosthetic device”). During compression, the area filled with gas is compressed, and fluid can flow into the

volume formerly occupied by the uncompressed gas when the piston was in a decompression stroke. APPX0029 at 12:5-39. The excess volume area is the area that can be filled with fluid during the compression stroke, and filled with gas when the system is not under compression. When the piston is on its backstroke, the excess volume area returns to being occupied by a compressible gas. *Id.* The excess volume area is not a specific structure with rigidly defined boundary locations throughout the pressure cycle of the test system. Rather, the excess volume area is the location where fluid can flow when the system is under compression by the drive system.

Using one (or more) compliance chambers is one way to provide an excess volume area, but it is not the only way. In describing Figure 4, the specification states:

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 liquid working fluid within the test chamber 106.

APPX0029 at 12:4-9 (emphasis added). The “structure” (if any exists) is the compliance chamber and the excess volume area is an *area* that can accommodate the additional return chamber fluid volume when the piston is applying compression.

In ruling that the specification “suggests that [the excess volume area] would be at least a separate space, if not a separate structure altogether,” APPX0006, the

district court committed two “cardinal sins” of claim interpretation: it limited the claim language based on two figures depicting a preferred embodiment, and it construed the terms in such a way to render a claim term and dependent claim meaningless. *SciMed Life Sys., v. Advanced Cardiovascular Sys.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001). At ViVistro’s invitation, the district court pointed to the structure surrounding a compliance chamber in one preferred embodiment and concluded, without explanation, that the “excess volume area”—a completely separate term—must have structure. APPX1724 (ViVistro argued: “But up to this point, the only thing that they have ever identified as providing an excess volume is a compliance chamber. ... So all of that is to say that when you interpret what is an excess volume area, that it really is just a compliance chamber. Or if it’s not a compliance chamber, it has to have some type of structure.”); *Resonate Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1367 (Fed. Cir. 2003) (“[L]imitations may not be read into a claim from a preferred embodiment when the claim language is broader than that embodiment.”); *RF Del., Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1264 (Fed. Cir. 2003) (“An independent claim usually covers a scope broader than the preferred embodiment, especially if the dependent claims recite the precise scope of the preferred embodiment.”).

Nowhere does the specification require the excess volume area to have

structure.² Rather, the use of the term excess volume area in the claims and specification differentiates itself from a specific structure, *i.e.* the compliance chamber. *See, e.g., Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1369 (Fed. Cir. 2004) (“The district court relied on the written description of Figures 5 and 6 to import the limitation of a perfectly helical flow. There is no language in the claim requiring such a perfectly helical flow. We have consistently warned against this approach to claim construction.”).

This construction also fails because it would render meaningless any distinction between “compliance chamber” and “excess volume area.” It is black-letter law that patent claims must be “interpreted [to] giv[e] effect to all terms in the claim.” *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006). These two terms—excess volume area and compliance chamber—are not the same thing. Yet, the district court’s construction makes them so. The district court’s error is highlighted by the structure of the claims: Claim 1 requires an “excess volume area,” and dependent Claim 9 recites the “device of Claim 1, wherein the excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber.” APPX0032 at 17:46-47, 18:29-31; *see Praxair, Inc. v. ATMI, Inc.*, 543

² ViVitro cannot contend that this is an instance of the inventors being their own lexicographers, defining a term within the specification. *Vitronics Corp. v. Conceptiontronic*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (“Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.”).

F.3d 1306, 1326 (Fed. Cir. 2008) (the term “capillary” would not be construed in independent claim as requiring uniform structure, in light of dependent claim reciting requirement of uniform capillary passages).

B. For the “Excess Volume Area” to be “In Fluid Communication with the Fluid Return Chamber,” It Need Not be Outside the Return Chamber, and the Test Fluid Need Not Touch the Gas

The district court incorrectly construed the term “in fluid communication with the fluid return chamber” to require the gas to touch the fluid, and to require the excess volume area to be located outside of the fluid return chamber. Neither requirement is supported.

As described above, and as stated in Claim 1, the purpose of the excess volume area is to accept extra fluid when the system is under compression. To do so, that *area* must be in fluid communication with the return chamber to allow test fluid to occupy the *area*. The '935 Patent does not require that the gas be adjacent to or touching the test fluid; the patent claims features of the areas, not what is inside them. In fact, the '935 Patent gives an example of an excess volume area in which a membrane separates the fluid from the gas:

The air or other gas may be indirect [sic] contact with the working fluid in the test chamber 106 ***or a membrane may be provided*** within the compliance chambers 135 ***to separate the air or gas from the working fluid.*** ... In each case, the purpose of the compliance chambers is to act as a resilient spring force to dampen the effects of large, quickly changing pressure gradients within the test chamber 106.

APPX0028 at 9:20-28.

The district court erroneously ruled that “no fluid communication exists between the tubes and any other part of the device” because “the area within the tubes is a closed chamber.” APPX0008. The question is not whether the *gas* and the test fluid are “in fluid communication”—the question is whether the *return chamber* is in fluid communication with the *excess volume area* into which the volume of fluid can flow when the system is under compression. The district court incorrectly substituted terms: gas for “excess volume area” and fluid for “fluid return chamber.” In so doing, the district court committed legal error, and it interpreted the sole independent claim of the patent in such a way as to *exclude* the invention described in the specification. See *Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1276 (Fed. Cir. 2008) (“We normally do not interpret claim terms in a way that excludes embodiments disclosed in the specification.”); *Verizon Servs. Corp.*, 503 F.3d at 1304 (rejecting claim construction that “would exclude several examples in the specification”).

The district court committed further legal error by construing the term “in fluid communication with the fluid return chamber” to exclude elements that are *within* the fluid return chamber. Independent Claim 1 recites an excess volume area “in fluid communication with” the fluid return chamber. APPX0032 at 17:46-47. Dependent Claim 9 narrows this claim to excess volume areas that are “compliance

chambers within the fluid return chamber.” *Id.* at 18:29-31. Because the district court had already erroneously equated the “excess volume area” with the “compliance chamber,” it reasoned that the only way to distinguish these two claims was to focus on the further limitation “within.” APPX0009. The district court then compounded its error by concluding that because dependent Claim 9 requires the excess volume area to be “within” the return chamber, independent Claim 1 from which it depends must require that the excess volume area be *outside* of the return chamber. This is error: in the independent claim, which lacks a modifier as to the location of the excess volume area, the excess volume area could be within, outside of, adjacent to, or in some other position with respect to the fluid return chamber.

Moreover, the district court’s interpretation is contrary to the structure of independent and dependent claims. The dependent claims must include all the elements of the independent claim. Here, the district court determined that the scope of claims 1 and 9 do not overlap. This is error: Claim 9 must necessarily be a subset of Claim 1. 35 U.S.C. § 112, ¶4 (“[A] claim in dependent form shall ... specify a further limitation of the subject matter claimed ... [and] shall be construed to incorporate by reference all the limitations of the claim to which it refers.”); *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1242 (Fed. Cir. 2003) (“[D]ependent claims are presumed to be of narrower scope than the independent claims from which they depend.”). Under a proper construction of Claim 1, an excess volume area “in fluid

communication with” the return chamber may be either “within” or not within the return chamber, but cannot logically be restricted to only those “not within” the return chamber.

C. The District Court Misunderstood BDC’s Comments in a Patent Office Proceeding and Compounded the Error by Finding it Disclaimed Claim Scope

At ViVistro’s urging, the district court misinterpreted statements from a prior IPR and erroneously used them to narrow the scope of the patent claims. Per the district court: “Stated differently, BDC takes the position that material deformation that provides compliance is *not* a space for fluid to flow into. ... BDC’s prior position raises substantial infringement questions ... [because] ViVistro’s ... ‘compliance rings’ absorb pressure by material deformation.” APPX0008. Statements describing a different patent and separate art in an abandoned IPR are not binding. But even if they were, the statement was misconstrued by the district court. That statement had nothing to do with limiting an excess volume area that is created through compression of gas.

The prior art at issue in that IPR, U.S. Patent No. 5,916,800 (Elizondo), described a circulating system for culturing and testing biological materials, including a heart valve and vascular grafts simultaneously. The vascular grafts, which are shaped like straws, are within a chamber that receives test fluid from the heart valve being tested. Neither party to the IPR, nor ViVistro, contended that these

vascular grafts are filled with gas.³ These grafts may change in shape—material deformation of the graft—but the overall volume of the test fluid in the system remains the same. BDC accordingly distinguished Elizondo:

Assuming these [vascular grafts] act as compliance, unlike compliance chamber 135 of the '224 Patent, ***they do not increase the volume of the channel***. That is, the pressure to the extent mitigated presumably is through the deformation of a material—***not by providing a space*** in addition to the channel for storing excess fluid.

APPX1368 (emphasis added).⁴ As ViVistro's expert conceded, fluid is not compressible; a chamber entirely filled with fluid cannot accept additional fluid even under compression. APPX1174 ¶19; APPX1206 ¶94.⁵ Because the entire Elizondo chamber is filled with incompressible fluid, there is no “excess volume” created by the presence of a compressible gas that would provide a space into which excess fluid could flow.

BDC continued in that IPR response that material deformation *alone*, without a volume to hold excess test fluid, does not meet the “excess volume” limitation of the '935 Patent. Specifically, BDC stated:

Petitioner's construction [of “excess volume”] covers simply pumping fluid into the channel in a circulatory fashion. In that case, there is no “excess volume” as the volume of fluid in the

³ Indeed, Elizondo, which is in the public record, notes that the grafts in the relevant figure contain a “nutrient solution,” *i.e.*, liquid. U.S. Patent No. 5,916,800 at 10:26-29.

⁴ See also APPX1356-1358, APPX1363-1371.

⁵ Both experts treat the terms “test fluid” or “fluid” to mean something in liquid form, and exclude “gas” or “air” from the term “fluid” for these purposes. See, *e.g.*, APPX1175 ¶21 (ViVistro's expert); APPX0910 ¶15 (BDC's expert).

channel doesn't change. Indeed, as will be shown, Petitioner attempts to read "excess volume area" on Elizondo (St. Jude), *even though the there is no change in the channel volume.*

APPX1353 (emphasis added). In both the '935 Patent preferred embodiment and the Accused Product, the volume of test fluid in test chamber increases during the drive stroke, when the gas is compressed to allow more volume for the test fluid; in Elizondo the volume of the channel remains constant at all times.

The district court fundamentally misinterpreted BDC's words in finding that "[s]tated differently, BDC takes the position that material deformation that provides compliance is *not* a space for fluid to flow into." APPX0008 (emphasis in original). Rather, BDC merely made the unremarkable point that material deformation *alone*—in the absence of any volume into which excess fluid can flow—is not an excess volume area within the meaning of the '935 Patent. BDC did *not* say that the presence of material deformation negates the existence of an excess volume area.

Excess volume and material deformation are not mutually exclusive. Indeed, the '935 Patent expressly discloses examples of compliance chambers that would have a volume of gas that could be compressed *and also* material deformation. APPX0029 at 12:33-39; *see also supra* Section A.2. Indeed, dependent claim 7 specifically recites "an elastomeric material that forms at least a portion of a boundary of the excess volume area and that expands and contracts in response to changes in pressure on the test system fluid within the test system." APPX0032 at

18:19-24.

Even if BDC had made the argument the district court erroneously ascribes to it, such a statement does not rise to the level of disclaimer of claim scope. “For a statement during prosecution to qualify as a disavowal of claim scope, it must be ‘so clear as to show reasonable clarity and deliberateness,’ and ‘so unmistakable as to be unambiguous evidence of disclaimer.’” *Genuine Enabling Tech. LLC v. Nintendo Co.*, 29 F.4th 1365, 1374 (Fed. Cir. 2022). BDC’s statement was not made during prosecution of the ’935 Patent; it was made in a Preliminary Patent Owner Response for an IPR of a different patent, one that was never decided by the PTAB. Nor was it an unmistakable disavowal of claim scope. “If the challenged statements are ambiguous or amenable to multiple reasonable interpretations, prosecution disclaimer is not established.” *Id.* Thus, the district court erred in treating BDC’s statement as a disavowal of claim scope.

II. APPLYING THE CORRECT CLAIM CONSTRUCTIONS, BDC MET ITS BURDEN TO SHOW LIKELIHOOD OF SUCCESS FOR INFRINGEMENT

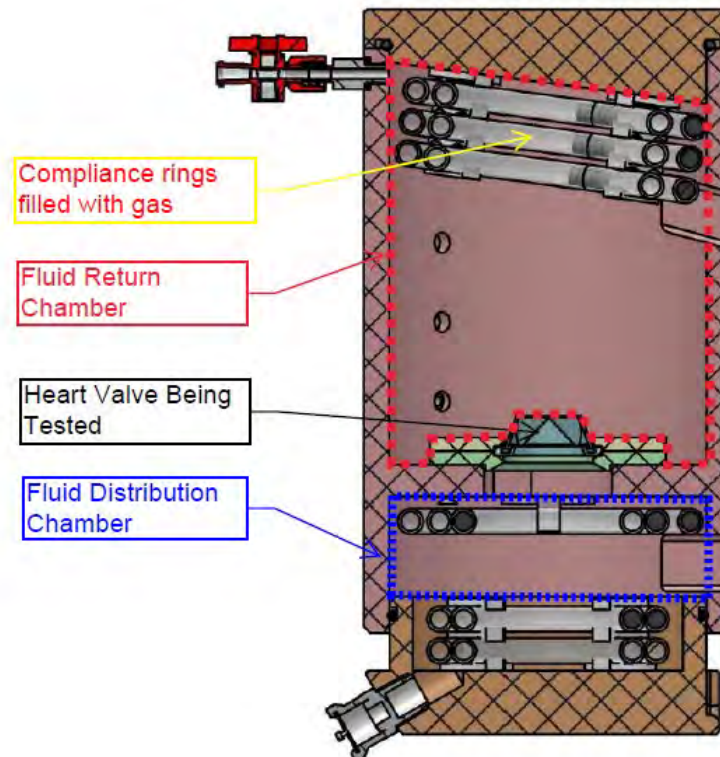
A district court’s denial of a preliminary injunction is reviewed for an abuse of discretion; such an abuse of discretion occurs when the district court’s decision relies upon an error of law, as here. Thus, “to the extent that a district court’s decision to grant [or deny] a preliminary injunction hinges on questions of law, [this Court’s] review is *de novo*.” *Mylan Pharms.*, 268 F.3d at 1329. There are no disputed facts as to the components or operation of the Accused Product; the only question is

whether it meets the claims as properly construed.

Only a single limitation is at issue here: whether the Accused Product has an “excess volume area ... 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.” APPX1205 ¶91 (ViVitro challenging this single limitation); APPX0006-0010 (addressing only “excess volume area” limitation).⁶ Because the Accused Product does so, BDC has met its burden to show, at this stage, that it is “more likely than not” to succeed on its claim of infringement. *Revision Military, Inc. v. Balboa Mfg., Co.*, 700 F.3d 524, 526 (Fed. Cir. 2012).

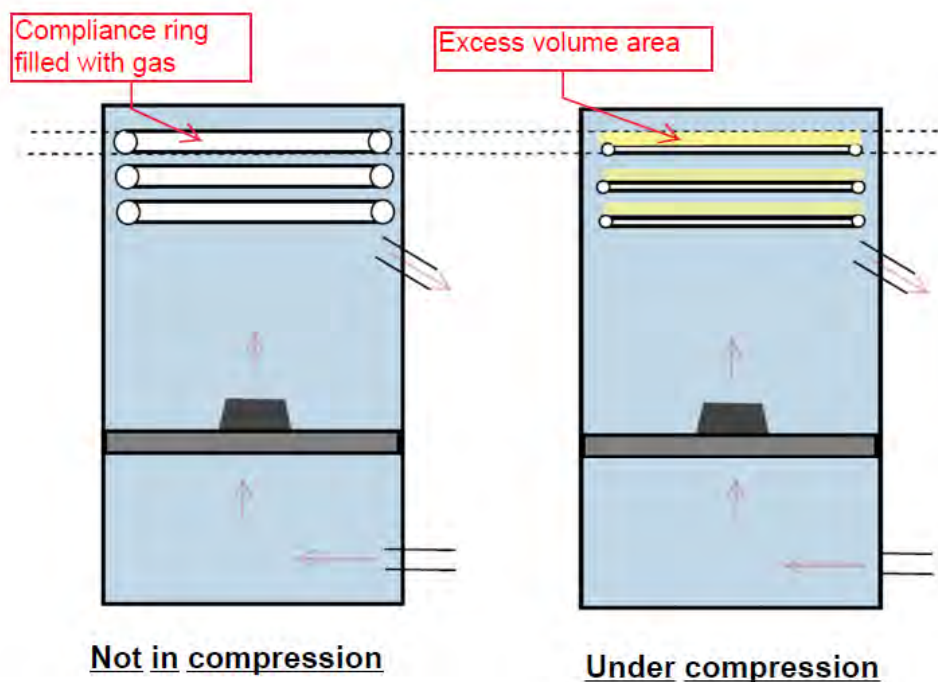
⁶ ViVitro’s expert does not offer any other defense to infringement for independent claim 1, nor does the expert offer any separate defenses to the seven asserted dependent claims. *E.g.*, APPX1205 ¶91.

The Accused Product contains a pressurizable test chamber with a fluid distribution chamber positioned underneath the prosthetic valve being tested, and a fluid return chamber located above the valve. APPX0913-0914 at ¶¶23-25; APPX0918.



The ADC Heart Valve Durability Tester has three hollow compliance rings within the fluid return chamber. 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. APPX0924 ¶30. The Accused Product contains an “excess volume area,” which is the volume adjacent to the annular compliance rings. APPX0924-0926 at ¶¶29-34.

When the system is under compression, the gas in the rings compresses, creating additional volume to accommodate the excess volume that is created by the drive stroke. APPX0924-0925 ¶¶31. When the gas in the compliance rings is compressed, the excess fluid flows into the space adjacent to the compliance rings. APPX0924-0926 at ¶¶31-33. In the illustration below, the excess volume is identified in yellow:



ViVistro's compliance rings provide *the same excess volume area and compliance function* described in Claim 1 of the '935 Patent. APPX0924-0925 at ¶31. Thus, the excess volume area is in direct communication with the fluid in the fluid return chamber as described in the '935 Patent. APPX0918.

For these reasons, BDC has met its burden to show likelihood of success on infringement.

III. THE DISTRICT COURT ERRED IN DETERMINING VIVITRO HAD RAISED SUFFICIENT EVIDENCE TO CREATE A “SUBSTANTIAL QUESTION” AS TO VALIDITY

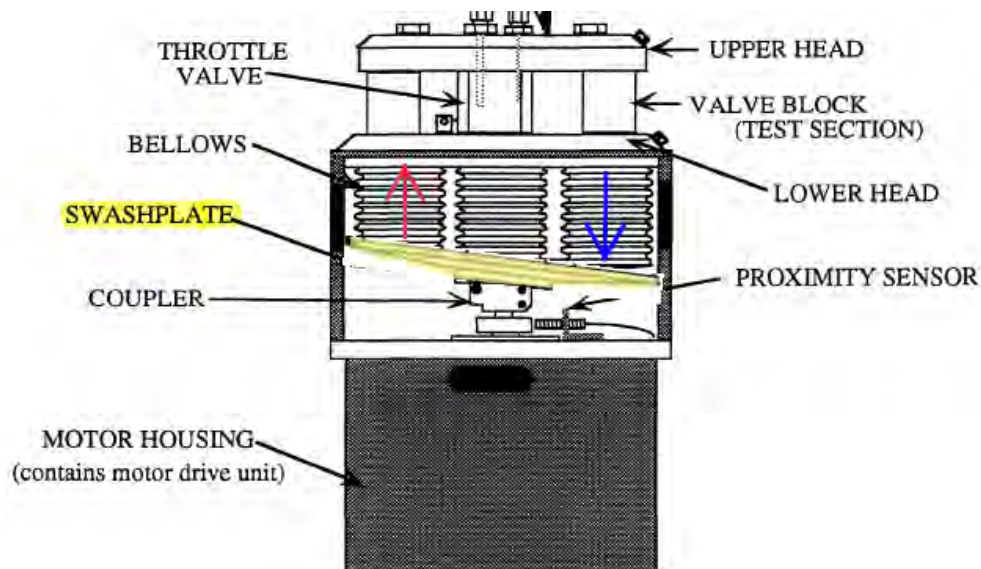
The '935 Patent is “presumed valid ... at every stage of the litigation.” *Canon Computer Sys., Inc. v. Nu-Kote Int’l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1998). A “patent enjoys the same presumption of validity during preliminary injunction proceedings as at other stages of litigation.” *Titan Tire, Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1377 (Fed. Cir. 2009) (internal citation omitted). “At trial, the party challenging validity must prove that the claims are invalid by clear and convincing evidence.” *Polara Eng’g, Inc. v. Campbell Co.*, 894 F.3d 1339, 1348 (Fed. Cir. 2018). To oppose a preliminary injunction, the accused infringer must establish a “substantial question” of invalidity, bearing in mind the clear and convincing burden that will apply to it at trial. *Titan Tire*, 566 F.3d at 1378-80. Although a “substantial question” need not rise to the level of clear and convincing evidence, it must be enough for the district court to conclude that ViVitro is “more likely than not” to satisfy its clear and convincing evidence burden by the time trial comes. *Id.*

A. The District Court Abused Its Discretion in Determining There Were “Substantial Questions” Regarding Anticipation

In finding a substantial question of invalidity, the sum of the district court’s reasoning was this: ViVitro’s expert “declaration supports the view that Dynatek discloses every element of Claim 1 and thus anticipates Claim 1 and other dependent

claims.” APPX0011.⁷

The Dynatek M6 system referenced in the manual (“Dynatek”) is an accelerated tester using a swashplate, which is a circular disk mounted at an angle on a shaft. APPX0927-APPX0928 at ¶¶39-41; APPX1018, APPX1020. When the shaft turns the lower edge of the circumference travels in a circle, making it appear as if the disk is oscillating. It is essentially a three-dimensional seesaw moving fluid within the system. The figure below, which was annotated and amended from Figure 1A in the Dynatek manual, APPX0928 at ¶41, shows the flow of fluid when the swashplate is in operation at a specific point:

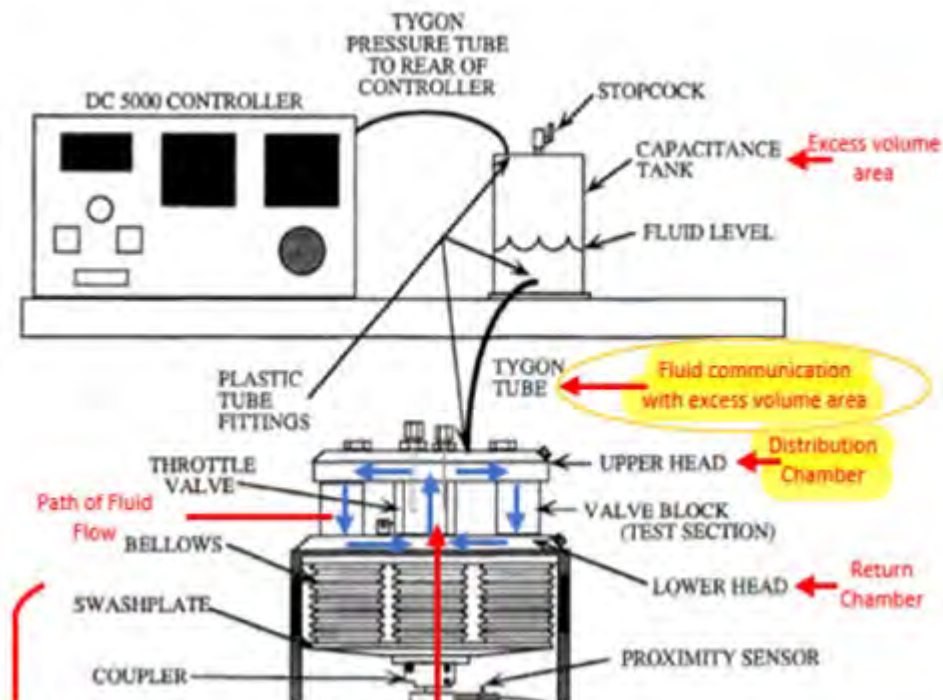


In such a system, the associated bellows move fluid from one chamber to

⁷ ViVitro has never contended that Xi anticipates the '935 Patent. Compare APPX0324-0325 ¶45; APPX1183 ¶45; APPX1690; with APPX0011 (incorrectly stating “BDC argues that Xi and Dynatek do not anticipate the '935 Patent ...”).

another, with flow moving through each “test section” and central channel as it rotates. The Dynatek manual instructs users to “debubble” the test section, because the presence of air in the test chamber has negative effects. APPX1022-1029. The test chamber is connected to a capacitance tank by 1/8 inch tubing that is 5 feet in length. APPX1020; APPX1025 ¶6. This capacitance tank is designed to buffer small variations from transient leaks or thermal effects. APPX1032.

Dynatek does not anticipate the '935 Patent, for four independent reasons. **First**, Dynatek lacks “an excess volume area ... in fluid communication with the fluid return chamber”: it is connected on the wrong side of the valve. Both experts agree that the Dynatek capacitance tank is in fluid communication with the **distribution** chamber, **not** the **return** chamber. ViVistro’s own annotation demonstrates this:

Dynatek FIG. 1A, annotated:

APPX1187-1188 ¶59 (ViVistro’s annotation of Dynatek) (yellow highlighting added by BDC); APPX0930 ¶49. The district court abused its discretion in failing to consider this evidence; this alone demonstrates that Dynatek does not anticipate. *Jamesbury Corp. v. Litton Indus. Prods.*, 756 F.2d 1556, 1563 (Fed. Cir. 1985) (“[A] reference which does not satisfy one limitation of a claim does not anticipate....”).

Second, Dynatek does not disclose “an excess volume area ... providing a volume for storing a volume of test system fluid when the test system fluid is under compression”: the test system is never “under compression.” Because Dynatek uses a swashplate to see-saw water back and forth, the Dynatek system is not under

compression. APPX1018; APPX0928-APPX0929 at ¶¶41-44. 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 based on the movement of the plate. *Id.*⁸ Dynatek does not anticipate, because its test system fluid is never “under compression,” as required by the ’935 Patent, and thus there is no “excess volume” to fill an “excess volume area.”

Third, Dynatek lacks an “excess volume area capable of operating at the accelerated pulsed rate”: it cannot operate as quickly as required. The ’935 Patent’s excess volume area provides a volume into which fluid can flow when operating at an accelerated rate, ultimately to provide compliance. *See* APPX0028 at 9:25-28. By contrast, the Dynatek “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.” APPX0929 at ¶47; APPX1032. The tank is not designated as one to accept excess volume at an accelerated rate. Plus, as a matter of ordinary physics, the 5-foot-long, 1/8 inch tubing—the diameter of an iPhone charging cord—is incapable of adequately transmitting fluid back and forth to the capacitance tank 200+ times

⁸ To use an analogy, when one shakes a snow globe, the system is not under compression. The fluid moves around within the globe to make it “snow,” but the any compression on any bubble in the snow globe remains the same.

per minute as required by Claim 1 of the '935 Patent. APPX0929-0930 ¶48.

Indeed, the Dynatek reference ***teaches away*** from using an excess volume area with gas to dampen pressure effects in the system; it instructs that all gas must be removed from the system before operation. Dynatek's set-up instructions contain **13 steps** devoted to ***removing*** all gas from the Dynatek test chambers. APPX1025-1027 (steps 5-11, 14-17, 24 and 33); APPX1022 (“[B]ubble removal is one of the biggest challenges facing a valve tester.”). “[W]here a reference teaches away from the claimed invention, the patents are more likely to be non-obvious.” *Gator Tail, LLC v. Mud Buddy LLC*, 618 F. App'x 992, 998 (Fed. Cir. 2015); *see also Arctic Cat Inc. v. Bombardier Rec. Prods.*, 876 F.3d 1350, 1360 (Fed. Cir. 2017) (“Prior art teaches away when ‘a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.’”).

Finally, ViVitro only alleged that Dynatek anticipated half of the asserted claims. APPX1186. The district court's ruling on anticipation does not affect the four unchallenged claims, which maintain their presumption of validity and are infringed.

B. ViVitro Has Not Met Its Burden to Show Obviousness

The district court order contains contradictory language regarding obviousness: it states that “[s]imilar doubts remain for obviousness,” perhaps (but

not necessarily) referring to the “substantial question” test, **but also** states that “the Court will benefit from further briefing to determine whether the teachings of Xi, Dynatek and Lu could have been combined.” APPX0011-12. BDC contends that this statement is best read as a holding that ViVitro has failed to provide sufficient evidence of a motivation to combine, and thus has failed to meet its burden to show a substantial question of obviousness. Indeed, considering ViVitro’s burden here—to show it is more likely than not to succeed in proving invalidity by clear and convincing evidence at trial—this is the only reasonable reading.

If, however, the Order were interpreted as recognizing a substantial question of obviousness, BDC contends it is an abuse of discretion. ViVitro’s obviousness analysis is an improper hindsight reconstruction, using the invention as a roadmap. “Hindsight reconstruction for litigation ends is not of probative value,” because “that which may be made clear and thus ‘obvious’ to a court, with the invention fully diagrammed and aided ... by experts in the field, may have been a break-through of substantial dimension when first unveiled.” *Zoltek Corp. v. United States*, 815 F.3d 1302, 1313-14 (Fed. Cir. 2016) (cleaned up).

In an attempt to supply the “excess volume area” missing from Dynatek, ViVitro points to Xi. Xi is an unexamined Chinese patent application, and discloses an accelerated tester using a drive motor. The Xi system attached the heart valve to a rod, then moves the heart valve up and down through the test fluid. APPX0930

¶50; APPX0982. On the downward stroke, the valve is closed and pushes test fluid through the system. On the upward stroke, the valve is open and fluid flows through it. The test valve is the pressure source, *i.e.*, the source of the pressure moving the fluid through the system. Xi has an “air chamber” connected to the distribution chamber that receives fluid driven by the valve on its downward stroke.

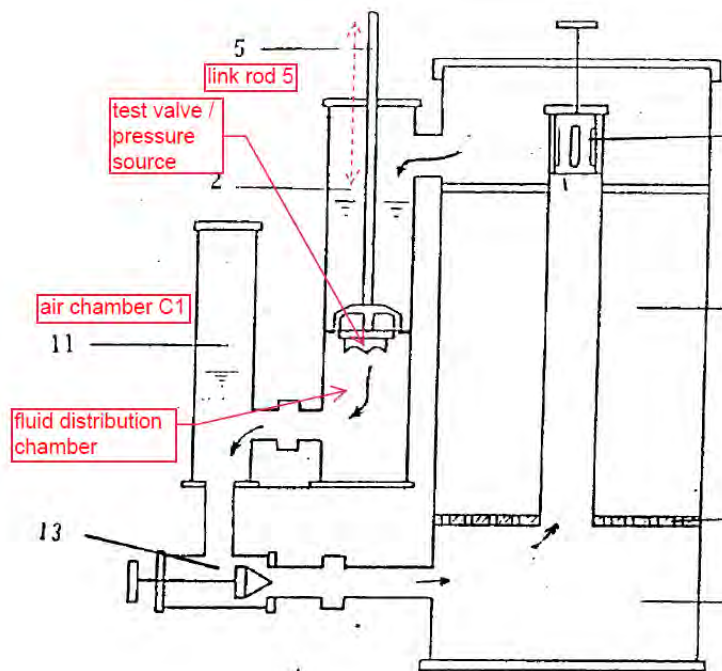
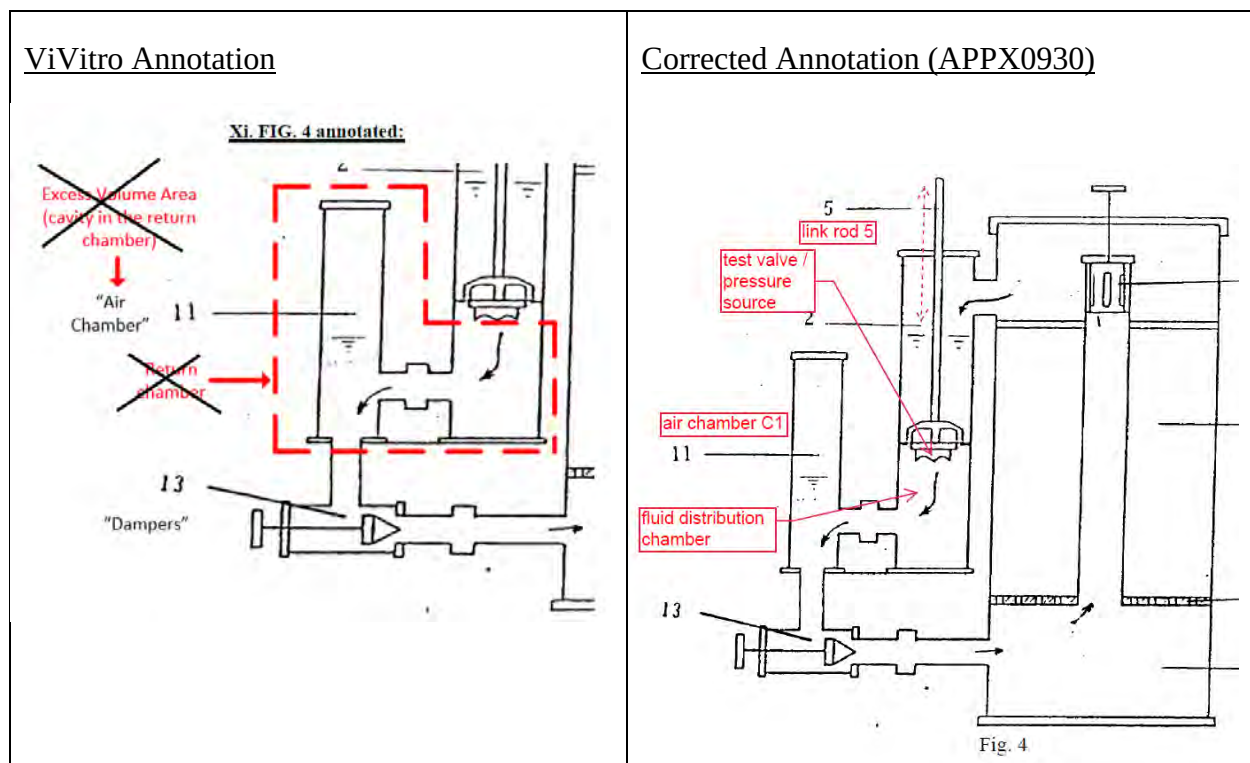


Fig. 4

ViVibro relies upon Xi to supply the “excess volume area” limitation when combined with Dynatek, an implicit admission that the Dynatek capacitance tank is not an excess volume area. This combination fails, for three reasons.

First, neither Dynatek nor Xi supplies the missing limitation of an “excess volume area.” The Xi area fails to satisfy this limitation, because it is connected on the wrong side of the valve. APPX0931 ¶¶51-53. The air chamber in Xi is not in fluid communication with the fluid return chamber. APPX0931 ¶54. As defined in

the '935 Patent, the fluid distribution chamber is “positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source.” APPX0032 at 17:37-39. Since the air chamber of Xi is positioned adjacent to the pressure source—the closed valve being driven downward—it is “in fluid communication with” the **distribution** chamber, not the **return** chamber as required for the '935 Patent’s excess volume area. ViVistro’s incorrect labeling is shown below, along with corrected labeling of Figure 4 of Xi.



Second, as recognized by the district court, ViVistro cannot articulate why a POSITA would have been motivated to combine these teachings to achieve the claimed invention, and why that POSITA would have reasonably expected success in doing so. See APPX0931-0932 ¶55 (describing the “fundamentally different”

ways the systems operate and that Dynatek teaches away from Xi); *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012) (to invalidate on obviousness, a party must “demonstrate 'by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings ... and ... would have had a reasonable expectation of success in doing so.’”). ViVitro improperly started with the patented invention and looked back to find any reference that touched on the individual elements of the '935 invention, using **impermissible hindsight**. *Id.* at 1368; APPX0931-0932 ¶55. A POSITA would not combine these two. They operate in completely different ways: Xi, by using the valve itself to drive fluid through the system, and Dynatek by using a swashplate to see-saw fluid through the system. And Dynatek clearly and repeatedly warns users that all air must be removed from the test chamber, **teaching away** from the notion of combining the Xi air chamber. Replacing the Dynatek capacitance tank with the Xi air chamber does not make sense; it is contrary to the numerous warnings in Dynatek that all air must be removed from the test chamber. ViVitro is simply using the patent owner’s disclosure and hindsight analysis, and is improper. *Cheese Sys. v. Tetra Pak Cheese & Powder Sys.*, 725 F.3d 1341, 1352 (Fed. Cir. 2013) (“Obviousness cannot be based on the hindsight combination of components selectively culled....”); *Arctic Cat Inc.*, 876 F.3d at 1360.

Third, even if the Xi an air chamber were added to Dynatek, it would still not

meet the limitations of Claim 1, because there is no compression for the excess volume area to address in Dynatek. “The excess volume area [is] ... for storing a volume of a test system fluid when the test system fluid is under compression.” APPX0025 at 3:8-11. The pressure in the Dynatek system is a net constant. APPX0928 at ¶¶42-43. Since there is no “net compression,” there is no “excess volume” in the fluid return chamber, and thus no “excess volume area” that stores this (non-existent) fluid. APPX0932 ¶56.⁹ Adding the Xi air chamber to Dynatek would not make any sense since there is not pressure to absorb. In other words, a POSITA would not combine the two as the combination would not solve any problem.

Finally, the district court (and ViVitro) failed to address secondary considerations of nonobviousness—*e.g.*, unexpected results, copying, commercial success, praise by others, failure by others, and long-felt need. These factors must be considered, are “often ... the most probative and cogent evidence,” and help inoculate the obviousness analysis against hindsight. *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012); *see also Kinetic Concepts*, 688 F.3d at 1370 (focusing heavily on “significant objective indicia of nonobviousness”). Here, the evidence of nonobviousness—BDC’s novel system that more closely mimics the

⁹ To continue the snow globe analogy: if a snow globe had air within the globe, it would not act as an excess volume area, because the system would not be under compression when shaken—*i.e.*, the compression of the system would not change.

human physiological configuration, made possible by the excess volume area, that took over the market—is substantial and compelling. Indeed, ViVidro’s President admits that BDC achieved “substantial commercial success” with its new tester. APPX1158-1159 ¶16. That ViVidro’s own system became obsolete, along with the Dynatek system ViVidro claims to be invalidating, is strong evidence of nonobviousness. Further evidence includes industry praise and copying: ViVidro mimicked BDC’s service offerings and developed a new system that drives fluid through a valve, using an excess volume area. Where several objective indicia of nonobviousness are present, a patent is likely to withstand a validity challenge and preliminary injunctive relief is proper. *See Merial, Ltd. v. Velcera, Inc.*, 877 F. Supp. 2d 1348, 1361 (M.D. Ga. 2012) (such indicia as “tremendous commercial success,” being “copied by others,” “industry praise,” and “me[e]t[ing] a long-felt industry need” support nonobviousness). In failing to consider this evidence, the district court abused its discretion.

CONCLUSION

For the reasons described herein, BDC respectfully asks this Court to reverse the denial of its Motion for Preliminary Injunction, hold that BDC has met its burden to show a likelihood of success on the merits, and remand to the district court for consideration of the remaining factors in light of this Court’s clear precedent finding irreparable harm on similar facts.

Respectfully submitted this 24th day of October, 2023.

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**CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATION**

This motion complies with the relevant type-volume limitations of the Federal Rules of Appellate Procedure and the Federal Circuit Rules. According to the word-processing system used to prepare this document, excluding portions exempted by the Rules, this motion contains **11,559** words.

/s/ Gregory S. Tamkin

Gregory S. Tamkin
Dorsey & Whitney LLP

ADDENDUM

ADDENDUM

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U.S. Patent No. 9,237,935 (McCloskey, et al.).....	APPX0013

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Case No. 2:23-CV-04291-HDV

**BIOMEDICAL DEVICE CONSULTANTS
& LABORATORIES OF COLORADO,
LLC,**

Plaintiff,

v.

VIVITRO LABS, INC.,

Defendant.

**ORDER DENYING PLAINTIFF'S
MOTION FOR PRELIMINARY
INJUNCTION**

Petitioner's Exhibit 1022
VIVITRO v. BDC
IPR2024-00320

APPX0001

I. INTRODUCTION

Before the Court is a motion for a preliminary injunction filed by Plaintiff Biomedical Device Consultants & Laboratories of Colorado, LLC (“BDC”), seeking to enjoin Defendant Vivitro Labs, Inc. (“Vivitro”) from offering its ADV Heart Valve Durability Tester device (“Motion”) [Dkt. No. 60]. BDC contends Vivitro’s disputed device infringes on one of its patents, U.S. Patent No. 9,237,935 (“’935 Patent”) [Dkt. No. 1-1, Exh. A]. Vivitro filed a response on July 20, 2023. Opposition to Plaintiff’s Motion for Preliminary Injunction (“Opp.”) [Dkt. No. 80]. And on August 3, 2023, BDC filed its reply. Reply Memorandum in Support of Motion for Preliminary Injunction (“Reply”) [Dkt. No. 89]. The Court held oral argument on the Motion on August 17, 2023, and took the matter under submission.

For the reasons discussed below, the Court **DENIES** the motion for preliminary injunction. BDC has not shown a likelihood of success on the merits because it has failed to make a “clear showing” that Vivitro likely infringed based on the claim language and evidence presented. Moreover, Vivitro has raised substantial questions regarding the patent’s validity in light of prior art.

II. BACKGROUND

Both BDC and Vivitro manufacture heart valve durability testers. *See* Motion at 1. The patent at issue, the ’935 Patent, entitled, “Fatigue Testing System for Prosthetic Devices,” was issued to BDC on January 19, 2016. Complaint (“Compl.”) ¶ 27 [Dkt. No. 1]. BDC incorporated this technology into its VDT-3600i, which tests the durability of prosthetic heart valves and launched “around 2010,” according to its former CEO. Declaration of Craig Weinberg (“Weinberg Decl.”) ¶ 11 [Dkt. No. 61]. The VDT-3600i is the company’s “highest-revenue generating product,” and sells for between \$75,000 and \$85,000 each. Weinberg Decl. ¶ 20, Motion at 14. The ’935 Patent allows the VDT-3600i to rapidly test prosthetic heart equipment many times faster than a human heart, while still “closely approximating human physiology.” *Id.* at 2. This innovation is done through an “excess volume area” that mitigates pressure spikes, thus reducing testing malfunctions. *Id.* Claim 1 of the ’935 Patent, discloses:

A device for accelerated cyclic testing of a valved prosthetic device comprising ... an excess volume area capable of operating at the accelerated pulsed rate, wherein the

Petitioner's Exhibit 1022
VIVITRO v. BDC
IPR2024-00320

1 excess volume area is in fluid communication with the fluid return chamber providing
2 a volume for storing a volume of a test system fluid when the test system fluid is
3 under compression.
4 '935 Patent at 17:29–50.

5 Vivitro is alleged to have infringed on the '935 Patent through its ADV Heart Valve
6 Durability Tester, a competitive test system. Motion at 4. BDC first learned that Vivitro was
7 distributing marketing materials for its new tester in the summer of 2022. Weinberg Decl. ¶ 34.
8 While Vivitro has not delivered any of its testers, BDC alleges that Vivitro has “at least one
9 agreement with a customer for sale” of the device. Compl. ¶ 19. No facts have been alleged in
10 briefing or during oral arguments that any testers have been shipped yet. Plaintiff’s complaint in this
11 action was filed on April 7, 2023. A half-day hearing on the Motion was held on August 17, 2023,
12 and the Motion was taken under submission [Dkt. No. 90].

13 III. LEGAL STANDARD

14 “A preliminary injunction is an extraordinary remedy never awarded as of right.” *Winter v.*
15 *Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). A district court should enter a preliminary
16 injunction only “upon a clear showing that the plaintiff is entitled to such relief.” *Id.* at 22. When a
17 patentee sues an alleged infringer for patent infringement and moves under 35 U.S.C. § 283 for the
18 extraordinary relief of a preliminary injunction, the patentee’s entitlement to such an injunction is a
19 matter largely within the discretion of the district court. *See Genentech, Inc. v. Novo Nordisk A/S*,
20 108 F.3d 1361, 1364 (Fed. Cir. 1997). A party seeking a preliminary injunction must establish that:
21 (1) it “is likely to succeed on the merits,” (2) it “is likely to suffer irreparable harm in the absence of
22 preliminary relief,” (3) “the balance of equities tips in [its] favor,” and (4) “an injunction is in the
23 public interest.” *Winter*, 555 U.S. at 20. The Ninth Circuit has adopted an alternative sliding scale
24 approach, in which the elements are balanced, “so that a stronger showing of one element may offset
25 a weaker showing of another.” *All. of the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir.
26 2011). Specifically, “serious questions going to the merits and a hardship balance that tips sharply
27 towards the plaintiff can support issuance of an injunction, assuming the other two elements of the
28 *Winter* test are also met.” *Id.* at 1132 (interpreting *Winter* and explaining that the “sliding scale” test

1 for preliminary injunctive relief remains valid) (quotations omitted). A “serious question” is one on
2 which the movant “has a fair chance of success on the merits.” *Sierra On-Line, Inc. v. Phoenix*
3 *Software, Inc.*, 739 F.2d 1415, 1421 (9th Cir. 1984).

4 **IV. DISCUSSION**

5 **A. Likelihood of Success on the Merits**

6 “With regard to the first factor—establishing a likelihood of success on the merits—the
7 patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely
8 prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent.”
9 *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009); *see also Trebro*
10 *Mfg., Inc. v. Firefly Equipment, LLC*, 748 F.3d 1159, 1166 (Fed. Cir. 2014) (a likelihood of success
11 requires “prov[ing] that success in establishing infringement is more likely than not”). “If the accused
12 infringer raises a substantial question concerning either infringement or validity, then the patentee has
13 not established that it is likely to succeed on the merits, and a preliminary injunction is not
14 appropriate.” *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361, 1366 (Fed. Cir. 2013)
15 (quotations omitted).

16 Additionally, when considering the *Winter* factors, a preliminary injunction may only be
17 awarded “upon a clear showing” of evidence that supports each relevant preliminary injunction factor.
18 *Winter*, 555 U.S. at 22. “This ‘clear showing’ requires factual support beyond the allegations of the
19 complaint, but the evidence need not strictly comply with the Federal Rules of Evidence.” *CI Games*
20 *S.A. v. Destination Films*, No. 2:16-CV-05719-SVW (JCx), 2016 WL 9185391, at *11 (C.D. Cal. Oct.
21 25, 2016) (citing *Flynt Distrib. Co., Inc. v. Harvey*, 734 F.2d 1389, 1394 (9th Cir. 1984)). The
22 “[l]ikelihood of success on the merits is the most important *Winter* factor”; thus, “if a movant fails to
23 meet this threshold inquiry, the court need not consider the other factors ... in the absence of serious
24 questions going to the merits.” *Disney Enters., Inc. v. VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir.
25 2017) (quotations omitted).

26 Here, substantial questions have been raised concerning infringement, particularly as to
27 whether the “excess volume area” limitation is met in the way that Plaintiff argues.
28

1 **i. Infringement**

2 “Determining literal infringement is a two-step process: the ‘proper construction of the
3 asserted claim and a determination whether the claim as properly construed reads on the accused
4 product or method.’” *ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1319
5 (Fed. Cir. 2012) (quoting *Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1330 (Fed. Cir.
6 1999). Literal infringement requires that “every limitation ... in a claim must be found in an accused
7 product, exactly.” *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995).

8 Infringement analysis begins first with claim construction, followed by an analysis of “the
9 allegedly infringing product to determine whether the product embodies every limitation of the
10 claims.” *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1301 (Fed. Cir. 2005). “To
11 determine likelihood of success on the patent infringement issue, the court may construe disputed
12 claim language as a matter of law.” *Sofamor Danek Grp., Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216,
13 1220 (Fed. Cir. 1996). “The court then determines whether the accused device is likely to fall within
14 the scope of the claims.” *Id.*

15 “Claim terms are generally given their ordinary and customary meaning as understood by a
16 person of ordinary skill in the art when read in the context of the specification and prosecution
17 history.” *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1358 (Fed. Cir. 2016). “The
18 appropriate starting point ... is always with the language of the asserted claim itself.” *Comark*
19 *Commc’ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). For purposes of this Motion,
20 the Court assigns the words of the claims “their ordinary and customary meaning,” meaning that “the
21 term would have to a person of ordinary skill in the art in question at the time of the invention.”
22 *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2015). “Importantly, the person of
23 ordinary skill in the art is deemed to read the claim term not only in context of the particular claim in
24 which the disputed term appears, but in the context of the entire patent, including the specification.”
25 *Id.* at 1313. The specification is “[u]sually ... the single best guide to the meaning of a disputed
26 term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The parties both
27 argue that plain and ordinary meaning applies to the asserted claim limitations, and the Court applies
28 plain and ordinary meaning here. *See* Motion at 7; *see also* Opp. at 5.

1 BDC and Vivitro disagree about the meaning of key claim terms. If the meaning of the term
 2 is disputed, “the specification and prosecution history can provide relevant information about the
 3 scope and meaning of the claim.” *Electro Med. Sys., S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048,
 4 1054 (Fed. Cir. 1994) (quotations omitted).

5 After analyzing the key terms, patent specification, prosecution history, and the totality of
 6 evidence presented, the Court finds that substantial questions exist as to the key issue of
 7 infringement. BDC has not shown at this stage it is more likely than not that the accused product has
 8 an “excess volume area” that is “in fluid communication with the fluid return chamber....” ’935
 9 Patent, 17:45–50. As shown below, Vivitro has raised substantial questions concerning whether its
 10 current configuration falls within the ’935 Patent, and therefore BDC has not met its burden.

11 BDC alleges that Vivitro infringes all elements of claims 1–4, 8, 9 and 12–13 of the ’935
 12 Patent. Motion at 7–10. For purposes of this Motion, the Court focuses on Claim 1, the only
 13 independent claim, as all other claims depend on it. Claim 1 states in part: “an excess volume area
 14 capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid
 15 communication with the fluid return chamber providing a volume for storing a volume of a test
 16 system fluid when the test system fluid is under compression.” ’935 Patent at 17:45–50. Plaintiff’s
 17 position is that Vivitro’s device at issue also has “an excess volume area,” which consists of “the
 18 volume adjacent to the annular compliance rings¹” “within the fluid return chamber.” Motion at 9.

19 The Court concludes at this stage that substantial questions exist on the issue of whether the
 20 extra space *within* the chamber can be the excess volume area, as contemplated and defined in the
 21 ’935 Patent. More specifically, the Court finds that Plaintiff has failed to meet its burden on
 22 likelihood of success concerning infringement at this stage for at least four reasons.

23 First, the specification outlined in the ’935 Patent teaches that to make the system shown in
 24 Figs. 1–5B of the ’935 Patent, the system needs a “compliance chamber” to hold the excess volume.
 25 This suggests that it would be at least a separate space, if not a separate structure altogether. The
 26 specification states in relevant part:

27
 28 ¹ In cardiology, “compliance” is the ability of a fluid system to absorb pressure changes. See ’935 Patent, 9:11–14.

1 **“The compliance chambers provide excess volume area for fluid to move into**
 2 when the piston performs a compression stroke. As the pressure of the gas in the
 3 compliance chamber increases, **the volume occupied by the gas decreases to**
 4 **provide additional volume for displacement of the liquid working fluidly within**
 5 **the test chamber.”**

6 ’935 Patent at 12:4–9 (emphasis added).

7 As Vivitro’s system is all connected, it would be inconsistent with the specification. *See*
 8 *Phillips*, 415 F.3d at 1313 (“the person of ordinary skill in the art is deemed to read the claim term
 9 not only in the context of the particular claim in which the disputed term appears, but in the context
 10 of the entire patent, including the specification.”). There also exists a separate question as to Claim
 11 9 of whether the area inside the “compliance rings” in Defendant’s device can fairly be characterized
 12 as a “compliance chamber.” The plain and ordinary meaning of “chamber” suggests that it should
 13 be its own separate area. The claim requirement that the “excess volume area” is “in fluid
 14 communication with the fluid return chamber” also implies a separate structure. If it consisted of
 15 simply more space in the chamber, the patent would not need to include the phrase “in fluid
 16 communication with.” The claim language suggests that the excess fluid is going somewhere, and
 17 the specification implies it is the *chamber* where the fluid is moving into.

18 Second, Plaintiff’s interpretation is at odds with the position that it took in prior proceedings
 19 before the PTO. In BDC’s preliminary response to an Inter Partes Review (IPR) in 2018 for a
 20 related patent, BDC argued that in a competitor design:

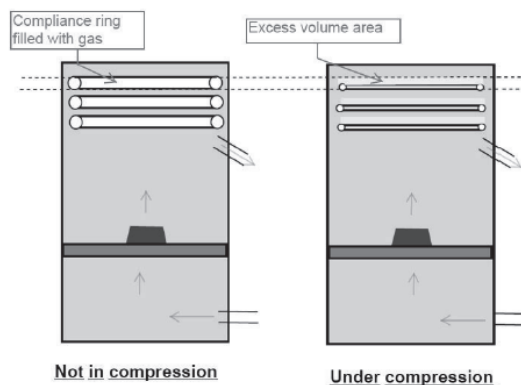
21 “flexible bags/containers act as compliance, however, unlike compliance chamber
 22 135 of [BDC’s patent], the total volume of the channel remains constant. That is, any
 23 pressure being mitigated would presumably be through **material deformation**—not
 24 by providing a space in addition to the channel to store some of the excess introduced
 25 fluid. **Therefore**, [the competing design] has **no ‘excess volume area’** for storing
 26 fluid in excess of that contained in the channel.”

27 *Waters Technologies Corp. v. Biomedical Device Consultants & Laboratories*, IPR2018-00498,
 28 Patent Owners’ Preliminary Response (“Opp., Ex. 7”) at 37 (emphasis added) [Dkt. No. 80-7].

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1 Stated differently, BDC takes the position that material deformation that provides compliance is *not*
 2 a space for fluid to flow into. Later, BDC adds that “the pressure to the extent mitigated presumably
 3 **is through the deformation of a material**—not by providing a space in addition to the channel for
 4 storing excess fluid. Thus, [the competing design] has **no ‘excess volume area’ for storing fluid in**
 5 **excess to that contained in the channel, as required by claim 1.**” Opp., Ex. 7 at 47 (emphasis
 6 added). BDC’s position is inconsistent with its prior interpretations. “[T]he same claim term in ...
 7 related patents carries the same construed meaning.” *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d
 8 1314, 1334 (Fed. Cir. 2003). During the claim construction phase, the parties will have an
 9 opportunity to brief the issue in more depth, but at this phase, BDC’s prior position raises substantial
 10 infringement questions. Vivitro’s disputed device works like the competing design from the IPR
 11 proceeding, as its closed “compliance rings” absorb pressure by material deformation. Reply at 5.

12 Third, Vivitro’s disputed device does not include an “excess volume area” “in fluid
 13 communication with the return chamber,” which is at odds with the claim language. ’935 Patent at
 14 17:45–50. BDC argues that in Vivitro’s disputed device, the excess volume area is “the area within
 15 the tubes that is occupied by gas when the system is not under compression and is occupied by the
 16 excess volume of test fluid when the system is under compression.” Motion at 10. But examining
 17 Vivitro’s designs, “the area within the tubes” is a closed chamber. *See* Opp., Ex. 8 [Dkt. No. 88-8].
 18 No “fluid communication” exists between the tubes and any other part of the device. The “fluid
 19 communication” requirement of Claim 1 is not met. BDC further alleges that the excess volume
 20 area is “the volume adjacent to the annular compliance rings” when those rings are allegedly
 21 compressed. Motion at 9. To demonstrate, BDC includes the following illustrations below. *Id.*



1 BDC suggests that the “excess volume area” can be a temporarily available area, which is not
 2 supported by the language of Claim 1 or the specification. In these illustrations, the excess volume
 3 area of Vivitro’s device only exists when under compression but becomes non-existent when not in
 4 compression. Nothing in the patent suggests that the extra volume area can exist only *temporarily*.
 5 BDC’s prior position in the IPR proceeding supports this view, as “material deformation” does not
 6 meet the excess volume area limitation. Opp., Ex. 7, at 37, 47. Vivitro’s design uses the material
 7 deformation of these closed rings, not the fluid flow into an excess volume area, to provide
 8 compliance. The “volume adjacent to the annular compliance rings” is not an excess volume area
 9 and thus raises substantial questions as to infringement of the ’935 Patent. Motion at 9. Since
 10 Plaintiff has not shown that Claim 1 has more likely than not been infringed, the asserted dependent
 11 claims 2, 3, 4, 8, 9, 12, and 13 are also not likely to have been infringed. *Wahpeton Canvas Co. v.*
 12 *Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989) (“One who does not infringe an independent
 13 claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim”).

14 And fourth, Claim 9 (a dependent claim of Claim 1) raises substantial questions about BDC’s
 15 theory as to what “excess volume area” means under the doctrine of claim differentiation. This
 16 doctrine applies a presumption of difference in meaning and scope when different words or phrases
 17 are used in separate claims. *See Comark Commc’ns, Inc.*, 156 F.3d at 1187 (invoking doctrine to
 18 support claim construction; although “the doctrine of claim differentiation is not a hard and fast rule
 19 of construction, it does create a presumption that each claim in a patent has a different scope”).
 20 Here, this doctrine is appropriate to apply given that Claim 9 contemplates new features that
 21 alternative interpretation would render moot. Claim 9 states in relevant part: “The device of claim 1,
 22 where in the excess volume area comprises a compliance chamber defining **a cavity within the fluid**
 23 **return chamber.**” ’935 Patent at 18:29–32 (emphasis added). If BDC’s interpretation of “excess
 24 volume area” in Claim 1 always contemplated “within the fluid return chamber,” then Claim 9
 25 would not add anything. *See* Motion at 9.

26 “To show literal infringement of a patent, a patentee must supply sufficient evidence to prove
 27 that the accused product or process meets every element or limitation of a claim.” *Rohm & Haas Co.*
 28 *v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997). While BDC may be able to prove this in

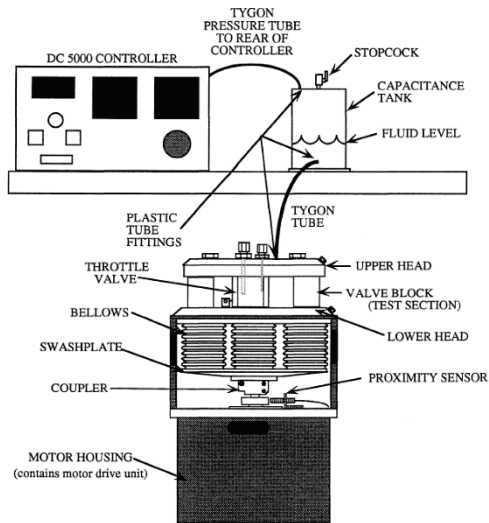
1 further proceedings, substantial questions have been raised at this point to justify a denial of
2 Plaintiff's motion for preliminary injunction. The plain and ordinary meaning of "excess volume
3 area," as used in Claim 1 and as supported by the teachings of the specification, is a compliance
4 chamber that is *separate* and *needs to be fluidly connected*. Plaintiffs may prevail during claim
5 construction proceedings in the future, where the Court can more closely examine briefing around
6 the prosecution history of the patent, the Inter Partes Review (IPR) proceedings, and extrinsic
7 evidence to discern the patent's meaning. But based on the existing record, the Court finds that
8 substantial questions have been raised as to whether Plaintiff's patent was infringed by Defendant.

9 **ii. Validity**

10 "Vulnerability is the issue at the preliminary injunction stage," not whether the patent is
11 invalid by the clear and convincing evidence standard that will be used at trial. *Amazon.com, Inc. v.*
12 *Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1359 (Fed. Cir. 2001). If there are "substantial questions
13 as to the validity" of the asserted patents, then "the necessary prerequisites for entry of a preliminary
14 injunction" have not been satisfied even if the patentee has established a likelihood of success on the
15 issue of infringement. *Amazon.com, Inc.*, 239 F.3d at 1366. The Court "does not resolve the validity
16 question" at this stage, but instead "assess[es] ... the persuasiveness of the challenger's evidence,"
17 recognizing that it is a preliminary stage. *Titan Tire Corp.*, 566 F.3d at 1377 (quotations omitted).
18 "Instead of the alleged infringer having to persuade the trial court that the patent is invalid, at this
19 stage it is the patentee, the movant, who must persuade the court that, despite the challenge
20 presented to validity, the patentee nevertheless is likely to succeed at trial on the validity issue." *Id.*
21 Here, Vivitro has presented evidence of invalidity, and BDC has not demonstrated at this point that
22 Vivitro's assertions lack substantial merit.

23 Patents can be invalid over the prior art by being either anticipated or obvious. A claim is
24 anticipated where "each and every [limitation] is found within a single prior art reference. *Biogen*
25 *MA Inc. v. EMD Serono, Inc.*, 976 F.3d 1326, 1331 (Fed. Cir. 2020). A patent is obvious if "the
26 differences between the claimed invention and the prior art are such that the claimed invention as a
27 whole would have been obvious at the time the invention was made to a person having ordinary skill
28 in the art..." 35 U.S.C. § 103.

Examining the prior art, the Court finds a substantial question concerning whether the prior art included “excess volume areas” to absorb pressure changes in accelerated test systems, raising substantial concerns that the ’935 Patent is invalid. First, the Dynatek M6 user manual published in 1993 appears to include an annotated figure with an “excess volume area” that is described as a “capacitance tank.” Opp., Exh. 5, Fig. 1A (“Dynatek”) [Dkt. No. 80-5].



Dr. Dasi’s declaration supports the view that Dynatek discloses every element of Claim 1 and thus anticipates Claim 1 and other dependent claims. Dasi Declaration (“Dasi Decl.”) ¶ 59.

Vivitro also points to another patent, the Xi patent from 1997, that includes an “air chamber” placed downstream of the device being tested, where “liquid flows from the test chamber into the air chamber” during operation.” Opp., Ex. 3 at 5 (“Xi patent”) [Dkt. No. 80-3]. Together with Dynatek, Vivitro asserts that “the ’935 Patent claims are all obvious variations on Dynatek and Xi, and so all the asserted claims are invalid as obvious.” Opp. at 12; *see also* Dasi Decl. ¶ 45.

BDC argues that Xi and Dynatek do not anticipate the ’935 Patent, arguing that Xi’s “piston” and Dynatek’s “see-saw” are “completely different” from the ’935 Patent, even presenting video reproductions at oral arguments to demonstrate how the different devices deal with fluid and pressure. But the ’935 Patent does not specify the “pressure source” that moves the fluid, so substantial doubt remains as to validity based on the plain language of the patent. ’935 Patent at 17:31. Similar doubts remain for the concept of obviousness, and the Court will benefit from future

1 briefing to determine whether the teachings of Xi, Dynatek, and Lu could have been combined.

2 **V. CONCLUSION**

3 In summary, BDC has failed to show a likelihood of success on the merits in terms of
4 infringement, and Vivitro has raised additional (and substantial) questions regarding the validity of
5 Plaintiff's underlying patent. For all of these reasons, Plaintiff's motion is denied.²

6 **IT IS SO ORDERED.**

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8 Dated: August 29, 2023



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Hernán D. Vera
United States District Judge
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24 ² The parties have presented extensive evidence and briefing on the questions of irreparable harm
25 and the balance of equities. After reviewing, the Court finds that “hardship balance” does not “tip[]
26 sharply toward the plaintiff” and thus does not support the issuance of an injunction, even under the
27 Ninth Circuit’s sliding scale approach. *All. for the Wild Rockies*, 632 F.3d at 1132. Because the
28 Court has concluded that Plaintiff failed to meet its burden to show a likelihood of success on the
issues of infringement and validity, the Court need not discuss the merits of these latter arguments,
as they would not change the outcome.



US009237935B2

(12) **United States Patent**
McCloskey et al.

(10) **Patent No.:** **US 9,237,935 B2**
(45) **Date of Patent:** **Jan. 19, 2016**

(54) **FATIGUE TESTING SYSTEM FOR PROSTHETIC DEVICES**

(71) Applicant: **Biomedical Device Consultants and Laboratories of Colorado, LLC**, Wheat Ridge, CO (US)

(72) Inventors: **Benjamin McCloskey**, Evergreen, CO (US); **Craig Weinberg**, Denver, CO (US); **Steven Weinberg**, League City, TX (US)

(73) Assignee: **Biomedical Device Consultants and Laboratories of Colorado, LLC**, Wheat Ridge, CO (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 265 days.

(21) Appl. No.: **14/137,313**

(22) Filed: **Dec. 20, 2013**

(65) **Prior Publication Data**

US 2014/0109651 A1 Apr. 24, 2014

Related U.S. Application Data

(63) Continuation of application No. 12/718,316, filed on Mar. 5, 2010, now Pat. No. 8,627,708.

(60) Provisional application No. 61/158,185, filed on Mar. 6, 2009.

(51) **Int. Cl.**
A61B 19/00 (2006.01)
G01N 3/32 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61B 19/46** (2013.01); **A61F 2/2472** (2013.01); **G01M 99/007** (2013.01); **G01N 3/32** (2013.01);
(Continued)

(58) **Field of Classification Search**

CPC G01N 3/32; G01N 2203/0089; G01N 2203/0246; G01N 2203/0204; G01N 2203/0476; A61B 19/46; G01M 99/007; A61F 2/2472
USPC 73/37
See application file for complete search history.

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Primary Examiner — Lisa Caputo

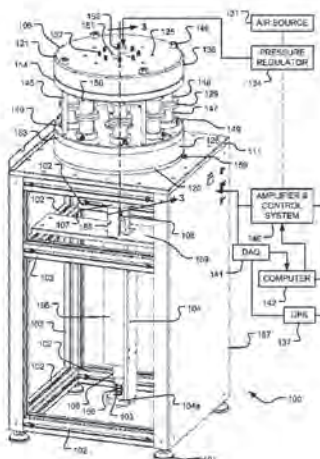
Assistant Examiner — Philip Cotey

(74) *Attorney, Agent, or Firm* — Dorsey & Whitney LLP

(57) **ABSTRACT**

A fatigue testing system provides simultaneous cycle testing for a plurality of prosthetic devices under simulated physiological loading conditions. A plurality of sample holders containing test samples of prosthetic devices is positioned between a distribution chamber and a return fluid chamber to form an integrated test chamber. A reciprocating linear drive motor operates a rolling bellows diaphragm to cyclically pressurize fluid within the test chamber and drive the pressurized fluid through the prosthetic devices being tested. The test chamber defines a return flow conduit in fluid communication with each of the sample holders, the return fluid chamber, and the distribution chamber. Compliance chambers and throttle valves associated with each of the sample holders regulate the pressure gradient and back pressure across the prosthetic devices being tested.

13 Claims, 9 Drawing Sheets



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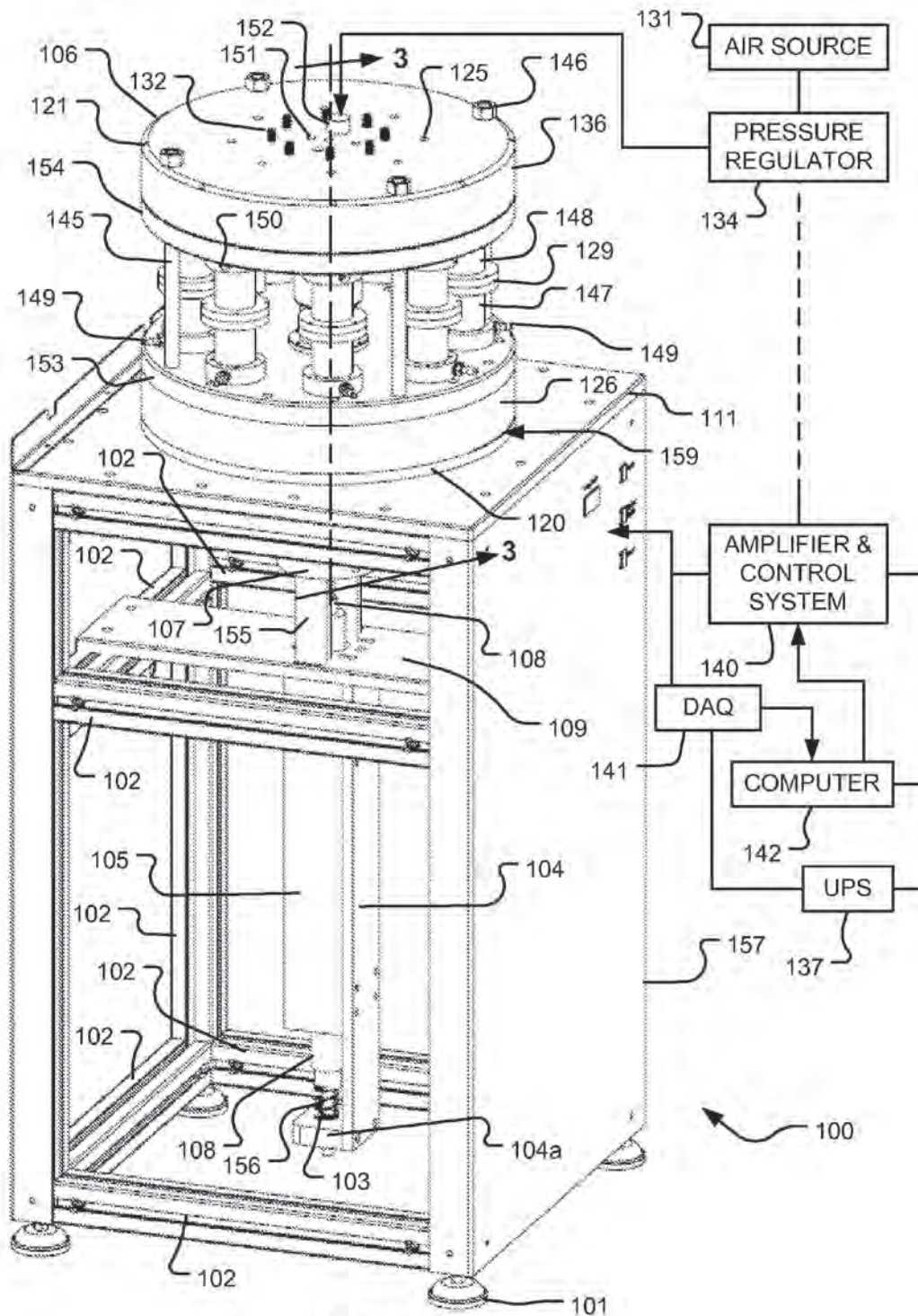
- (51) **Int. Cl.**
G01M 99/00 (2011.01)
A61F 2/24 (2006.01)
- (52) **U.S. Cl.**
CPC *G01N 2203/0089* (2013.01); *G01N 2203/0204* (2013.01); *G01N 2203/0246* (2013.01); *G01N 2203/0476* (2013.01)
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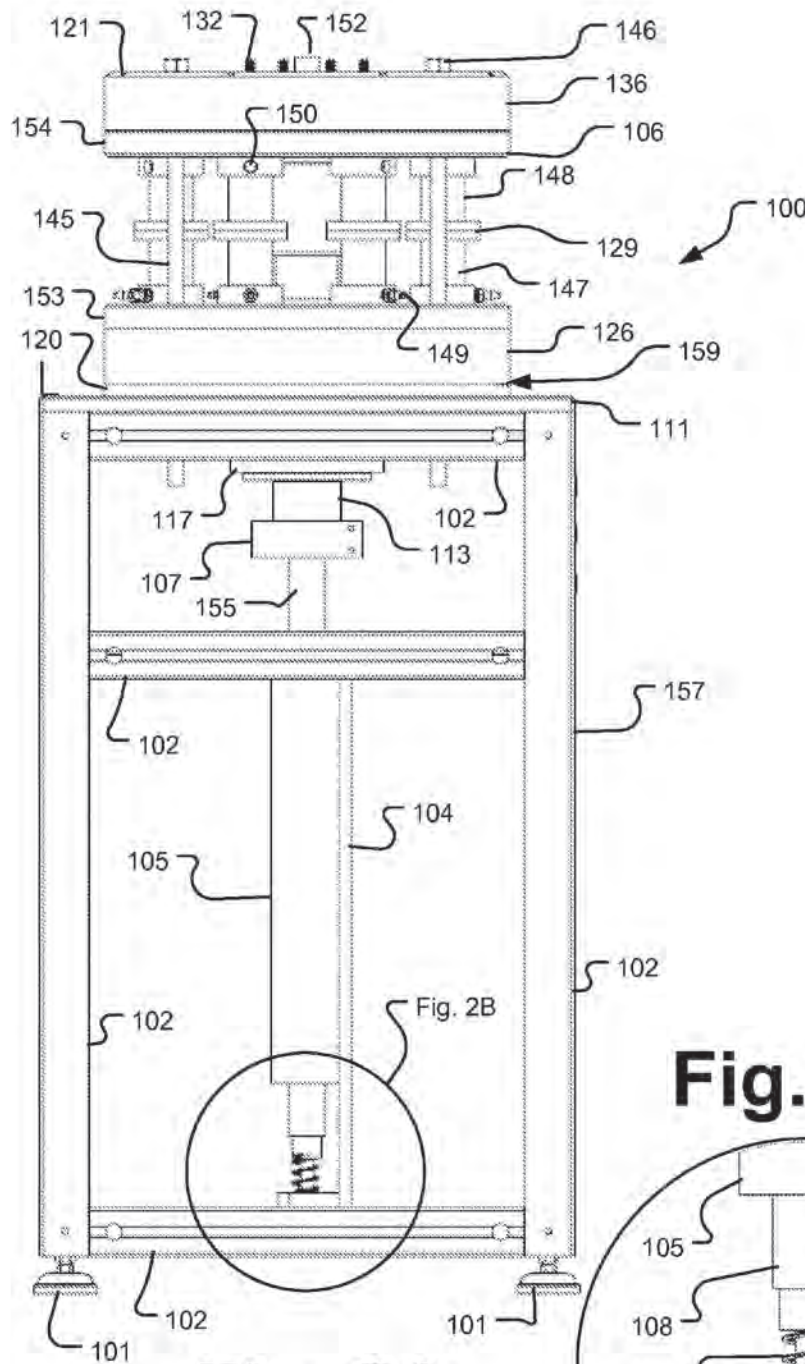
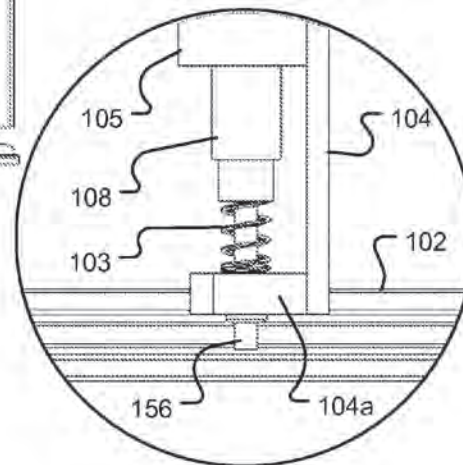


Fig. 2A

Fig. 2B



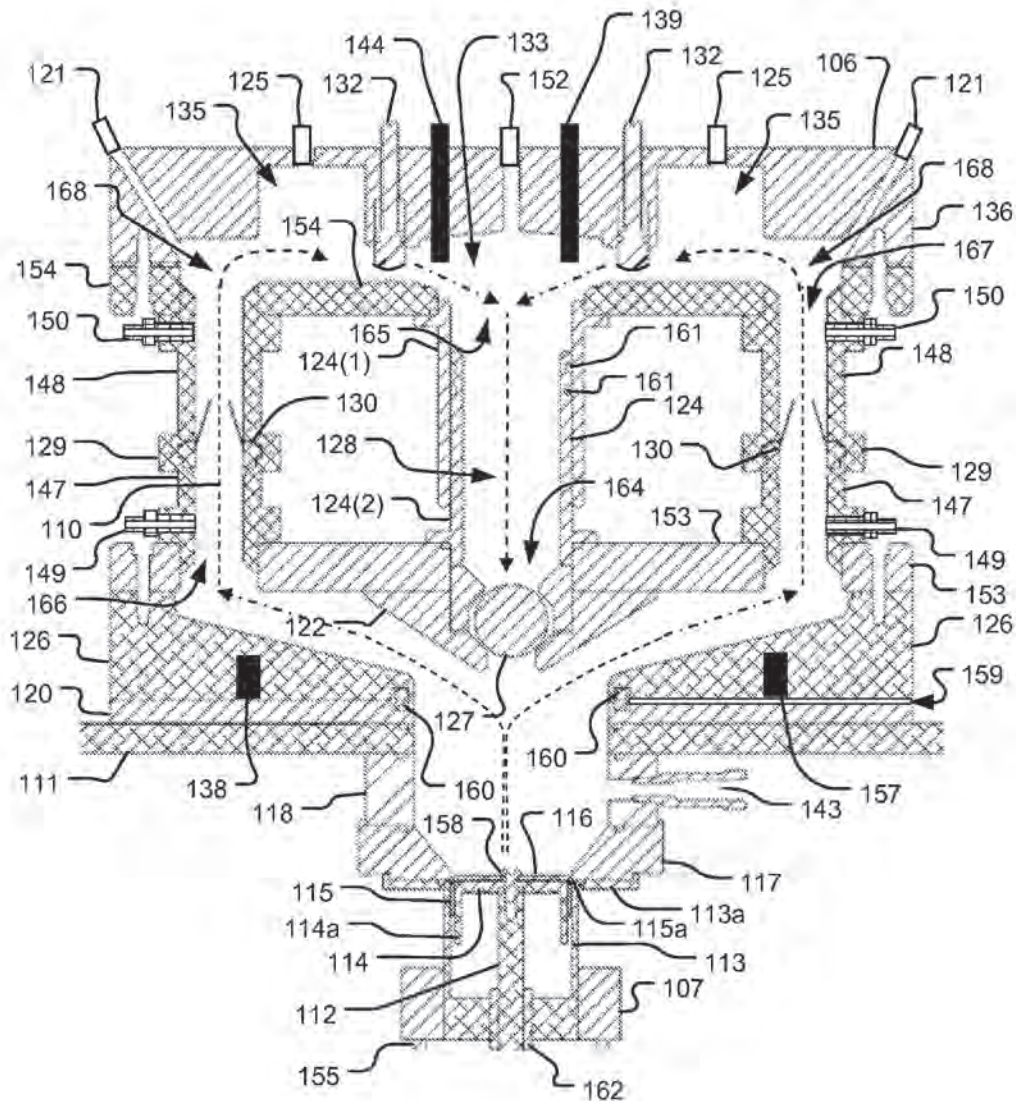


Fig. 3

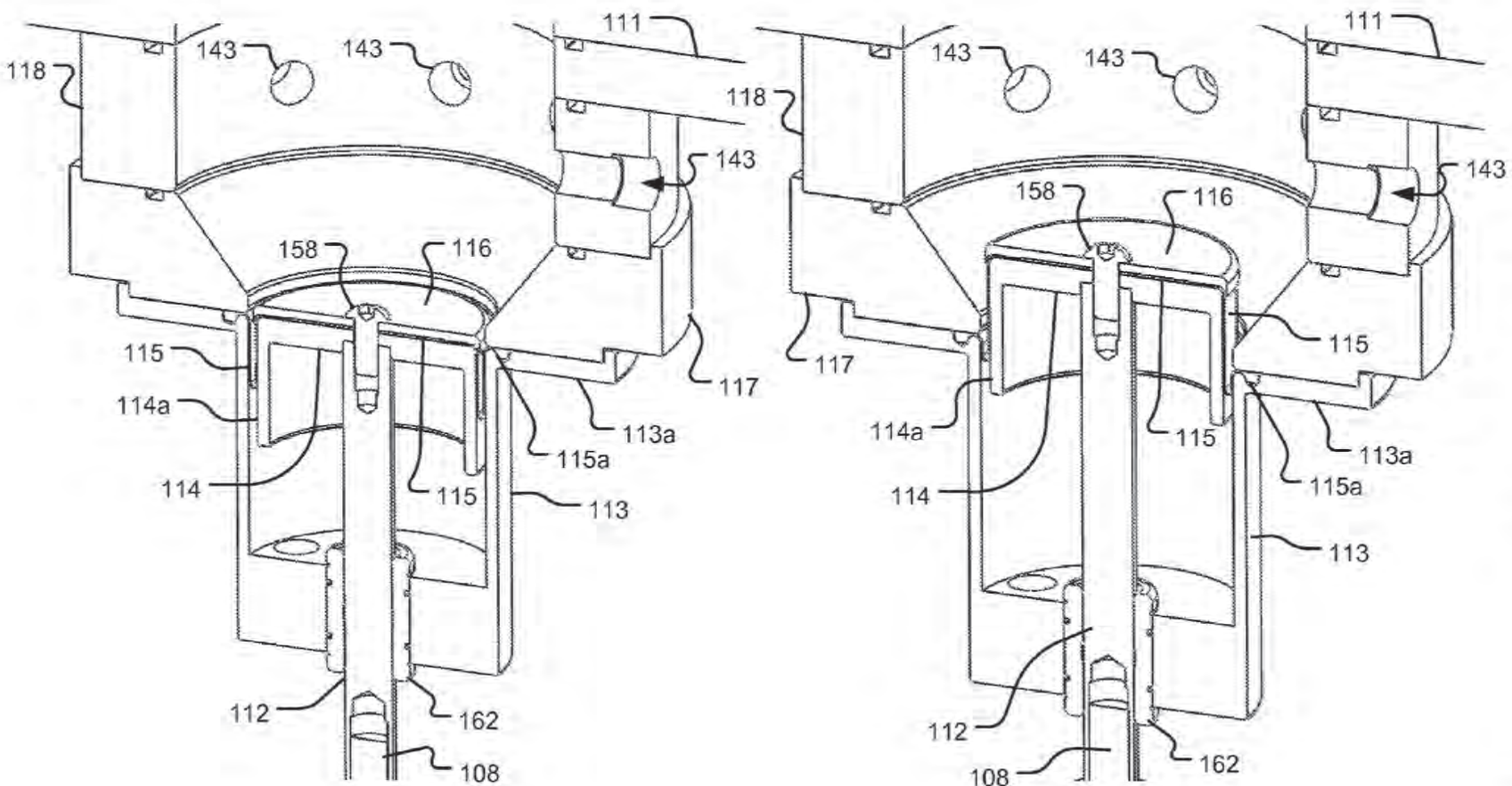


Fig. 4A

Fig. 4B

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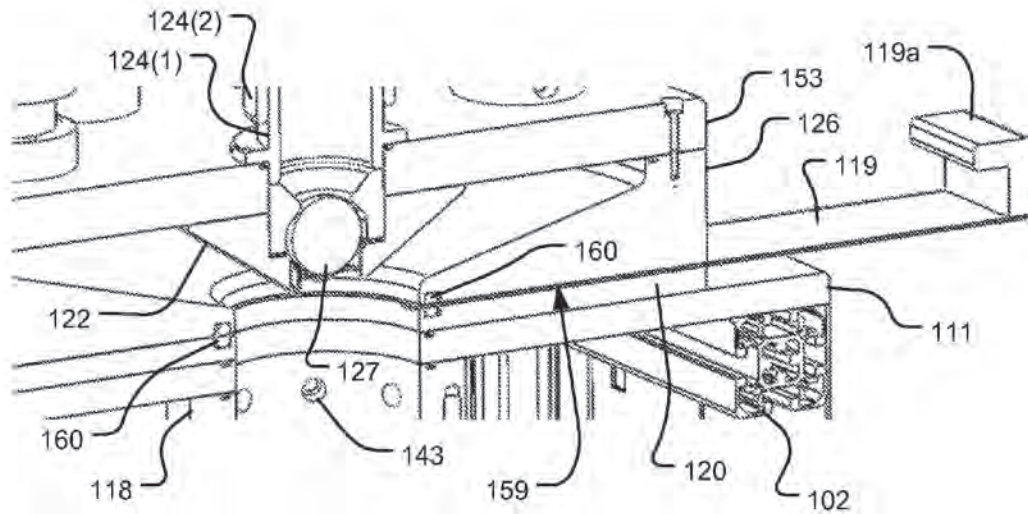


Fig. 5A

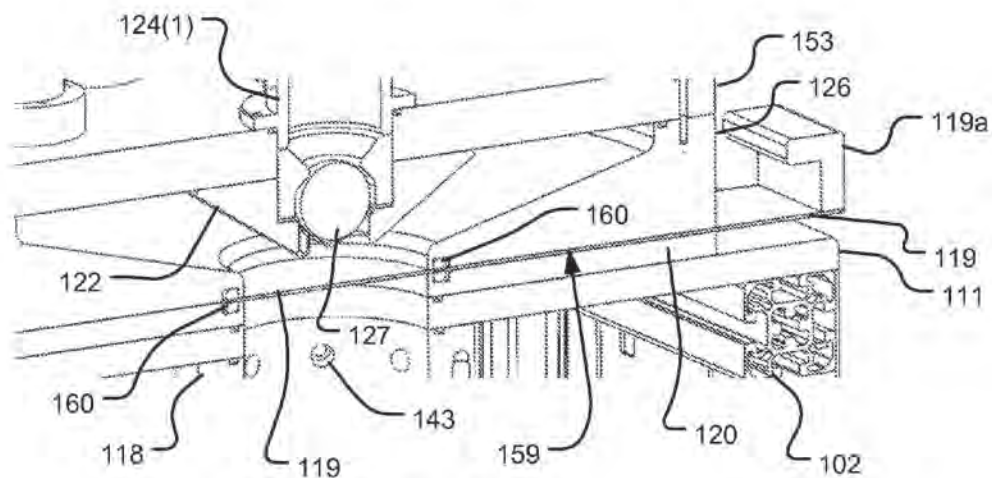


Fig. 5B

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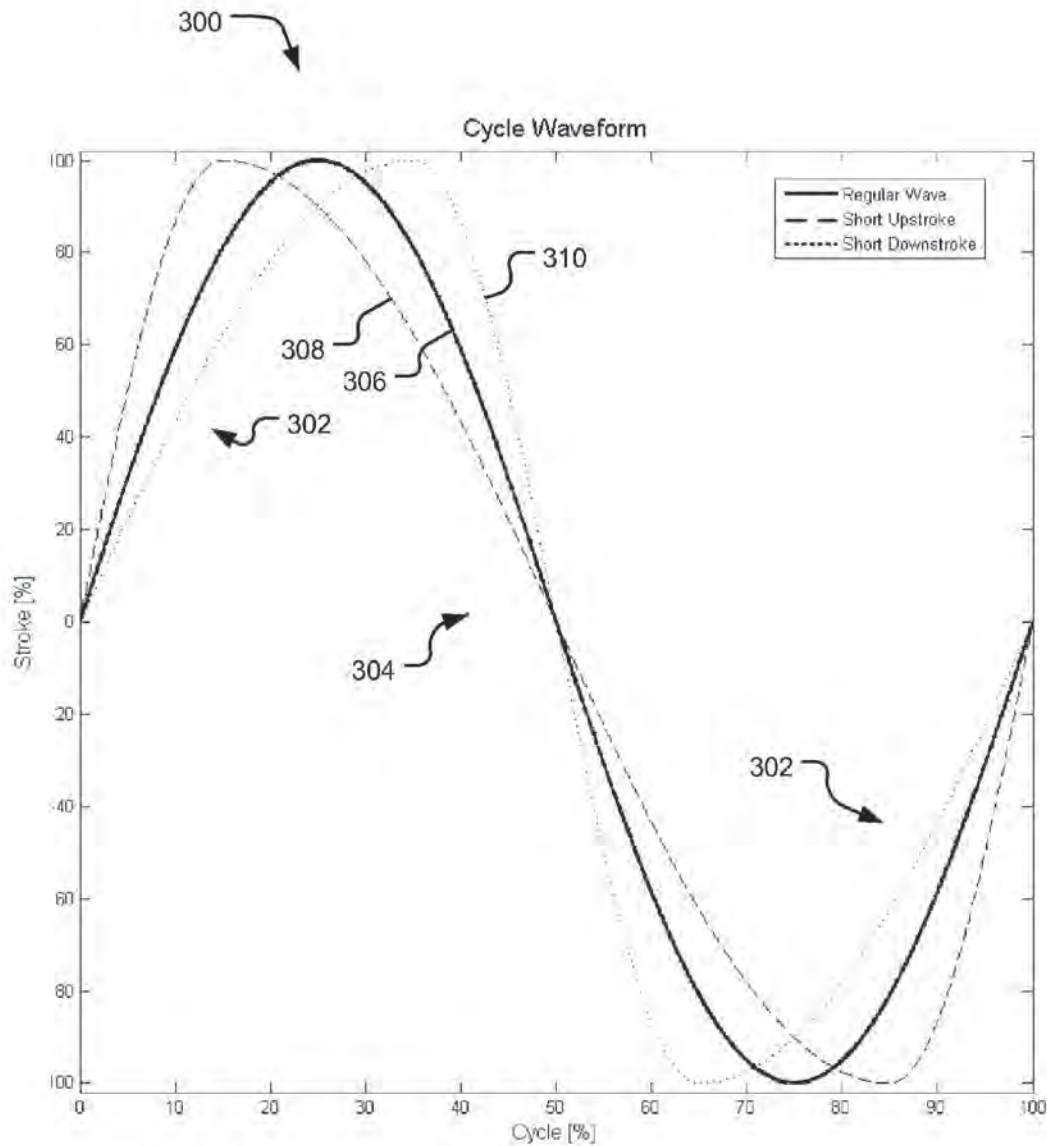


Fig. 7

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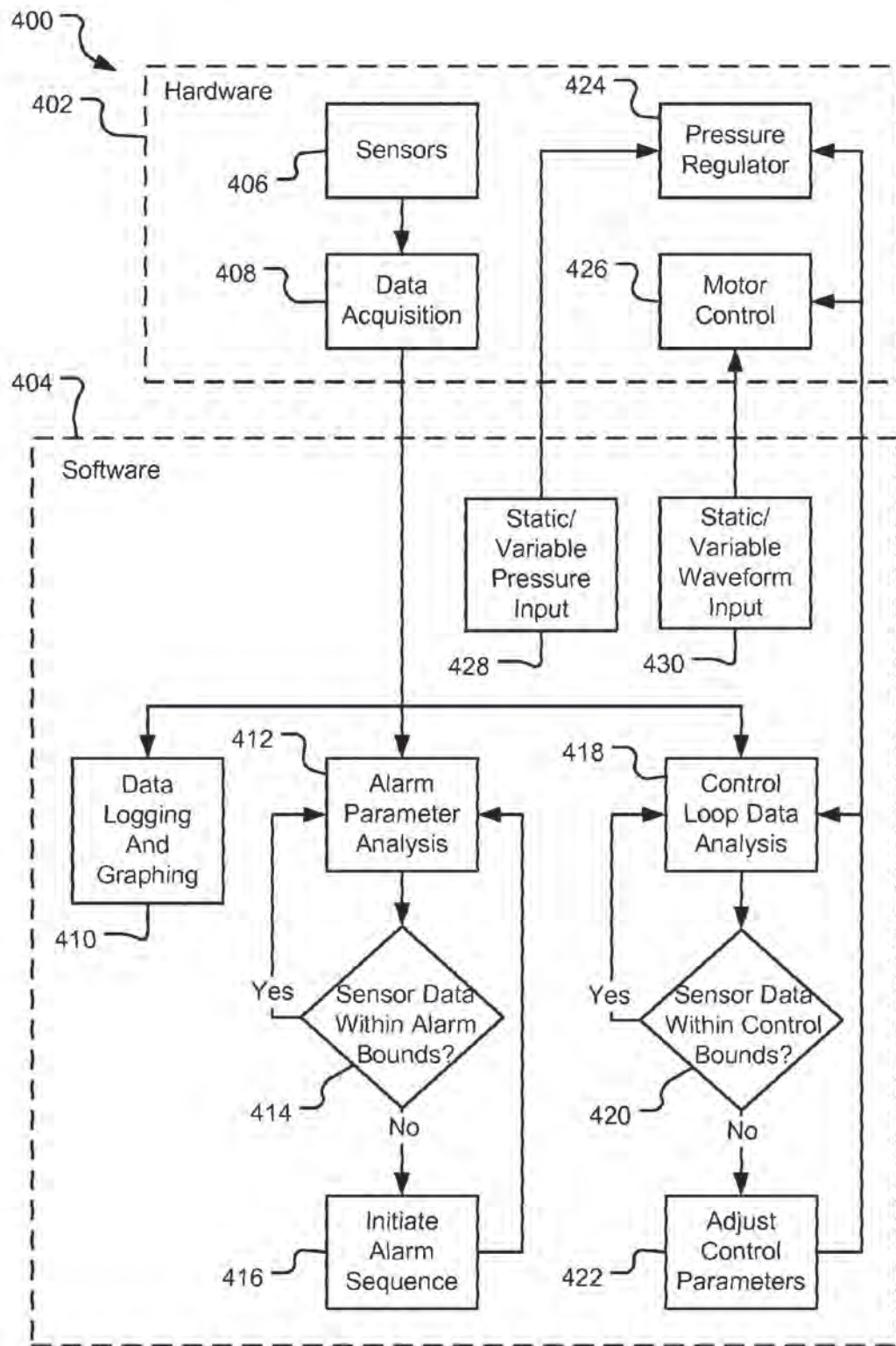


Fig. 8

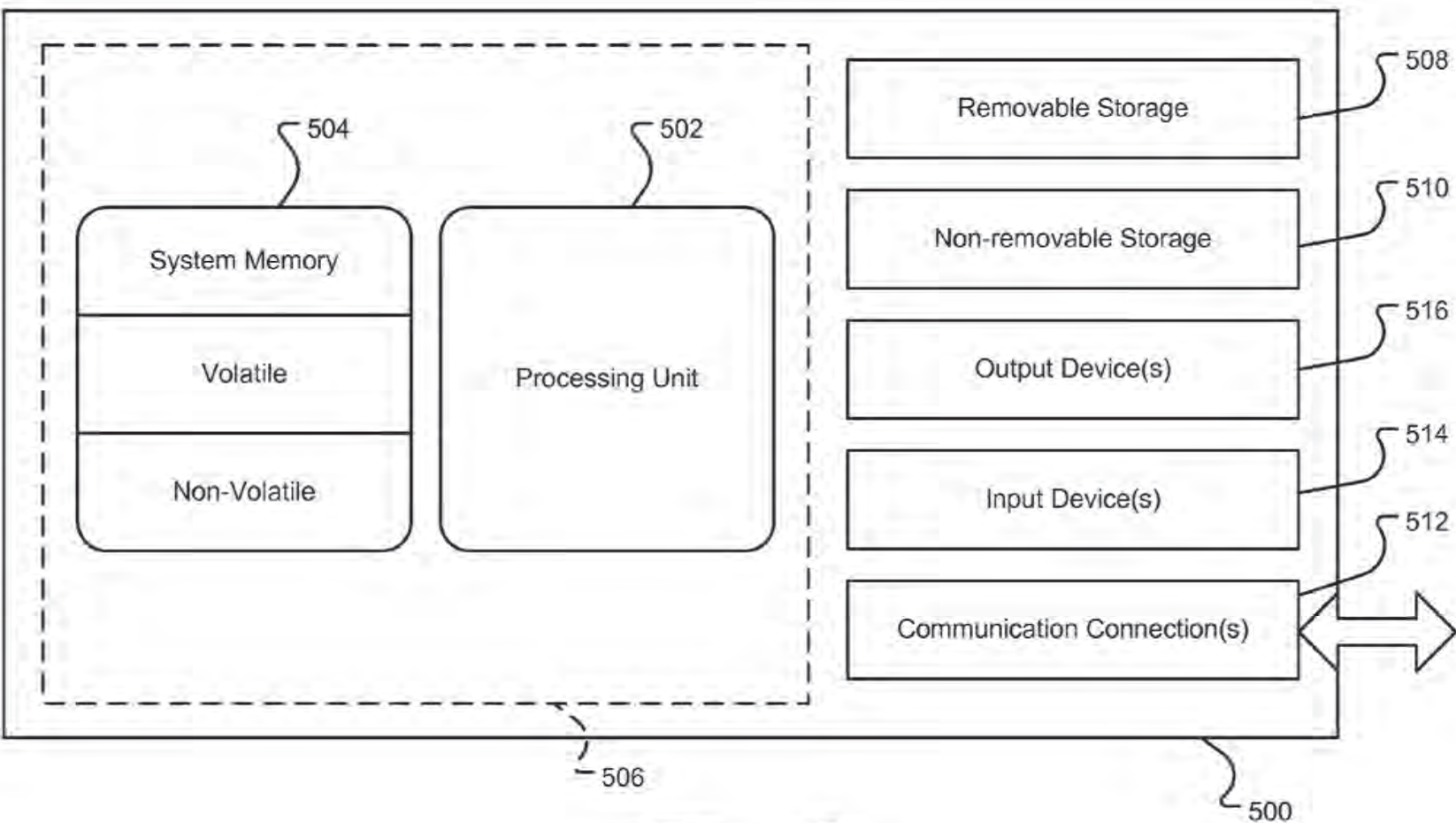


Fig. 9

APPX0023

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FATIGUE TESTING SYSTEM FOR PROSTHETIC DEVICES

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/718,316 filed 5 Mar. 2010 entitled "Fatigue testing system for prosthetic devices," which claims the benefit of priority pursuant to 35 U.S.C. §119(e) of U.S. provisional application No. 61/158,185 filed 6 Mar. 2009 entitled "Apparatus and method for fatigue testing of prosthetic valves," which are hereby incorporated herein by reference in their entirety.

TECHNICAL FIELD

The technology described herein relates to systems and methods for fatigue testing of prosthetic devices, in particular, but not limited to, prosthetic vascular and heart valves, under simulated physiological loading conditions and high-cycle applications.

BACKGROUND

Prior prosthetic valve testing apparatus and methods typically use a traditional rotary motor coupled with mechanisms to produce regular sinusoidal time varying pressure field conditions. To accurately simulate physiologic conditions and/or produce a more desirable test condition, especially at accelerated testing speeds, a non-sinusoidal time dependent pressure field may be desired. This is not easily accomplished with a mechanistic approach. Furthermore, current systems employ a flexible metallic bellows or conventional piston and cylinder as drive members to provide the pressure actuation. Flexible metallic bellows are not ideal because they require high forces to operate and resonate at frequency, necessitating the use of larger driving systems and limiting the available test speeds. Piston and cylinder arrangements are not ideal because the seals employed in these systems are subjected to friction and thus have severely limited life in high cycle applications.

The information included in this Background section of the specification, including any references cited herein and any description or discussion thereof, is included for technical reference purposes only and is not to be regarded subject matter by which the scope of the invention is to be bound.

SUMMARY

A design for a fatigue testing system for cyclic, long-term testing of various types of prosthetic devices (e.g., cardiac valves, vascular valves, stents, atrial septal defect technologies, vascular linings, and others) is designed to impart a repeating loading condition for the test samples during a test run. However, the system is also designed to be variable in its abilities so it can accurately test multiple technologies. Thus, the system may be variably configured depending upon the device being tested to impart a particular loading profile to repeatedly expose the prosthetic device being tested to desired physiological loading conditions during a testing run. The purpose is to simulate typical or specific physiologic loading conditions on a vascular or heart prosthetic valve, or other prosthetic technology, at accelerated frequency over time to determine the efficacy, resiliency, and wear of the devices.

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Fatigue testing is accomplished by first deploying the prosthetic device in an appropriately sized sample holder, e.g., a rigid or flexible tube, canister, housing or other appropriate structure for holding the device being tested. The sample holder is then placed between two halves of a test chamber that together form a reservoir for a working fluid. The test chamber is in turn mounted to a drive system. The sample holder and valve being tested are then subjected to physiological appropriate conditions which may include: pressure, temperature, flow rate, and cycle times.

An implementation of a drive system for the fatigue testing system may include a linear actuator or magnetic-based drive motor coupled to a flexible rolling diaphragm. The drive system is coupled to a lower opening in the test chamber and is in fluid communication with the fluid reservoir in the test chamber. The flexible rolling diaphragm (or "rolling bellow") is reciprocally moveable to pressurize and depressurize fluid and interacts with the lower section of the fluid reservoir to provide a motive force to drive the working fluid through its cycles within the test chamber, including the sample holders.

Testing and test conditions are controlled by a control computer that permits both input of test conditions and monitors feedback of the test conditions during a testing run. Computer system control may be either an open loop control that requires user intervention in the event a condition falls outside pre-set condition parameters or a closed loop control system in which the computer monitors and actively controls testing parameters to ensure that the test conditions remain within the pre-set condition parameters.

The fatigue tester is capable of simulating physiologic conditions on prosthetic devices at an accelerated rate. The fatigue tester may also be configured to create either sinusoidal or non-sinusoidal pressure and/or flow waveforms across the prosthetic devices. Pressure waveforms may also be applied that produce a pre-defined pressure gradient over time to a prosthetic device being tested.

In one exemplary implementation, a device for simultaneous cyclic testing of a plurality of prosthetic devices is composed of a test chamber, a drive motor and a fluid displacement member. The test chamber is pressurizable and has a fluid distribution chamber with a first manifold defining a plurality of ports configured to receive and fluidically couple with a first end of each of a respective plurality of sample holders. The fluid distribution chamber also defines an aperture in a lower face in fluid communication with a pressure source. The test chamber also has a fluid return chamber with a second manifold disposed opposite and spaced apart from the first manifold of the fluid distribution chamber. The manifold of the return chamber defines a plurality of ports configured to receive and fluidically couple with a second end of each of the respective plurality of sample holders. A fluid return conduit both structurally and fluidly connects the fluid distribution chamber to the fluid return chamber. The test chamber also has a compliance chamber which provides a volume for holding a gas or an elastic material that compresses under a pressure placed upon fluid in the test chamber and allows fluid in the test chamber to occupy a portion of the volume. The drive motor is configured to operate cyclically, acyclically, or a combination of both. The fluid displacement member is connected with and driven by the drive motor to provide the pressure source that increases and decreases a pressure on fluid in the test chamber. In this manner, cyclic and acyclic fluid pressures may be maintained throughout the test chamber.

In another exemplary implementation, a device for accelerated cyclic testing of a valved prosthetic device includes a pressurizable test chamber. The pressurizable test chamber

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contains test system fluid and is further composed of a fluid distribution chamber, a fluid return chamber, a fluid return conduit, and an excess volume area. The fluid distribution chamber is positioned on a first side of the valved prosthetic device and is in fluid communication with a pressure source. The fluid return chamber is positioned on a second side of the valved prosthetic device. The fluid return conduit is both structurally and fluidly connects the fluid distribution chamber to the fluid return chamber. 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.

In a further exemplary implementation, a method is presented for operating an accelerated cyclic test system for evaluating a valved prosthetic device. 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.

This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used to limit the scope of the claimed subject matter. A more extensive presentation of features, details, utilities, and advantages of the present invention is provided in the following written description of various embodiments of the invention, illustrated in the accompanying drawings, and defined in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a combined isometric view and schematic diagram of an exemplary implementation of a fatigue testing system and a corresponding control system.

FIG. 2A is a front elevation view of the fatigue testing system of FIG. 1.

FIG. 2B is an enlarged view of the motor support in the area surrounded by the circle labeled 2B in FIG. 2A.

FIG. 3 is a partial cross sectional view of a test chamber of the fatigue testing system taken along line 3-3 of FIG. 1.

FIG. 4A is an isometric view in cross section of a portion of the fatigue testing system of FIG. 1 detailing a flexible rolling diaphragm pump connected to a linear piston drive system in a down stroke position.

FIG. 4B is an isometric view in cross section of a portion of the fatigue testing system of FIG. 1 detailing a flexible rolling diaphragm pump connected to a linear piston drive system in an upstroke position.

FIG. 5A is an isometric view in cross section of a portion of the test chamber of the fatigue testing system detailing an isolation valve in an open position.

FIG. 5B is an isometric view in cross section of a portion of the test chamber of the fatigue testing system detailing the isolation valve in a closed position.

FIG. 6 is a schematic diagram in cross section of an alternative implementation of a test chamber for use in a fatigue testing system.

FIG. 7 is a graph depicting three exemplary pressure control waves for generation by test control software to provide pressure across a sample device being tested.

FIG. 8 is a schematic diagram of a software and hardware implementation for controlling a fatigue testing system.

FIG. 9 is a schematic diagram of an exemplary computer system for controlling a fatigue testing system.

DETAILED DESCRIPTION

The system of the present invention generally includes a linear actuator or magnetic based drive coupled to a flexible

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rolling bellows diaphragm to provide variable pressure gradients across test samples mounted in a test chamber housing a fluid reservoir. These components operate together to act as a fluid pump and, when combined with a fluid control system, provide the absolute pressure and/or differential pressure and flow conditions necessary to cycle test prosthetic devices mounted in the test chamber. The flexible rolling diaphragm thrusts toward the lower section of the test chamber to provide a motive force to drive the working fluid through cycles within the test chamber. The flexible diaphragm is coupled to a lower opening in the test chamber and is reciprocally moveable to pressurize and depressurize fluid within the lower section of the main housing. The flexible rolling bellows diaphragm drive system has a very low inertia as compared to other drive systems, e.g., a metal bellows or a standard piston-in-cylinder drive. The flexible diaphragm is highly compliant with low resistance to axial deformation across its entire axial range of motion.

Plural sample holder tubes are coupled in parallel across the test chamber which has plural fluid distribution channels in communication with each of the sample holders. The lower distribution chamber of the test chamber has a single fluid reservoir in fluid flow communication with each of the plurality of sample holders. The distribution chamber includes a manifold with a plurality of fluid outlet ports, and each fluid outlet port communicates with an inflow opening of a test holder. The upper return chamber of the test chamber includes a similar manifold with a plurality of fluid inflow ports and compliance chambers. Each fluid inflow port communicates with an outflow opening of a respective sample holder. A central return flow channel is provided between the return chamber and the distribution chamber of the test chamber reservoir to provide a return flow of the working fluid from the outflow section of the sample holders. A throttle control and a check valve are disposed at the inflow and outflow ends of the central return flow channel, respectively, to regulate fluid flow during testing. The throttle control serves to partially regulate the pressure across the prosthetic devices being tested as well as the return flow of the working fluid in the fluid test chamber.

These components operate together to provide a differential pressure and flow conditions necessary to cycle the prosthetic device. The internal conditions, which may include, among other things, temperature, differential pressure, and system pressure, are electrically communicated to monitoring and controlling software on a test system computer. The motion of the fluid pump and therefore the system dynamics are controlled via test system control software. The pressure field resulting from the pump motion is easily controlled and can be set as a simple sine wave or as any complex user created waveform.

One exemplary implementation of a fatigue testing system 100 for any of a variety of prosthetic devices is depicted in FIGS. 1 through 5B. The fatigue testing system 100 may be understood as having two primary components, a test chamber 106 and a drive motor 105. The fatigue testing system 100 may be both partially mounted upon and housed within a base housing 157 formed and supported by a number of frame members 102. In the implementation shown, the drive motor 105 is housed within the base housing 157 while the test chamber 106 is supported on a base plate 111 forming a top surface of the base housing 157. The base housing 157 may be open on its sides or enclosed with removable panels as desired. A number of leveling feet 101 may be attached to the bottom of the base housing 157 to provide for leveling of the fatigue testing system 100 and thereby assist in testing com-

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sistent operating conditions across each of the multiple sample chambers of the fatigue testing system 100 as further described below.

In the embodiment shown in FIGS. 1 and 2A with greater detail shown in FIG. 2B, the drive motor 105 may be a linear motor. The linear drive motor 105 is mounted vertically on a motor stabilizer 104 and is centered underneath the test chamber 106. The lower end of the drive motor 105 is supported by a spring 103 that interfaces with a horizontal foot 104a of the motor stabilizer 104 that extends underneath the linear drive motor 105. A lower shaft extension 156 is attached to and extends downwardly from a thrust rod 108 of the linear drive motor 105, through the spring 103, and through a bearing-lined aperture in the foot 104a of the motor stabilizer 104 where it is secured on the underside of the foot 104a as shown in FIG. 2B. The spring 103 is mounted concentrically about the lower shaft extension 156 and abuts the lower end of the thrust rod 108 of the linear motor 105 to support the weight of the thrust rod 108 of the linear drive motor 105 when the linear drive motor 105 is in an unpowered state. Further, in the event of a power failure during operation, the spring 103 prevents the thrust rod 108 from dropping quickly and causing an extremely large pressure gradient across test samples in the test chamber 106, which could damage the test samples.

The upper end of the linear drive motor 105 is fixed to a motor support plate 109 that is in turn supported by several frame members 102 of the base housing 157. An aperture in the motor support plate 109 provides for passage of the upper end of the thrust rod 108 for alignment and mechanical connection with components interfacing with the test chamber 106. It should be noted that while a linear drive motor 105 is depicted in the figures, other types of motors, for example, a regular DC motor or a voice coil, may be used to offer alternate functionality than the linear drive motor 105 of desired for a particular prosthetic device. The number of cycles completed during a test session may be monitored by a cycle counter (not shown) that monitors the motion of the thrust rod 108 of the linear motor 105, which may be affixed to the motor support plate 109.

Several linkage components are provided between the drive motor 105 and the test chamber 106 as shown to best advantage in FIGS. 2A and 3. These components together form the drive member for creating a driving pressure on fluid in the system. An upper shaft extension 112 is fixed to and extends from an upper end of the thrust rod 108 and further extends axially within a cylinder 113. The cylinder 113 is supported about the upper shaft extension 112 within an alignment collar 107. The alignment collar 107 is further supported by a pair of alignment mounts 155 that are fixed to and extend upward from the motor support plate 109. The alignment collar 107 ensures that the cylinder 113 and the drive motor 105 maintain axial alignment.

A central aperture in the bottom of the cylinder 113 receives the upper shaft extension 112. This aperture in the bottom wall of cylinder 113 is lined with a bearing 162 to provide a low friction interface between the cylinder 113 and the upper shaft extension 112 as the upper shaft extension 112 moves within the cylinder 113 as further described below. A piston 114 in the shape of an inverted cylindrical cup may be mounted to the top of the upper shaft extension 112 for axial displacement within the cylinder 113 as the linear drive motor 105 drives the upper shaft extension 112 up and down.

The fluid drive member can be sized based on the volumetric requirements of the test chamber 106 or test samples. Depending on the volume displacement required for a particular application, the cylinder 113 and corresponding piston 114 may be swapped out for sizes of larger or smaller diam-

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eter. The cylinder 113 and corresponding piston 114 may thus be provided in a variety of diameters in order to provide different volume displacements for a given stroke, and thereby pressure differentials, within the test chamber 106 depending upon the type of sample being tested or the particular testing protocol being implemented.

The top edge of the cylinder 113 extends radially to form a flange 113a that interfaces with a bottom surface of a drive adapter 117. The drive adapter 117 may also be provided in a variety of alternative different sizes to interface with different types of cylinders 113 of various diameters. Thus, corresponding drive adapters 117 and alignment collars 107 are similarly swapped for adjustment to the size of the cylinder 113. For example, as shown in FIG. 3, the aperture in the drive adapter 117 is shaped as a frustum with a wider upper mouth toward the test chamber 106 and walls that then taper to a smaller opening at the interface with the top of the cylinder 113. In another embodiment with a larger diameter cylinder 113, the drive adapter 117 may have a larger diameter lower opening defining more sharply angled sidewalls of the frustum-shaped aperture and, in some embodiments, might even be cylindrical to accommodate a larger cylinder 113 of a common diameter.

In one implementation, the fluid drive member has a flexible diaphragm drive system as illustrated in FIGS. 3, 4A, and 4B. The diaphragm 115 may be a cap-like or cup-like member constructed of a non-reactive and flexible thin rubber, polymeric or synthetic based material. The flexible diaphragm 115 is highly compliant with low resistance to axial deformation across its entire axial range of motion within the cylinder 113 and the aperture in the drive adapter 117. However, alternative configurations of the diaphragm 115 may be employed so long as the configuration is capable of low friction and low resistance to deformation under the influence of the piston 114. The outer diameter of the sidewalls 114a of the piston 114 is slightly smaller than the inner diameter of the cylinder 113 to provide a uniform gap therebetween. The gap is designed to be large enough to allow the sidewall of the diaphragm 115 to fold in half against itself, i.e., evert, within this gap when the sidewalls 114a of the piston 114 are positioned within the sidewalls of the cylinder 113. It may thus be noted that in operation flexible diaphragm 115 will operate as a rolling bellows when the linear drive motor 105 is actuated.

Many advantages of a low friction flexible diaphragm 115 as opposed to a rigid metallic bellows or traditional piston and cylinder drive may be appreciated. The lateral surfaces of the diaphragm 115 evert between the sidewalls 115a of the piston 115 and the sidewalls of the cylinder 113 as the piston 114 reciprocates within the cylinder 113 and drive adapter 117. However, this eversion occurs with very low friction and low heat generation, and exerts very little resistance to piston 114 movement. As such, the drive motor can operate with a low driving force for either small or large displacements requiring low current draw and thus low energy expenditure. The flexible diaphragm 115 is highly compliant with low resistance to axial deformation across its entire axial range of motion. Alternative configurations of the diaphragm 115 may also be employed so long as the configuration is capable of very low friction and very low resistance to deformation under the influence of the piston 114.

The cup-shaped flexible diaphragm 115 is mounted on top of the piston 114. The end wall of the diaphragm 115 is held against the top of the piston 114 by a rigid, disk-shaped cap 116, which is fastened to the upper shaft extension 112 via fastener 158 (e.g., a set screw). The diaphragm 115 extends radially outward and circumferentially around the opening of the cap

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ity of the cup-shaped diaphragm 115. This flange surface 115a is sandwiched between the flange surface 113a of the cylinder 113 and the bottom surface of the drive adapter 117 to maintain a pressure seal between the test chamber 106 and the drive components. In view of FIG. 3, the tapering of the frustum-shaped wall defining the aperture in the drive adapter 117 to an opening of comparable diameter to the diameter of the sidewalls forming the cylinder 113 becomes apparent, i.e., the need for corresponding surfaces between the flange of the cylinder 113 and the bottom surface of the drive adapter 117 to retain the flange surface 115a of the diaphragm 115.

A top surface of the drive adapter 117 is fastened to a plenum 118 that defines a center cylindrical aperture aligned coaxially with the aperture of the drive adapter 117 and the cavity defined by the cylinder 113. As shown in FIGS. 4A and 4B, a plurality of ports may be defined within the sidewall of the plenum 118 to provide fluid fill, drainage, or other functionality within the linkage components below the test chamber 106. For the sake of clarity, the plenum 118 shown in FIG. 3 depicts only a single sidewall port 143 that, in this embodiment, is used as a fluid inflow port. However, additional ports may be defined within the plenum 118 if desirable (see, e.g., FIGS. 4A and 4B). If not in use for a particular test configuration, the sidewall ports 143 in the plenum 118 may be plugged. The plenum 118 may be of constant diameter to interface with an aperture in the base plate 111 of the base housing 157. For this reason it can now be understood why in some embodiments the opening in the top surface of the drive adapter 117 may be of a larger diameter than the opening in the bottom surface of the drive adapter 117 as the drive adapter 117 mates with a constant diameter plenum 118 in contrast to a variable diameter cylinder 113.

As previously indicated, the test chamber 106 sits atop of the base plate 111 on the base housing 157. The foundation of the test chamber 106 may in some embodiments include a gate guide plate 120 that also defines a central aperture that is coextensive in diameter with and concentrically aligned with the aperture in the base plate 111. A distribution chamber 126 is supported by the gate guide plate 120. The gate guide plate 120, the distribution chamber 126, and the base plate 111 may all be fastened together via bolts (not shown) extending upward from the underside of the base plate 111. A pair of gate seals 160 may be positioned between the gate guide plate 120 and the distribution chamber 126. The gate seals 160 may be a set of stacked O-rings surrounding the central apertures in the gate guide plate 120 and the distribution chamber 126. The gate seals 160 may be slightly recessed within corresponding annular grooves formed in a bottom surface of the distribution chamber 126 and a top surface of the gate guide plate 120.

A shallow flat channel 159 of a width at least slightly greater than the diameter of the gate seals 160 may be formed to extend radially from the center aperture within the top surface of the gate guide plate 120. A flat rectangular knife or gate valve 119, shown to best advantage in FIGS. 5A and 5B, may be positioned within the channel in the gate guide plate 120. The gate valve 119 is shown in a radially withdrawn, open position in FIG. 5A, such that there is an open passage between the center apertures defined within the gate plate 120 and the distribution chamber 126. In this position, the gate seals 160 press against each other to create a fluid tight seal about the central apertures.

In a closed state as depicted in FIG. 5B, the gate valve 119 is pushed radially inward such that the flat plate forming the gate valve 119 extends completely across the center apertures and is sealed between the gate seals 160 to fluidically separate the gate guide plate 120 and the linkage elements below it

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from the rest of the test chamber 106 above it. Closure of the gate valve 119 thus allows for easy maintenance of the drive motor 105 or the piston driver 114 (e.g., replacement of the flexible bellows diaphragm 115) without having to drain the test chamber 106.

As previously noted, the distribution chamber 126 is positioned on top of the gate guide plate 120. The distribution chamber 126 defines a much wider but shallow cavity with an interior bottom wall that slants radially inward until it reaches a common diameter with the aperture of the gate plate 120. In this embodiment, one or more resistive heaters 130 may be embedded within the bulk of the distribution chamber 126 underneath the fluid cavity defined by distribution chamber 126. In one embodiment a separate heater 138 may be located immediately beneath each sample holder 129 (as further described below) to aid in the uniformity of heat distribution within the fluid in the test chamber 106.

A distribution chamber manifold 153 is mounted to a top surface of the distribution chamber 126, for example, by bolting the two surfaces together about the perimeter. The distribution chamber manifold 153 may form a conical diverter surface 122 that extends downward into the cavity of the distribution chamber 126. A center bore 164 extends through the distribution chamber manifold 153, including through the diverter 122. This center bore forms part of a return flow path 128 as further described below. The distribution chamber manifold 153 may further define a plurality of bores 166 spaced about the perimeter of the distribution chamber manifold 153. In the embodiment shown in FIGS. 1 through 3, eight perimeter bores 166 are defined at a uniform radial distance from the center and are equiangularly spaced apart. However, in alternative embodiments, there may be greater or fewer perimeter bores 166 and different or non-uniform spacing may be implemented if desired. A sample inlet tube 147 forming the bottom half of a sample holder 129 is connected within and seals against each of the perimeter bores 166 of the distribution chamber manifold 153.

Similarly, a lower conduit wall 124(2) of a telescoping center conduit 124 mounts within and seals against the center bore 164 in the distribution chamber manifold 153. A one-way valve 127 or similar check valve is positioned within the center bore 164 of the distribution chamber manifold 153 below the lower conduit wall 124(2) of the center conduit 124. The second half of the center conduit 124 is formed as a cylindrical upper conduit wall 124(1) with an inner diameter substantially the same as an outer diameter of the lower conduit wall 124(2) such that the center conduit 124 can be expanded or contracted in length. One or more center seals 161, for example, in the form of O-rings mounted within annular recesses in the outer surface of the lower conduit wall 124(2) provide a fluid tight seal interface with the interior surface of the upper conduit wall 124(1).

Each of the sample holders 129 is also composed of a sample outlet tube 148 that sits atop a respective sample inlet tube 147. The actual test sample 130 (e.g., a prosthetic device) may be sandwiched between the sample inlet tube 147 and sample outlet tube 148 to hold it in place within the test chamber 106. In other embodiments (not shown) each of the sample holders 129 may be an integral unit with a test sample 130 mounted within by any of a variety of means that may be specific to the nature of the particular test sample 130.

A return chamber manifold 154 is positioned atop each of the sample outlet tubes 148 and the upper conduit wall 124(1) of the center conduit 124. The return chamber manifold 154 defines corresponding perimeter bores 167 for mating with each of the sample outlet tubes 148 and a center aperture 165 for mating with the upper conduit wall 124(1) of the center

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conduit 124. Each of the interfaces between the sample outlet tubes 148 and the center conduit 124 with the return chamber manifold 154 is configured to provide a fluid tight seal between the components.

A return chamber 136 is mounted on top of the return chamber manifold 154 in a similar manner as the distribution chamber 126 is mounted to the distribution chamber manifold 153. The return chamber 136 defines one or more compliance chambers 135 which, in the embodiment of FIGS. 1-3, are composed of cavities associated respectively with each of the sample holders 129. 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. The compliance chambers 135 assist in minimizing the effects of large and quickly changing pressure gradients across test samples 130 placed within the test chamber 106. In some implementations, the compliance chambers 135 may merely contain air or another gas. The air or other gas may be indirect contact with the working fluid in the test chamber 106 or a membrane may be provided within the compliance chambers 135 to separate the air or gas from the working fluid. In other embodiments, the compliance chambers 135 may house a porous material or an elastomeric material. In each case, the purpose of the compliance chambers is to act as a resilient spring force to dampen the effects of large, quickly changing pressure gradients within the test chamber 106.

The return chamber 136 further defines separate return conduits 168 that are in fluid communication with respective pairs of the sample holders 129 and compliance chambers 135. A respective throttle valve 132 is housed within the return chamber 136 and placed between each respective return conduit 168 and a central return basin 133 that empties into the center return conduit 124. Each of the throttle valves 132 may be operably raised or lowered to restrict or enlarge the fluid flow passage between the return conduits 168 and the central return basin 133 and assist in the regulation of the pressure across the test samples 130 in the sample holders 129.

The return chamber 136 may also define a number of bores variously in communication with the return conduits 168, the compliance chambers 135, the central return basin 133. For example, system input bores 121 may be provided for relatively direct access to each of the sample holders 129 via the return conduits 168. The system input bores 121 may be used for a variety of purposes, for example, for the placement of sensing or diagnostic equipment or for access to the test samples 130 in the sample holders 129. In a particular example, when testing a valve design with removable valve leaflets, the system input 121 could be used to access the sample holder 129 and remove and replace the valve leaflets while leaving the permanent valve mounting structure in place within the sample holder 129. This obviates the need to disassemble the test chamber 106 for replacement of components of the test samples 130.

An access port 125 may also be associated with each of the compliance chambers 135. The access port 125 may be used for the attachment and introduction of sensing equipment or for providing additional air or gas pressurization to the compliance chambers 135. Additional sensors may further be placed in access ports positioned for communication with the central return basin 133. For example, as shown in FIG. 3, a temperature transducer 139 and a water level sensor 144 may be placed in communication with the central return basin 133. It should be understood that any number of other sensor devices could also be placed in contact with or introduced

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within the test chamber 106 by any of the various apertures, bores, or ports provided within the return chamber 136.

The various sensors of the fatigue testing system 100 may be operably connected to a data acquisition (DAQ) device 141. An amplifier and control system 140 may also be connected with the drive motor 105 to provide output control of the same. In some embodiments, the DAQ device 141 and amplifier/control system 140 may be mounted within the base frame 157. An air source 131 connected in line with a pressure regulator 134 may also be under control of the control system 140. These components are, in turn, either directly or indirectly operably connected to a microprocessor-based computer 142. All systems may also be connected to an uninterrupted power supply (UPS) 143.

Software provided on the computer 142 can direct the system controller 140 to provide full closed-loop control based on feedback measurements received from the DAQ device 141 coupled with the sensors. In one example of this functionality, software may be configured to control the driving amplitude and velocity of the drive motor 105 based upon differential pressure transducer feedback. The system 100 may therefore compensate for any changes during the high cycle testing cycle providing the test samples 130 with the most optimal testing conditions. An automated test interface may be provided as part of the fatigue testing system 100 to run the test chamber 106 without direct management, ensuring proper testing conditions and safety mechanisms. The test interface may be configured to provide closed-loop control based off any system measurement feedback.

An implementation of operation of the exemplary fatigue testing system 100 of FIGS. 1-5B may be understood as follows. Initially, test samples 130 need to be placed within the test chamber 106. In order to introduce test samples 130, the sample holders 129 must be accessed. The adjustment nuts 146 on the top of the return chamber 136 may be rotated to raise the adjustment posts 145 from their tightened positions within the distribution chamber manifold 153 and distribution chamber 126. Once the return chamber 136 and return chamber manifold 154 are raised, the sample holders 129 may be removed and replaced with alternate sample holders or, as shown in this embodiment, samples positioned between sample inlet to 147 and sample outlet to 148, may be removed and replaced with new samples 130. The adjustment nuts 146 may then be tightened to lower the return chamber 136 and return chamber manifold 154 back into contact with the sample holders 129 to create fluid-tight flow path through each of the sample holders 129 between the distribution chamber 126 and the return chamber 136. Note that when the return chamber 136 and return chamber manifold 154 are raised, the center conduit 124 telescopes upward with the upper conduit wall 124(2) sliding along the exterior of the lower conduit wall 124(1), thus maintaining a fluid-tight connection within a center conduit 124.

In many applications, it may be desirable to monitor the pressure gradient across the sample holder 129. For such purposes, a conduit with a sensing device, for example, a pressure transducer, may be placed in a conduit that is attached at one end to a monitor outlet port 149 in the sample inlet tubes 147 and a monitor inlet port 150 on the sample outlet tubes 148. In an alternative implementation, individual sensors (e.g., pressure transducers) may be attached directly to each of the monitor outlet ports 149 and monitor inlet ports 150 to measure absolute pressure at each of these locations. The absolute pressure data may be collected by the data acquisition component 141 and transferred to the computing device 142 for calculation of the pressure differential.

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taking the difference between the absolute pressure values on either end of the sample holders 129.

Presuming that the correct size of cylinder 113 and corresponding drive adaptor 117 are already attached, the fatigue testing system 100 may be charged with the desired type and amount of working fluid through any one of the inflow ports 143 in the plenum 118. The working fluid may be water, saline, a saline/glycerin solution, a glycerin/water solution, a blood analog or substitute, or other type of fluid. In some embodiments, the working fluid may be selected to simulate one or more attributes of human blood, such as density, viscosity or temperature. For example, in certain instances, physiological saline which does not simulate the viscosity of blood, but simulates density, may be used. In other cases saline/glycerin solution may be employed to simulate blood viscosity.

Depending upon the particular test samples 130 and desired testing conditions and dynamics, the fatigue system 100 may be filled with fluid up to an appropriate or desired level in the compliance chambers 135. 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. In some embodiments, a pressure regulator 134 may be interposed between the air source 131 and the air inlet 152 to regulate the pressure within the test chamber 106. Alternatively, the system 100 can be pressurized by first sealing the system 100 and then changing the position of the fluid driving piston 114 such that the available volume is decreased.

The working fluid temperature is controlled via the fluid heaters 138 and the temperature transducer 139. Upper and lower temperature bounds may be set in the test software. At startup the system 100 will begin to heat until the upper bound is reached. As the input temperature falls below the lower bound, the heaters 138 are again activated, thus maintaining a mean temperature within acceptable bounds. This mean temperature is typically set to 37° C. to simulate physiologic conditions.

Once the system is filled with fluid, heated, and properly pressurized, testing operations under control of the computer 142 may be initiated. The computer 142 may control the operations of the linear drive motor 105 to move the piston 114 and thus the diaphragm 115 up and down within the cylinder 113 and drive it after 117 to cyclically increase and decrease the pressure within the test chamber 106. Under computer control and depending upon the size of the cylinder 113, the linear drive motor 105 may cause the thrust rod 108 and the attached upper shaft extension 112 to move up and down thereby moving the cylinder 113 and diaphragm 115 up and down to create a displacement of any size, small or large, to change the pressure within the test chamber 106. The rolling or eversion of the diaphragm 115 exerts very little resistance to piston 114 movement. Thus, power requirements on the linear drive motor 105 are small and current draw is minimized.

Fluid flow 110 through the test chamber 106 is indicated by the dashed lines initiating at the drive adaptor 117 traveling through the plenum 118 and then through the sample holders 129 to exit through the return conduit 168, the central return chamber 133, and the center conduit 124. Fluid flow can be prevented from moving upward in the center conduit 124 by the one-way valve 127 housed within the distribution chamber manifold 153. The conical diverter 122 helps direct fluid

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flow from the piston 114 regularly and uniformly to each of the sample holders 129 about the perimeter of the test chamber 106.

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 liquid working fluid within the test chamber 106. The throttle valves 132 restrict the rate of return flow of fluid within the test chamber 106 into the central return basin 133. The combination of the compliance chambers 135 and the throttle valves 132 help control undesirable pressure loading or pressure spikes within the sample holder 129 and consequent adverse effects on the test samples 130 when the piston 114 moves in a decompression stroke. The compliance chambers 135 and the throttle valves 132 also generally help tune the test conditions across the sample holder 129. In addition to selecting the piston size, the displacement range, frequency, and waveform settings, the system equilibrium pressure, and other settings, the compliance chambers 135 and the throttle valves 132 may be adjusted as an additional aid in fine-tuning appropriate differential pressure across the test samples 130 in the sample holder 129.

As the piston 114 moves downward in decompression stroke, pressure on the one-way valve 127 is released and fluid flow through the center conduit 124 is initiated at a controlled rate depending upon the position of the throttle valves 132. In this way, on the downward stroke, the pressure in the test chamber 106 returns to an initial level and excess volume returns to the compliance chambers 135. It should be noted that the compliance chambers 135 may be configured in a variety of different ways. In addition to merely containing a volume of air or other gas to act as an air spring, a membrane could be provided between the liquid and the air or other gas or alternatively the space could be filled with a porous foam or other elastomeric material, thereby reducing or otherwise adjusting the spring factor provided by the compliance chamber 135.

The dynamics of the system 100 can be controlled through the stroke pattern, frequency, and volume of the piston 114, the flow setting of the throttle valves 132, and the spring force of the compliance chambers 135. Additionally, the working fluid in the test chamber 106 may be preset to a base or ambient pressure using a separate pressure source. For example, an air/gas source 131 (e.g., an air compressor or gas tank) may be connected to and pressurize a fluid reservoir (not shown) in fluid contact with the working fluid in the test chamber 106. A pressure regulator 134 may be positioned between the air source 131 and the introduction into the test chamber 106 for controlling the desired system pressure. Alternatively, a pressurized gas may be introduced directly into the compliance chambers 135 through access ports 125, into the central return basin 133 through inlet 152, or through any other port (e.g., one of the sidewall ports 143 in the plenum 118) for charging the test chamber to an appropriate base pressure for proper function of the system 100 for the particular test configuration.

An alternate embodiment of a test chamber 206 for a fatigue testing system 200 is shown in FIG. 6. The test chamber 206 consists generally of a lower chamber composed of a distribution chamber 226, a flow conditioning chamber 272, and a manifold 253, and an upper chamber composed of a return chamber 236, a manifold 254 and a central compliance chamber 235. A fluid flow pathway 210 extends from the lower chamber to the upper chamber which passes through a plurality of sample holders 229 holding the device samples

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230 being tested and a return fluid flow pathway 228 extends from the upper chamber to the lower chamber to return fluid from the upper chamber to the lower chamber in preparation for a following cycle. A check valve 227 is inline with the return fluid flow pathway 228 between the upper and lower chambers to regulate back flow through the test chamber 206. A controllable central throttle valve 232 is also in-line with the upper and lower chambers to regulate the differential pressure across the test samples 230 during operation.

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. The piston 214 is mounted on the shaft extension 212 extending through the bearing 262 from the thrust rod of the linear motor (not shown). The flexible diaphragm is mounted on the piston 214 as in the prior embodiment and held in place by a cap 216. The diaphragm 15 is preferably a cap-like member constructed of a non-reactive and flexible thin rubber, polymeric or synthetic based material. The lateral surfaces of diaphragm 215 roll or evert as the piston 214 reciprocates within the cylinder 213 and drive adapter 217 between which the circumferential flange of the diaphragm is sealed. These components are affixed to the support plenum 218 and maintain the pressure seal along the circumference of the diaphragm 215. The plenum 218 serves as a mounting point for the drive system. The plenum 218 may also include fluid ports for pressure monitoring and system draining.

During the primary or pressurization portion of a test cycle, the piston 214 moves in a positive direction toward the test chamber 206 and creates an initial pressurization and the working fluid flows up through the base plate 211 into the distribution chamber 226. The working fluid impinges upon a generally conical flow baffle 222 and is directed radially outward to flow straighteners 271. The fluid is blocked from entering the central return conduit 224 by a one-way exit valve 227. The working fluid then passes from the distribution chamber 226 and into a flow conditioning chamber 272, wherein it passes through a flow straighteners 271, aligning the flow along the axis of the sample holders 229. Sample adapters 247, 248 attach the sample holders 229 to the distribution manifold 253 and the return manifold 255, allowing the sample holders 229 to be connected to the test chamber 206 in a leak free manner.

A collateral pressure-sensing conduit 269 may be coupled to the sample holder 229 and direct a fluid flow pathway toward a pressure transducer 270 that serves to monitor the differential pressure gradient across the test sample 330 within the sample holder 229. The differential pressure transducers 270 monitor the pressure field across each test sample 230 in the sample holders 229 during the testing cycle. Flexible or rigid tubing 269 is connected to the upper and lower sample adapters 247, 248, with the opposite ends of the conduit 269 being connected to the differential pressure transducer 270. Additional monitoring transducers can be introduced through the sensor ports 221 and other ports built into the return chamber 236 as necessary.

Once the fluid flow has exited the sample holders 229 it flows into the return manifold 254 and return chamber 236. The working fluid passes around a throttle valve 232 and a return fluid flow is communicated through return conduit 224 to the lower chamber during a secondary or depressurization portion of the test, thus completing the first portion of the test cycle. The throttle valve 232 is connected to the throttle valve handle 232a, which runs through a fluid-tight fitting on top of compliance chamber cap 221. The throttle valve handle 232a is adjustable, such as by a threaded coupling to the cap 221 on the compliance chamber 235. The throttle valve 232 can be

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adjusted up or down, increasing or decreasing the resistance to fluid returning to the central return conduit 224 to aid in controlling the differential pressure across the test sample 230. The amount of gas or the elasticity of the elastomeric material inside the compliance chamber 35 allows the user to control the damping of the system and provides an additional tool calibrate the ideal test conditions for the particular prosthetic device. In the embodiment of FIG. 6, a single compliance chamber 235 is axially centered over the test chamber 206 and provides a compliance volume for all of the sample holders 230 in the test chamber 235. Similarly, in this embodiment only a single throttle valve 232 is provided to control the return flow of the working fluid through the center return conduit 224.

FIG. 7 provides examples of three different pressure control signals generating three different cyclical pressure waveforms 300 across a prosthetic device being tested. Because of the vertical orientation of the displacement components, the term "upstroke" is synonymous with a pressurization stroke of the piston, i.e., that which exerts a positive pressure across the prosthetic device being tested and the term "down stroke" is synonymous with a depressurization stroke of the pump, i.e., that which exerts a negative pressure across the prosthetic device being tested. Typical test systems are only capable of driving the fluid with a regular sine wave 306. A non-regular pressure waveform may be desirable for testing of certain devices as it allows the user to control the rate of pressurization in the test system and optimize the test conditions, while maintaining a desired operating frequency. Two exemplary non-regular waveforms having short upstrokes 308 and down strokes 310, respectively, are illustrated in FIG. 7. However, any arbitrary pressure waveform may be generated and can be utilized to drive the motor and thereby the piston.

During the primary or pressurization portion 302 of the testing cycle, fluid is moved past the prosthesis within the housing tube. In an exemplary implementation in which valve prostheses are tested, the positive upstroke forces the valve prosthesis to the open state. During a secondary or depressurization portion 304 of the test cycle, the flow is reversed and the valve prostheses 30 are closed. As the secondary portion 304 of the cycle begins, the fluid moves through the throttle valves into the central return conduit and back into the distribution chamber through the one-way valve. During return flow, the valve prosthesis remains closed due to the flow reversal and differential pressure present between the distribution chamber and the return chamber. The drive system returns to its starting position and the process is repeated, cycling the prosthetic devices. A single test cycle consists of completion of both the primary portion 302 and secondary portion 304 of the test cycle such that the prosthetic device passes through one open and -closed cycle.

The exemplary pressure waveforms 306, 308, 310 depicted in FIG. 7 may be generated by the fatigue testing system or by other mechanical mechanisms. It is envisioned that alternative mechanical or electromechanical systems, such as those including gearing or cams to drive a pump, may be employed in a manner that generates the variable pressure waveforms as depicted in FIG. 7, in which the pressure gradients are variable over time.

As indicated above, the proposed technology may be integrated with system monitoring and controlling software. The computer software can be used to record and analyze data while controlling the dynamics of the system, as outlined in the exemplary process 400 shown in FIG. 8. Data is first obtained by system hardware 402, i.e., the system sensors 406, and then processed through data acquisition hardware

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408 and transmitted to the system computer for processing and formatting for presentation by the system software 404.

All system inputs and outputs may be continuously monitored and directed into software-based control and alarm system modules, allowing the system to automatically reconfigure or halt if any signal deviates outside of the user set bounds. The real-time data stream may be utilized for three primary purposes: data logging and graphing, alarm condition indication, and test system control. The data logging and plotting subroutine 410 generates graphs and plots of pertinent signals while also creating a data file to allow for test documentation and off-line analysis.

The alarm condition subroutine 412 analyzes data to determine if any of the test inputs or control signals have deviated outside of user defined alarm magnitudes. If an alarm is triggered, i.e. an alarm parameters exceeds its bounds as determined in operation 414, an alarm sequence is initiated as indicated in operation 416. This sequence could trigger a number of events. In one sequence, the software may halt the test system in a specific manner; in another alarm sequence, the test software may notify the operator; in yet another alarm sequence, the system may be halted and the user notified. As can be appreciated, there are a number of actions that are available as part of an alarm sequence and these sequence steps could be dependent on a number of parameters including the specific test samples and/or the specific test protocol.

The control loop subroutine 418 further monitors the control parameters based on a user defined target input signals and/or parameters. Exemplary user set parameters may include pressure input parameters 428 and motor drive waveform parameters 430. Each of these parameters may be set as static or variable. If the control loop determines that the real-time sensor data received is outside the bounds of the user parameters as determined in operation 420, then the software adjusts the input control parameters provided to the hardware control systems as indicated in operation 422. As one example, test system pressure may be set as the control parameter; therefore, the software will continually adjust the dynamics of the pressure regulator 424 to maintain the desired pressure. In another example, the displacement of the driver may be the control parameter; therefore, the software will continually adjust the system dynamics for the motor control 426 to maintain the desired displacement. Again, as one can appreciate, the closed-loop control of the test system can be applied to myriad parameters.

FIG. 9 illustrates an exemplary computer system 500 configured as part of the fatigue testing system as described herein. In one implementation, the computer system 500 typically includes at least one processing unit 502 and memory 504. Depending upon the exact configuration and type of the computer system 500, the memory 504 may be volatile (e.g., RAM), non-volatile (e.g., ROM and flash memory), or some combination of both. The most basic configuration of the computer system 500 need include only the processing unit 502 and the memory 504 as indicated by the dashed line 506.

The computer system 500 may further include additional devices for memory storage or retrieval. These devices may be removable storage devices 508 or non-removable storage devices 510, for example, memory cards, magnetic disk drives, magnetic tape drives, and optical drives for memory storage and retrieval on magnetic and optical media. Storage media may include volatile and nonvolatile media, both removable and non-removable, and may be provided in any of a number of configurations, for example, RAM, ROM, EEPROM, flash memory, CD-ROM, DVD, or other optical storage medium, magnetic cassettes, magnetic tape, magnetic disk, or other magnetic storage device, or any other memory

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technology or medium that can be used to store data and can be accessed by the processing unit 502. Alarm monitoring, data acquisition, and closed loop control software modules may be stored on the storage device for execution by the processing unit 502 using any method or technology for storage of data, for example, computer readable instructions, data structures, and program modules.

The computer system 500 may also have one or more communication interfaces 512 that allow the system 500 to communicate with other devices. The communication interface 512 may be connected with a network. The network may be a local area network (LAN), a wide area network (WAN), a telephony network, a cable network, an optical network, the Internet, a direct wired connection, a wireless network, e.g., radio frequency, infrared, microwave, or acoustic, or other networks enabling the transfer of data between devices. Data is generally transmitted to and from the communication interface 512 over the network via a modulated data signal, e.g., a carrier wave or other transport medium. A modulated data signal is an electromagnetic signal with characteristics that can be set or changed in such a manner as to encode data within the signal.

The computer system 500 may further have a variety of input devices 514 and output devices 516. Exemplary input devices 514 may include sensors, a keyboard, a mouse, a tablet, and/or a touch screen device. Exemplary output devices 516 may include a display and speakers. Such input devices 514 and output devices 516 may be integrated with the computer system 500 or they may be connected to the computer system 500 via wires or wirelessly, e.g., via IEEE 802.11 or Bluetooth protocol. These integrated or peripheral input and output devices are generally well known and are not further discussed herein. Other functions, for example, handling network communication transactions, may be performed by an operating system in the nonvolatile memory 504 of the computer system 500.

The technology described herein may be implemented as logical operations and/or modules in one or more systems. The logical operations may be implemented as a sequence of processor-implemented steps executing in one or more computer systems and as interconnected machine or circuit modules within one or more computer systems. Likewise, the descriptions of various component modules may be provided in terms of operations executed or effected by the modules. The resulting implementation is a matter of choice, dependent on the performance requirements of the underlying system implementing the described technology. Accordingly, the logical operations making up the embodiments of the technology described herein are referred to variously as operations, steps, objects, or modules. Furthermore, it should be understood that logical operations may be performed in any order, unless explicitly claimed otherwise or a specific order is inherently necessitated by the claim language.

In some implementations, articles of manufacture are provided as computer program products that cause the instantiation of operations on a computer system to implement the invention. One implementation of a computer program product provides a computer program storage medium readable by a computer system and encoding a computer program. It should further be understood that the described technology may be employed in special purpose devices independent of a personal computer.

All directional references (e.g., proximal, distal, upper, lower, upward, downward, left, right, lateral, longitudinal, front, back, top, bottom, above, below, vertical, horizontal, radial, axial, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding

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of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Connection references (e.g., attached, coupled, connected, and joined) are to be construed broadly and may include intermediate members between a collection of elements and relative movement between elements unless otherwise indicated. As such, connection references do not necessarily infer that two elements are directly connected and in fixed relation to each other. The exemplary drawings are for purposes of illustration only and the dimensions, positions, order and relative sizes reflected in the drawings attached hereto may vary.

The above specification, examples and data provide a complete description of the structure and use of exemplary embodiments of the invention. Although various embodiments of the invention have been described above with a certain degree of particularity, or with reference to one or more individual embodiments, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the spirit or scope of this invention. Other embodiments are therefore contemplated. It is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative only of particular embodiments and not limiting. Changes in detail or structure may be made without departing from the basic elements of the invention as defined in the following claims.

What is claimed is:

1. 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.

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2. The device in claim 1 further comprising
a drive motor; and
a fluid displacement member connected with and driven by the drive motor to provide the pressure source that increases and decreases a pressure on the test system fluid in the test chamber.
3. The device of claim 2, wherein the drive motor is configured to operate cyclically, acyclically, or a combination of both, to provide cyclic and acyclic fluid pressures within the test chamber.
4. The device of claim 2, wherein the drive motor comprises a linear motor.
5. The device of claim 2, wherein the fluid displacement member further comprises a flexible rolling bellows connected to a shaft of the drive motor.
6. The device of claim 1, wherein the excess volume area enlarges in response to compression of the test system fluid and decreases during depressurization of the test system fluid.
7. The device of claim 1 further comprising an elastomeric material that forms at least a portion of a boundary of the excess volume area and that expands and contracts in response to changes in pressure on the test system fluid within the test chamber.
8. The device of claim 1, wherein the excess volume area further contains a volume of a compressible gas that is compressed by the volume of the test system fluid to provide a spring force when the volume of the test system fluid is stored in the excess volume area.
9. The device of claim 1, wherein the excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber.
10. The device of claim 9 further comprising an elastomeric membrane separating at least a portion of the compliance chamber from fluid in the fluid return chamber.
11. The device of claim 9 further comprising a porous material at least partially filling the compliance chamber.
12. The device of claim 9, wherein the compliance chamber provides a volume for holding a gas or elastomeric material that compresses under a pressure placed upon the test system fluid in the test chamber and allows the test system fluid in the test chamber to occupy a portion of the volume in the compliance chamber.
13. The device of claim 1, wherein the test chamber defines a first port on a first side of the valved prosthetic device and a second port on a second side of the valved prosthetic device; and
the first port and the second port are configured to receive one or more sensor devices.

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CERTIFICATE OF SERVICE

The undersigned counsel of record for Plaintiff/Counterclaim Defendant/Appellant Biomedical Device Consultants & Laboratories of Colorado, LLC, certifies that the foregoing document was filed with this Court via CM/ECF and thereby served on all parties on October 24, 2023.

/s/ Gregory S. Tamkin
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