

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Waters Technologies Corporation
Petitioner

v.

Biomedical Device Consultants & Laboratories
Patent Owner

Case IPR2018-00498
Patent 9,186,224

PATENT OWNERS' PRELIMINARY RESPONSE

Petitioner's Exhibit 1014
VIVITRO v. BDC
IPR2024-00320

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EXHIBITS

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Ex. 2002	Declaration of Craig Weinberg in Support of Motion for Preliminary Injunction
Ex. 2003	ISO 5840-3 2013
Ex. 2004	'210 Patent
Ex. 2005	Gabbay Ed
Ex. 2006	'708 Patent
Ex. 2007	Response to Office Action 5.10-13
Ex. 2008	Notice of Allowance

I. Introduction

Pursuant to 37 C.F.R. §42.107(a), Biomedical Device Consultants & Laboratories of Colorado, LLC (“Patent Owner”) submit this Preliminary Response to the Petition for *Inter Partes* Review (“IPR”) of U.S. Patent No. 9,186,224 (“the ’224 patent”) filed by Waters Technologies Corporation (“Petitioner”).

Institution must be denied because Petitioner fails to meet its burden of showing a reasonable likelihood that it would prevail with respect to claims challenged in the Petition. Petitioner’s arguments largely mimic those of the Examiner during prosecution. Indeed, Petitioner’s primary reference, Pickard, was considered at length during prosecution. The Examiner’s rejections were overcome by amending the claims to make clear that the claimed invention is to an accelerated testing system. The Examiner was convinced that it is not obvious to combine pieces and parts from an accelerated durability testing system with those of a physiological ‘real-time’ hydrodynamic testing system. The two systems are fundamentally different and serve fundamentally different purposes. Driving a hydrodynamic testing system at accelerated rates would frustrate its purpose of

mimicking the human circulatory system. Yet, Petitioner argues for just that combination.

Specifically, the Petition is deficient in the following ways:

Pickard in combination with Woodward does not disclose an “accelerated cyclic test system,” “driving a test system fluid cyclically above the normal physiological rate,” nor “driving a test system fluid . . . at an accelerated pulsed rate of greater than 200 beats per minute.” While Woodward does disclose that hearts rates in young adults may reach 270 bpm, it does not disclose driving its or any hydrodynamic system at such rates. It specifically limits its system to rates below 200 bpm. Likewise, the ISO 5840 also limits its test rates to below 200 bpm.

In addition, Petitioner admits that 270 bpm is a “normal physiological rate.” So, even if one were motivated to drive Pickard’s system at 270 bpm, such a combination would still not satisfy the limitation of “driving a test system fluid cyclically above the normal physiological rate,” and consequently not satisfy the limitation of “accelerated cyclic test system.”

With respect to Elizondo, that reference does not disclose an “excess volume area” for storing fluid added during the compression stroke which alleviates some

of the pressure in the channel. Petitioner contends that Elizondo discloses the use of compliance in an accelerated durability system (which is unusual).¹ Even assuming that to be true, Elizondo does not disclose using the type of compliance provided in claim 1—an “excess volume area.” Any compliance in Elizondo mitigates pressure through material deformation (i.e., expanding a graft or bag). It does not store excess fluid being introduced into the channel as required by claim 1.

Petitioner fails to provide any reasonable rationale for combining Pickard and Elizondo, or Elizondo with Iwasaki. Instead, Petitioner makes generalized statements that the systems are similar and the substitution would be simple. Such conclusory statements are insufficient to prove motivation for combining references.

Accordingly, the Board should conclude that the information presented in the Petition and accompanying evidence do not establish a reasonable likelihood that Petitioner will prevail. Thus, the Board should deny institution of all grounds asserted in the Petition.

¹ The disclosure of how vascular grafts of bags provide compliance is not entirely clear in Elizondo. So, for the purposes of this Preliminary Response, Patent Owner will largely adopt Petitioner’s expert’s explanation of Elizondo.

II. Background

Heart disease remains the leading cause of death in the U.S., killing more than 600,000 Americans each year. More than five million Americans are diagnosed with heart valve disease each year. While heart valve disease can occur in any of the four heart valves, most commonly the aortic and mitral valves are diseased. Without a valve replacement, as many as 50 percent of patients with severe aortic stenosis will not survive more than an average of two years. An estimated 80,000-85,000 aortic valves are replaced each year in the U.S.²

To obtain regulatory approval for a prosthetic heart valve, a variety of tests need to be carried out and satisfactory results shown. In this regard, the International Organization for Standardization establishes verification testing and reporting guidelines for prosthetic heart valves in ISO 5840³. Ex. 1015. ISO 5840

² <https://www.johnmuirhealth.com/services/cardiovascular-services/intervention/transcatheter-aortic-valve-replacement/facts-and-figures.html>.

³ The Fourth edition of ISO 5840 was released in 2005 and was in effect in 2009 (the priority date of the '224 Patent). ISO 5840 was updated in 2013, the significance of which will be later addressed. References to ISO 5840 throughout this brief are to the 2005, Fourth edition. Ex. 1015. References to ISO 5840: 2013 are to the Fifth edition released in 2013. Ex. 2003.

sets forth two types of *in vitro* verification tests for prosthetic heart valves.

Ex. 2003 at 21 (Section 7.2 *In vitro assessment*).

One type is hydrodynamic performance assessment. *Id.* at 22 (Section 7.2.3). Hydrodynamic testing is performed to provide information on the fluid mechanical performance of the heart valve and indicators of its performance in terms of load to the heart and potential for damage to blood cells. *Id.* It is akin to a wind tunnel but with water or similar fluid. In other words, hydrodynamic testing is concerned with how the prosthetic valve will operate *in vivo* from a fluid dynamics perspective. The valve must satisfy certain minimum performance requirements—delivering a minimum output of fluid while operating at 70 bpm and a mean pressure of 100 mm Hg (i.e., a normal aortic blood pressure). *Id.* at 22. Guidelines for hydrodynamic testing are provided in Annex L. *Id.* at 68-73. The guidelines include running tests at pressures of 80-160 mm Hg and cycle rates of 45-120 bpm. *Id.* at 66-67 (Section L.4.3). Because the goal of hydrodynamic testing is to gauge the performance of the prosthetic valve *in vivo*, the tester would like to mimic the heart and circulatory system to the extent possible within confines of the testing apparatus. *Id.* at 66 (Section L.4.2) Also, hydrodynamic testing is carried out at normal heart rates (referred to as “real-time testing”),

usually around 70 bpm, even though as reflected in Table 1 it is known that normal heart rates in adults may reach 200 bpm for short periods of time. *Id.*

The second type of testing set forth in ISO 5840 is structural performance assessment (also referred to as durability testing). *Id.* at 23 (Section 7.2.4).

Durability testing is performed to assess continued function over a reasonable lifetime, that is, to ensure the prosthetic valve will last for a reasonable period of time (defined as 200 million cycles for a flexible heart valve and 400 million cycles for a rigid one). *Id.* Durability testing is performed at fluid pressures “consistent with normotensive conditions [i.e., normal blood pressure] specified in Table 1.” *Id.* While ISO 5840 allows for durability testing in real-time (i.e., at normal heart rates), doing so would take years. (At 70 bpm, it would take about five years to achieve 200 million cycles). Thus, the standard allows for “accelerated and quasi-real time durability testing,” although justification should be demonstrated and consideration should be given to the behavior of the tested materials. *Id.* Durability testing guidelines are set forth in Annex M. *Id.* at 74-75.

Quasi-real time testing may be performed “under conditions that fall within the range of those specified in Table 1.” *Id.* at 74 (Section M.3). Thus, the test cycle rate would need to be in the normal physiological rates of Table 1 (30-200

bpm). *Id.* at 17 (Table 1). Testing at 200 bpm instead of 70 bpm would still require almost two years to achieve 200 million cycles. However, the ISO standard only requires 80 million cycles of quasi-real time testing be carried out (*id.* at 74), thus, the testing could be completed in about nine months using the highest heart rate shown in Table 1 (i.e., 200 bpm).

Accelerated durability testing is also allowed (*id.* at 23) and quasi-real time testing “may be used to evaluate the validity of any accelerated durability test results” (*id.* at 74). While little specific guidance is provided, justification for the testing conditions is required. *Id.* at 23, 74. Using accelerated rates, above normal physiological rates, could shorten testing time considerably. Although, ISO 5840 admonishes the tester to consider the behavior of the materials at higher cycle rates. *Id.* at 23.

One known problem with using accelerated testing is that it introduces pressures and resultant forces that are beyond those found *in vitro* (sometimes referred to as a water hammer effect). *See e.g.*, Exs. 1013, 1014. In the Reul reference, the author compared forces under physiologic, real-time conditions (i.e., hydrodynamic testing) with those found above physiological or accelerated rates, concluding the back-pressures generated “during accelerated testing exceed the

real-time loading forces by far.” Ex. 1014 at 1. As noted in the Iwasaki article, “[a]ccurate estimation of durability in a timely manner [i.e., accelerated] is one of the most important unresolved issues.” Ex. 1013 at 1. Iwasaki reports that using accelerated rates notably shortened valve life. *Id.*

III. The '224 Patent

Around February 2008, BDC began researching and designing a new accelerated heart valve durability testing system. Ex. 2002 ¶ 3. One of the primary problems to be solved was mitigating the excessive forces created by accelerated cycling (i.e., the water hammer effect). This research resulted in the issuance of four, directly-related patents (including the '224 Patent), as well as, the launch of a commercial product—the VDT-3600i, an accelerated testing system for prosthetic heart valves. *Id.* ¶ 5.

Before BDC’s patents and product, commercial products which tested heart valves at an accelerate rate were unable to adequately control pressure rates. *Id.* ¶ 6. Consequently, these systems were susceptible to pressure spiking which prematurely deteriorated the materials used for the prosthetic heart valves being tested. *Id.* The VDT-3600i included a compliance chamber, as described in the '224 Patent, to better manage pressure spikes which provided more accurate testing

results. *Id.* ¶¶ 6-7. Essentially, the compliance chamber was a gas-filled space that excess fluid could be stored through compression of the gas and later released, akin to a water hammer arrestor. BDC revolutionized the market and within five years became the industry standard. *Id.* ¶¶ 8-10. The VDT-3600i currently accounts for about 80-90% of the worldwide market for heart valve durability testing systems. *Id.* at ¶ 11.

Waters launched a competing product, the DuraPulse, which is the subject of an on-going lawsuit. *Id.* at ¶ 15. Waters then filed the present IPR challenging the validity of the '224 Patent.

A. Overview

The '224 Patent relates to a method for fatigue or durability testing of prosthetic devices (such as heart valves). Ex. 1001, 1:21-25. Like most durability testing systems, it operates at accelerated cycle rates. *See e.g., id.* at 2:1-3.

As can be appreciated from Figure 3 (reproduced below), the apparatus disclosed comprises a drive mechanism (in pink) for pumping fluid into the system during the compression stroke. *See e.g., id.* at 11:49-65. (For convenience and clarity, the reference numerals have been removed from Figure 3 and the figure has been colorized and labelled.)

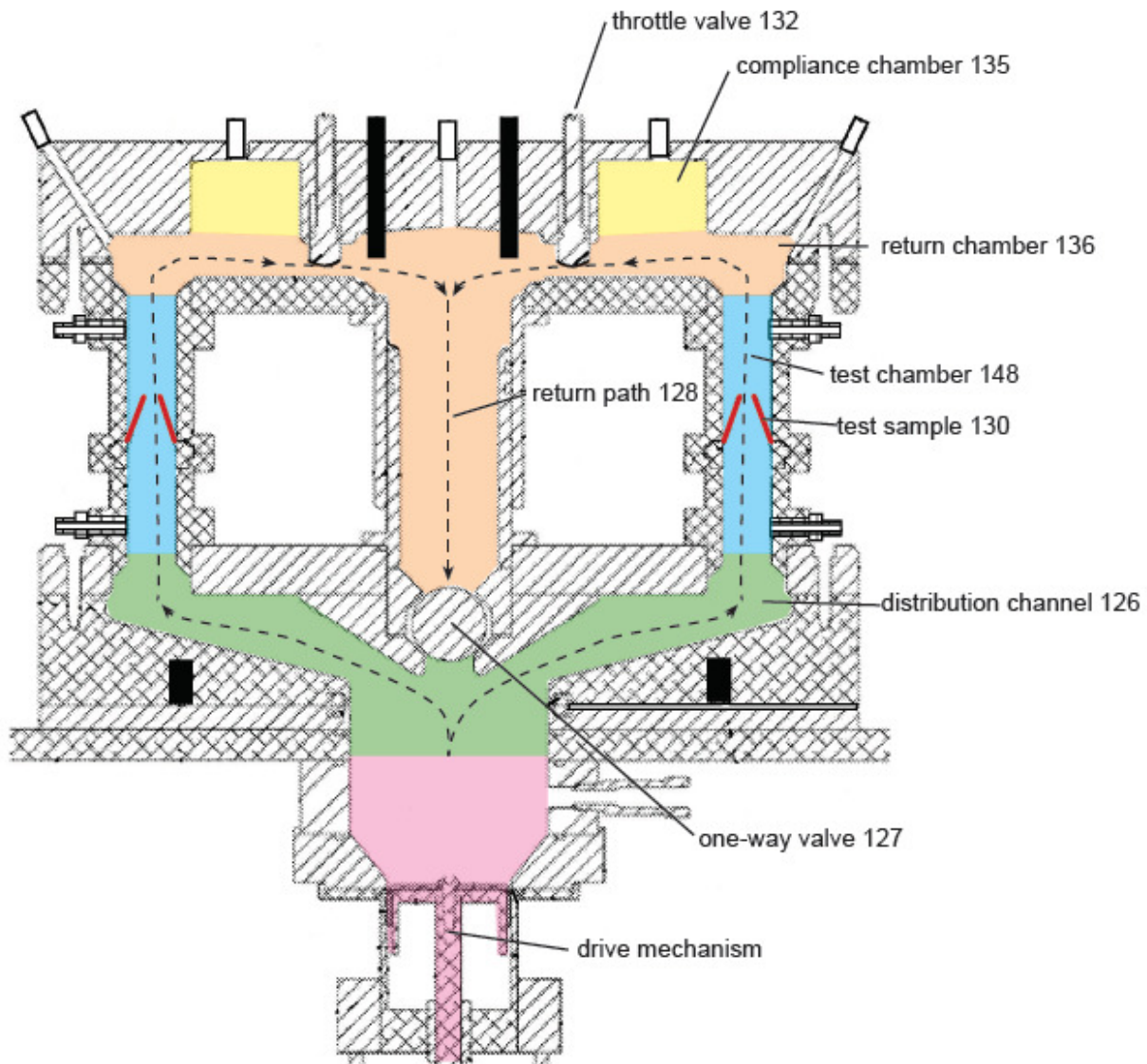


**Figure 3 of the '224 Patent
(colorized and labeled with reference numerals removed)**

As fluid is pumped into an already full channel, it enters distribution channel 126 (in green) and moves up to the left and right of one-way valve 127 in the center.

Id. at 11:66-9. The fluid continues moving up through the two test samples (e.g.,

heart valves) 130 (red) mounted in test chambers 148 (blue section) and then enters return chamber 136 (in orange). *Id.* Since the channel (green, blue, and orange sections combined) is full of fluid at the start, when the drive mechanism (in pink) pumps more fluid into the system, it increases the pressure in the channel. *Id.* at 11:49-65. The volume of the excess fluid (i.e., in addition to that already in the channel) is displaced into compliance chambers 135 (in yellow). *Id.* at 12:10-15. Throttle valves 132 are partially closed to restrict the rate of the return flow. *Id.* at 12:15-17.

On the decompression stroke of the driving mechanism, heart valve 130 closes (heart valves are one-way valves). *Id.* at 12:31-39. The volume of excess fluid leaves compliance chambers 135 and flows down return path 128 and through valve 164. *Id.* The cycle is then repeated. *See also* Ex. 2001 ¶¶ 13-16.

Compliance chambers 135 may be filled with a gas the pressure of which can be adjusted. Ex. 1001 at 12:37-49. Thus, by controlling the pressure in the compliance chambers and the position of the throttle valves, pressure spikes can be mitigated. *Id.* at 12:18-22; 12:58-64. As such the system may be operate at an accelerated rate while reducing the damage to the heart valve being tested, thus, mitigating against a premature failure in the same.

An alternative embodiment is depicted in Figure 6 (reproduced below without reference numerals, colorized, and labeled).

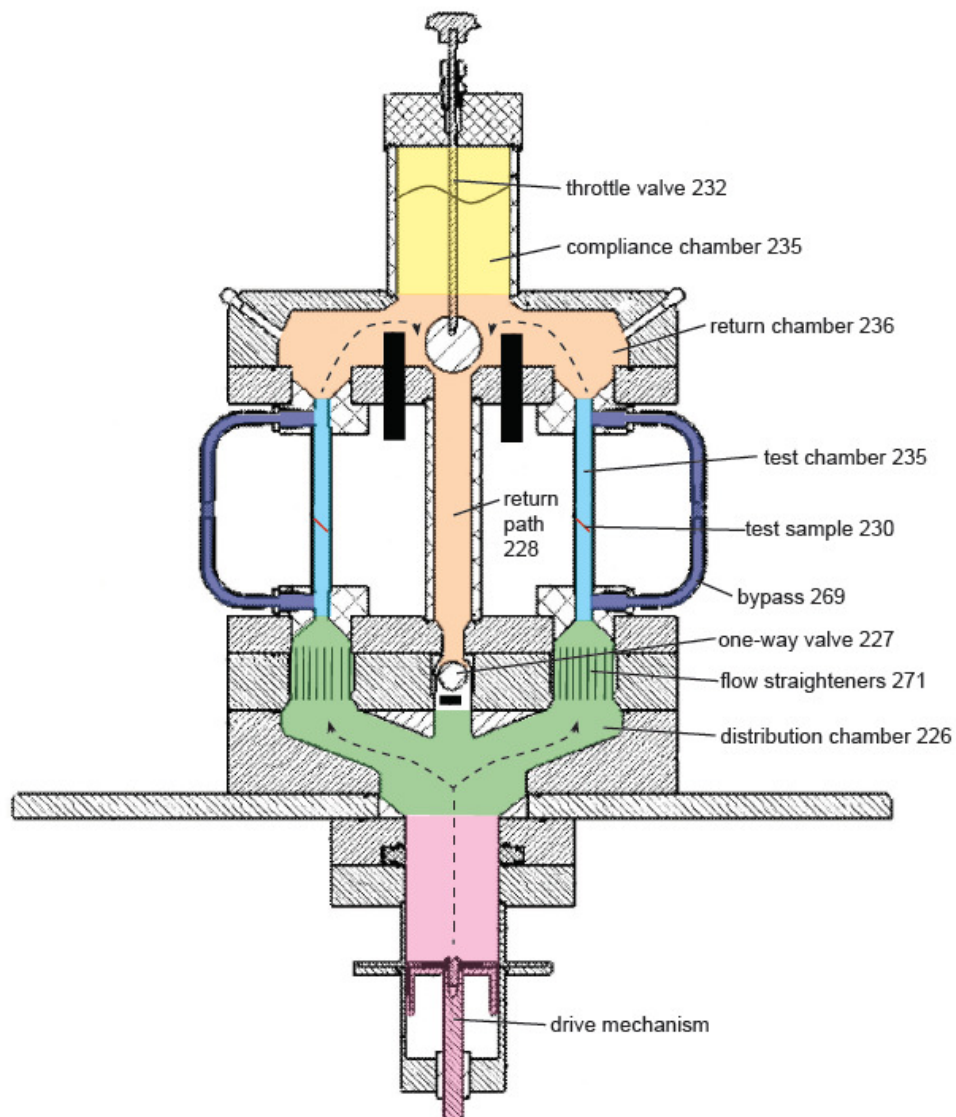


Figure 6 of the '224 Patent
(colorized and labeled with reference numerals removed)

Similar to Figure 3, Figure 6 depicts a drive mechanism (pink), distribution chamber 226 (green), return chamber 236 (orange), compliance chamber 235 (yellow), and test chamber 236 (blue) which holds test samples 230 (e.g., heart valves) (red). *Id.* at 12:65–13:15. On the compression stroke, additional fluid is introduced into the channel and the fluid flow moves to the left and right of one-way valve 227 through flow straighteners 271 and into test chamber 248 (blue). *Id.* at 13:34-49. Fluid passes through test samples 230. *Id.* The excess volume introduced into the channel displaces fluid into compliance chamber 235 (yellow). *Id.* at 13:63–14:20. During the decompression stroke, heart valves 230 close and the excess fluid volume re-enters the channel and flows around throttle valve 232 and returns to distribution chamber 226 (orange). *Id.* at 13:63–14:2. Thus, completing one cycle. *Id.* As with Figure 3, throttle valve 232 may be adjusted to change the resistance on the fluid returning to the lower chamber (orange) via the central return conduit, thus, aiding in controlling the differential pressure across the heart valves. *Id.* at 14:6-10. As before, the amount of gas inside compliance chamber 232 may be adjusted to damp the system. *Id.* at 14:10-14. The embodiment of Figure 6 additionally includes bypass pathways 269 (purple) which measure the pressure differential across heart valves 230. *Id.* at 12:50-62.

B. Prosecution History

1. '708 Patent

During the prosecution of the parent patent, U.S. Pat. No. 8,627,708 ('708 Patent), claims to the testing apparatus were rejected over Pickard. Ex. 2006 at 4. The preambles of all independent claims were amended to indicate that the system was an “accelerated” cyclical testing system for “valved” prosthetic devices. Ex. 2007 at 2, 5, 6. Applicant explained that:

Pickard discloses a real time system (e.g., 1 Hz) for testing heart valves immediately before implantation. Pickard is thus not an accelerated testing system (e.g., ≥ 5 Hz) like the presently claimed invention and trying to cycle the Pickard system faster would frustrate the purpose of the test it is trying to perform (i.e., characterize valve performance in a simulated circulatory system under which the valve is to be used) while not being able to perform the accelerated wear testing of the claimed invention.

Id. at 7. In other words, Pickard discloses a hydrodynamic testing system designed to mimic the human circulatory system and to operate at normal heart rates. It is not an “accelerated” testing system designed to measure durability. In view of the amendment and argument, the Examiner allowed the claims. Ex. 2008.

2. '224 Patent

During the prosecution the '224 Patent, the subject of this IPR, the Examiner rejected the claims over Pickard. Ex. 1005 at 4-6. During an Examiner interview, the term “accelerated” in the preamble of claim 1 was discussed. Ex. 1006 at 2. Applicant amended claim 1 adding in the limitation “driving a test system fluid cyclically above the normal physiological rate, at an accelerated pulsed rate of greater than 200 beats per minute within the test system.” Ex. 1007 at 2. The Applicant again explained that Pickard disclosed a real time hydrodynamic testing system rather than an accelerated durability testing system.

Pickard disclosed a “real-time” test system (e.g., operating at physiologic rates on the order of 72 beats per minute, or 1.2 Hz) for hydrodynamic performance testing of heart valves to characterize and define their anticipated fluid mechanical performance . . . Pickard’s disclosure is thus not an accelerated durability testing system (e.g., operating at rates ≥ 3.5 Hz or 200 beats/cycles per minute) like the presently claimed invention and trying to cycle the Pickard system faster would frustrate the purpose of the test it is trying to perform (i.e., characterizing valve performance in a simulated circulatory system under which the valve is to be used while not being able to perform the accelerated durability wear testing of the claimed invention.

Id. at 5. Applicant noted Examiner’s concern “that the term ‘accelerated’ in the preamble of claim 1 was insufficient to differentiate Pickard.” *Id.* “While the Applicant disagreed,” it nevertheless amended claim 1. *Id.*

Applicant noted that the ISO 5840 Standard provides guidelines for the accelerated durability testing of heart valves and that the industry (i.e., a person of ordinary skill in the art) recognizes an **“accelerated” valve test system to mean a system that cycles faster than a normal physiological rate**. It was discussed that the *typical* upper end of a normal physiological rate is above 200 beats per minute.

Id. at 6. (emphasis added). The Examiner apparently did not feel the preamble was necessarily limiting, even though it had been successfully used to distinguish the same reference during the examination of the ’708 Patent. To placate the Examiner, the phrase “driving a test system fluid cyclically above a normal physiological rate” was added to claim 1, thus, effectively adding “accelerated cyclic test system” into the body of the claim. The Applicant further added the limitation “an accelerated pulsed rate of greater than 200 beats per minute” which is the *typical* upper end of a normal heart rate. As will be discussed below, Waters attempts to read “accelerated cyclic test system” in the preamble and “driving a test system fluid cyclically above a normal physiological rate” both to mean “an accelerated pulsed rate of greater than 200 beats per minute,” thus, collapsing three

claim limitations into one. BDC will show that while “accelerated cyclic test system” in the preamble means “driving a test system fluid cyclically above a normal physiological rate,” it is not redundant in the sense that the Examiner demanded the limitation be placed in the body of the claim. However, “an accelerated pulsed rate of greater than 200 beats per minute,” is a limitation *in addition to* the “driving a test system fluid cyclically above a normal physiological rate” limitation.

IV. Person of Ordinary Skill in the Art

For the purposes of this IPR, Patent Owner agrees to Petitioner’s definition of a person of ordinary skill in the art (Pet. at 26).

V. Claim Construction

The claims at issue here must be given their broadest reasonable interpretation consistent with the specification as it would be interpreted by one of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316, (Fed. Cir. 2005) (en banc). Thus the focus of the inquiry regarding the meaning of a claim should be what would be reasonable from the perspective of one of ordinary skill in the art. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010).

There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1580 (Fed. Cir. 1996); MPEP § 2111.01. To act as his own lexicographer, a patentee must “clearly set forth a definition of the disputed claim term” other than its plain and ordinary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002); *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008) (the patentee must “clearly express an intent” to redefine the term).

As will be discussed below, Petitioner argues that Patent Owner defined the term “accelerated” during prosecution. As will be evident, however, Petitioner fails to show the alleged definition was “clearly set forth,” as required by law.

A. “accelerated cyclic test system” (claim 1)

The phrase “[a method for operating an] accelerated cyclic test system” means “driving a test system fluid cyclically above the normal physiological.” In the context of the patent and prosecution history, it is clear that the claimed method determines the durability of a prosthetic valve and does so using accelerated cycle rates in excess of normal physiological rates. This system is in contrast to

hydrodynamic test systems which are used to measure flow characteristics of a prosthetic valve in real-time (i.e., normal physiological rates).

1. Preamble is limiting

Petitioner argues that the preamble is not limiting. Pet. 12. However, where the preamble was relied upon, as it was here, to distinguish over the prior art, it is limiting. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808-809 (Fed. Cir. 2002) (“[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation.”); *Metabolite Labs., Inc. v. Corp. of Am. Holdings*, 370 F.3d 1354, 1358-62 (Fed. Cir. 2004). As discussed above, “accelerated” was added during the prosecution of the ’708 Patent to distinguish over Pickard. It was again argued as distinguishing Pickard during the prosecution of the ’224 Patent. Therefore, “accelerated” is a limiting term.

2. Specification

Petitioner argues that “driving a test system fluid cyclically above the normal physiological rate” means “an accelerated pulsed rate of greater than 200 beats per minute within the test system.” Pet. 11. Petitioner ignores the specification (stating only that the “term ‘accelerated’ is not defined in the

specification”) which is a legally insufficient reason to simply ignore what can be gleaned from the specification. *Id.* While the specification does not provide an explicit definition of “accelerated,” it certainly provides context.

As stated in the patent title, Abstract, and throughout the specification the invention described is a “fatigue testing system.” The specification refers to the fact that fatigue testing requires a high number of testing cycles which is carried out at accelerated testing speeds. *See e.g.*, Ex. 1001 at 1:21-25 (“technology described herein relates to systems and methods for fatigue testing . . . under . . . high-cycle applications”); 1:32-35 (to “produce a more desirable test condition, especially at accelerated testing speeds” a non-mechanistic approach is needed “current systems employ flexible metallic bellows”); 1:43-46 (“[p]iston and cylinder arrangements are not ideal . . . [as they] have severely limited life in high cycle applications”); 1:55-56 (“a fatigue testing system for cyclic, long-term testing”); 2:1-3 (“at accelerated frequency over time to determine the efficacy, resiliency, and wear of the devices”); 2:33-34 (“[t]he fatigue tester is capable of simulating physiologic conditions on prosthetic devices at an accelerated rate”). Thus, the specification makes clear that the invention is a fatigue testing system which requires a large number of cycles to be performed at an accelerated rate; this

is in direct contrast to a hydrodynamic testing system, like Pickard, which operates at a normal physiological rate.

This distinction between the claimed invention being a system which operates above physiological rates (i.e., is accelerated) for the purpose of durability/fatigue testing and hydrodynamic systems which operate at physiological rates for the purpose of flow testing was also made repeatedly during prosecution.

3. Prosecution History

During prosecution the Patent Owner consistently distinguished over Pickard on the basis that Pickard was a real-time (i.e., one operating at physiological rates) hydrodynamic testing system—not an accelerated durability testing system operating above physiological rates. To placate the Examiner’s concern that “accelerated” was only in the preamble, claim 1 was amended to add “driving a test system fluid cyclically above a normal physiological rate, at an accelerated pulsed rate of greater than 200 beats per minute within the test system.”

Petitioner, without explanation ignores the “driving a test system fluid cyclically above a normal physiological rate” limitation and claims that Patent

Owner defined “accelerated” to means cycling above 200 bpm. Pet. 13. In fact, the Patent Owner made clear that “accelerated” test system means a system that cycles faster than a normal physiological rate.

Applicant noted that the ISO 5840 Standard provides guidelines for the accelerated durability testing of heart valves and that the industry (i.e., a person of ordinary skill in the art) recognizes an *“accelerated” valve test system to mean a system that cycles faster than a normal physiological rate*. It was discussed that the *typical* upper end of a normal physiological rate is above 200 beats per minute.

Ex. 1007 at 6. (emphasis added). Therefore, the prosecution history makes clear that a person of ordinary skill in the art would have understood that an “accelerated cyclic test system” means a test system that cycles faster than a normal physiological rate.

Patent Owner also made clear that the claimed system was for accelerated durability testing rather than real-time hydrodynamic testing as in Pickard.

Dr. Weinberg discussed the differences between the invention claimed in claims 1-77 [sic-7] and the prior art references of record, namely Pickard and Lundell et al. Dr. Weinberg notes that Pickard discloses a “real-time” test system (e.g., operating at physiologic rates on the order of 72 beats per minute, or 1.2 Hz) for hydrodynamic performance post

implantation. Dr. Weinberg noted that Pickard's disclosure is thus not an accelerated durability testing system . . . and trying to cycle Pickard's system faster would frustrate the purpose of the test it is trying to perform (i.e., characterizing valve performance in a simulated circulatory system under which the valve is used) while not being able to perform the accelerated durability wear testing of the claimed invention.

Id. at 5. This distinction was emphasized again by the Patent Owner.

Further, with respect to Pickard, a piston pump is disclosed to drive the disclosed system. A piston pump may be adequate for a real-time (i.e., ~1.2 Hz) valve performance test system. However, it has significant drawbacks in the context of an accelerated test system such as claimed in claim 1. For example, recall the ISO 5840 standard requirement that the valved prostheses be loaded through 200,000,000 test cycles . . . This extremely high cycle requirement prohibits the use of a standard piston . . .

Id. at 9.

The prosecution history supports Patent Owner's construction of "accelerated cyclic test system" means "driving a test system fluid cyclically above the normal physiological rate." During prosecution, Patent Owner repeatedly distinguished Pickard on the basis that it is a real-time system (i.e., operating at

normal physiological conditions) as opposed to an accelerated system (i.e., operating above normal physiological conditions).

It is telling that *Waters’ own expert, Dr. Billiar, never claims that a person of ordinary skill in the art would construe “accelerated” as Waters proposes.*

Ex. 1002 ¶¶ 34-36. Her *sole* basis for the proposed construction is that the Patent Owner explicitly defined the term during prosecution. *Id.* And she relies upon the same prosecution history documents described above in the Prosecution History, ’224 Patent section. She does this by conflating the two limitations that were added into one. Dr. Billiar first admits, “‘Applicant noted that . . . the industry (i.e., a person of ordinary skill in the art) recognized an ‘accelerated’ valve test system to mean a system that cycles faster than a normal physiological rate.’ (Ex. 1007 at 6.)” Ex. 1002 ¶ 35. She then conflates this definition of “accelerated” which was explicitly defined in the sentence she quoted with the second added limitation. “Then, the ‘Examiner agreed that a limitation describing the system environment as being greater than 200 beats per minute would be sufficient to address this concern with the claim.’ (*Id.*)” *Id.* She then concludes, “[a]s such, it is my opinion that the term ‘accelerated’ was defined by Patent owner to refer to ‘cycling above 200 beats per minute.’” *Id.* ¶ 36.

Dr. Billiar's position seem to be that because the Examiner relied upon the "above 200 beats per minute" limitation in his notice of allowance, that amounts to the Patent Owner defining the term "accelerated." Patent Owner's statement that a person of ordinary skill in the art would understand that an "accelerated" valve test system means a system that cycles faster than a normal physiological rate, explicitly defines the term. Dr. Billiar never denies that Patent Owner's statement is true. Instead, she makes an illogical inference that because the Examiner mentioned the second limitation "above 200 beats per minute" that redefined "accelerated." Note that while the Examiner relied upon the limitation to distinguish over Pickard, he never suggested that he understood this limitation to be the definition of "accelerated."

Neither Waters nor Dr. Billiar explain how Patent Owner "clearly set forth a definition of ['accelerated']" to mean above 200 bpm as required by *CCS Fitness*, 288 F.3d at 1366. *See also, Thorner v. Sony Comp. Entmt. Amer. LLC*, 669 F.3d 1362, (Fed. Cir. 2012). They solely rely upon the statement: "[A] person of ordinary skill in the art) recognizes an "accelerated" valve test system to mean a system that cycles faster than a normal physiological rate. It was discussed that the *typical* upper end of a normal physiological rate is above 200 beats per minute." If

anything, the statement clearly defines “accelerated” as “faster than a normal physiological rate.”

4. Extrinsic evidence

The extrinsic evidence also supports Patent Owner’s construction of “accelerated.” ISO 5840, specifically relied upon during prosecution, is the standard for heart valve testing. The standard differentiates between hydrodynamic testing and structural performance assessment (also referred to as durability testing). Ex. 1015 at 21-23. Hydrodynamic testing is generally carried out at 70 bpm with some testing at 120 bpm. *Id.* Durability testing requires millions of cycles be performed and while it could be done in real-time (i.e., at normal heart rates), doing so would take years. Thus, the standard allows for “accelerated and quasi-real time durability testing.” *Id.* at 23. Quasi-real time testing may be performed at normal physiological cycle rates set out in Table 1 ($\leq$ 200 bpm). *Id.* at 74. Accelerated testing may be carried out at rates above normal physiological cycle rates. *Id.* at 23. Thus, ISO 5840 teaches three cycle rates, real-time (around 70 bpm), quasi-real time (at or below normal physiological rates), and accelerated (above normal physiological rates). It should be noted that ISO 5840, Table 1 (*id.* at 17) also supports Patent Owner’s representation to the

Examiner that “the *typical* upper end of a normal physiological rate is above 200 beats per minute.” Ex. 1007 at 6 (emphasis added).

Dr. Billiar and Waters avoid ever addressing the question of whether “accelerated” is a term of art which would be understood by a person of ordinary skill in the art. Ex. 1013 ¶¶ 34-36; Pet. 11-13. Undoubtedly, this is because they understand that it is and, in fact, both use the term in a manner consistent with Patent Owner’s construction.

For example, Waters’ product DuraPulse product operates at 900-1800 bpm and is touted as an “accelerated heart valve durability testing” system. Ex. 2001 at 10. Waters’ obtained a patent covering a narrow aspect of its commercial product, U.S. Pat. No. 9,66,210 (the ’210 Patent). *Id.* at 26-48. The ’210 Patent is directed to “systems and methods for accelerated life testing of prosthetic heart valves.” Ex. 2004 at 1:5-9. The ’210 Patent is replete with references to its “accelerated” system for evaluating the durability of prosthetic heart valves. Most importantly, the ’210 Patent defines “accelerated life testing (also known as accelerated wear testing or durability testing) is ***the process of testing an item by subjecting it to conditions (e.g., cycle time, stress, strain, temperatures, voltage, vibration, pressure, etc.) in excess of its normal service parameters*** in an effort to uncover

faults . . . in a reduced amount of time.” *Id.* at 1:11-16 (emphasis added). Note that the only condition listed which would reduce test time is increased cycle time (i.e., above normal heart rate). The only cycle time disclosed is 30 Hz (1800 bpm). Nowhere in the ’210 Patent is there any suggestion that “accelerated systems” are defined as being less than 200 bpm. To eliminate any argument to the contrary, it is noted that the ’210 Patent states that “all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art.” *Id.* at 5:25-27. Thus, Waters’ ’210 Patent discloses that a person of ordinary skill in the art would understand “accelerated” to mean in excess of normal parameters (i.e., above normal physiological conditions).

Dr. Billiar also uses the term “accelerated” repeatedly in a 1997 paper describing durability testing of heart valves. Ex. 2005. For example, she states that adequate fatigue life of a heart “is validated by accelerated testing . . . cycle at 15 to 20 times the normal heart rate.” *Id.* at 2. She carried out her durability testing using “standard accelerated testing used for Food and Drug Administration approval . . . at a rate of approximately 1000 cycles/min.” *Id.* at 3. The fact that she never explicitly defines “accelerated,” strongly suggests that the term was known by people of ordinary skill in the art.

The use of “accelerated” by Waters and Dr. Billiar further supports Patent Owner’s contention that a person of ordinary skill in the art understood that “[a method for operating an] accelerated cyclic test system” means “driving a test system fluid cyclically above the normal physiological.”

In addition, prior art cited and relied upon by Petitioner supports Patent Owner’s construction. For Example, Elizondo notes depending upon the purpose of the system, one may wish to use different cyclic rates—“below physiological conditions (e.g., 0-50 bpm, beats per minute), test the biological material at physiological conditions (about 70 bpm), and evaluate the durability of the biological material above physiological conditions (about 1000 bpm) . . .” Ex. 1011 at 11:1-10; 1:32-35 (“There is a need for a system and apparatus for evaluating biological material under normal and supra-physiological conditions. Some of this need is represented by a need to modify the current pulse duplicator and accelerated life testers.”). Thus, Elizondo differentiates between hydrodynamic testing at physiological conditions and accelerated durability testing above physiological conditions.

B. “driving a test system fluid cyclically above the normal physiological rate” (claim 1)

Patent Owner does not believe this limitation needs construction and notes that Petitioner did not construe it, and indeed, ignored it. There is no dispute that neither Pickard nor Woodward disclose “driving the system fluid above normal physiological rates.” Petitioner claims that Woodward “discloses that a normal physiological range can go up to 270 bpm.” Pet. 29. Therefore, even assuming Woodward teaches *driving a system at 270 bpm* (it does not), by Petitioner’s own admission, 270 bpm is not “above a normal physiological rate,” it is a normal physiological rate. Note the additional limitation “at an accelerated pulsed rate of greater than 200 beats per minute’ is just that—an additional limitation. And as Patent Owner explained to the Examiner 200 bpm is “the *typical* upper end of a normal physiological rate.” Ex. 1007 at 6. However, this limitation is “above the normal physiological rate,” *not* the *typical* normal physiological rate.

C. “excess volume area” (claims 1-4)

An “excess volume area” is a space for storing fluid in excess to the fluid contained in the channel. This excess fluid is forced into the system during the compression stroke.

The specification states that when the channel is filled with fluid, compliance chambers 135 are partially filled with fluid. Ex. 1001 at 11:24-36. The remainder of the compliance chamber is filled with air or gas and may be pressurized. *Id.* The gas in compliance chambers 135 may be in direct contact with the fluid or may be separated via a membrane. *Id.* at 12:39-45. Alternatively still, compliance chambers 135 could be filled with a porous foam or other elastomeric material instead of gas. *Id.* During the compression stroke, “the compliance chambers 135 provide excess volume area for fluid to move into.” *Id.* at 12:10-12. As the gas in the compliance chambers is compressed, it provides “additional volume for displacement of the liquid working fluid within the test chamber 106.” *Id.* at 12:12-15. In other words, as more fluid is introduced (during the compression stroke) into an already full channel, the fluid pressure increases, thus, compressing the gas or material in the compliance chambers which then allows for some of the excess volume that was introduced to be stored.

During decompression stroke, the pressure on the channel fluid returns to its initial state allowing the air or material in the compliance chambers to expand, thus, forcing excess fluid volume back into the channel. *Id.* at 12:31-37.

Petitioner's proposed construction, "a location or a space where fluid displaced by a pulsatile pump can flow into" is wholly without support. Pet. 16. In fact, Petitioner points to nothing in the specification or prosecution history and instead simply relies upon the conclusory opinion of its expert who alleges the construction is plain and ordinary meaning. *Id.* There is nothing in Petitioner's construction that addresses the plain and ordinary meaning of "excess volume." Petitioner's construction 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 channel doesn't change. Indeed, as will be shown, Petitioner attempts to read "excess volume area" on Elizondo (St. Jude), even though there is no change in the channel volume.

The specification makes clear that an "excess volume" is fluid in excess to that contained in the channel and an "excess volume area" is a place to store it, thus, alleviating some of the channel pressure during the compression stroke.

VI. Petitioner's Asserted References

A. Pickard

As explained to the Examiner a number of times, Pickard is a hydrodynamic testing system for determining flow through a prosthetic heart valve. As such, the system is designed to mimic the human circulatory system. *See e.g.*, Ex. 1010 at

1:6-20. In fact, Pickard distinguishes itself from durability or fatigue testing systems. *Id.* at 1:36-51 (“In the past, most techniques for testing heart valves have been directed to durability or fatigue testing . . . However, . . . manufacturers desire to test each heart valve for reliability and integrity rather than simply durability.” In contrast to the hundreds of millions of cycles required for durability testing, Pickard suggests that even 30 minutes of testing in its system is too long. *Id.* at 1:52-64 (“In the past, most circulatory simulating systems have . . . a complex flow channel, this procedure is extremely time consuming . . . Indeed, prior art apparatus of the type just described requires a period of up to thirty minutes to test a heart valve.”). One can appreciate the Pickard system by examining Figure 3 which has been reproduced below in colorized and labeled form with the previous reference numerals omitted for clarity.

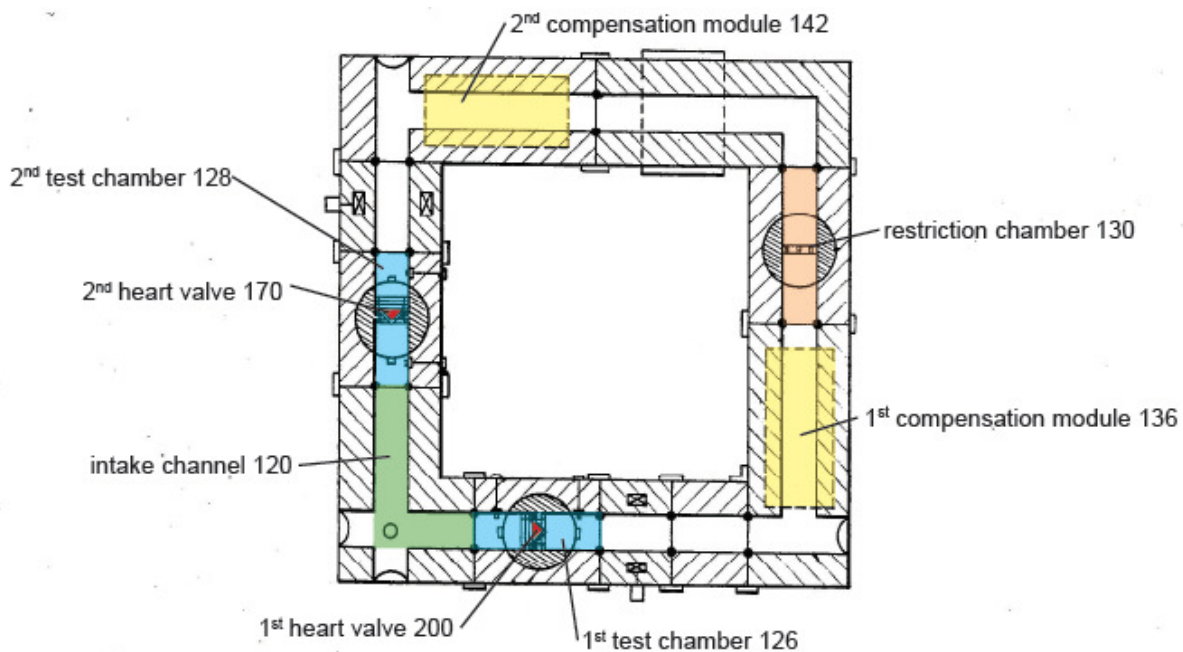


**Figure 3 of Pickard
(colorized and labelled with reference numerals removed).**

As shown in cross-section, circulatory loop 18 (i.e., the channel) is laid out in a square pattern and full of fluid. *Id.* at 7:30-52. On the compression stroke, pump 46 (*see* Fig. 1) introduces additional fluid into the channel at intake channel 120 (depicted in green); the fluid flows in from beneath the two-dimensional plane of Figure 3. *Id.* at 9:2-25; 8:14-21; 13:10-31. As heart 170 (red) is a one-way valve, the flow is counter-clockwise through first test chamber 126 (blue) and through heart valve 204 (red). *Id.* at 9:2-25; 13:42-64. Downstream from first test chamber 126 is restriction chamber 130 which restricts the flow through it and creates a backpressure. *Id.* at 9:26-45; 13:67-7:4. First compensation module 136

(yellow) alleviates some of the backpressure by expanding (beneath the plane of Figure 3) to accommodate some of the excess fluid being introduced by the pump. *Id.* On the decompression stroke, heart valve 200 closes and excess fluid from first compensation module 136 is returned to the channel and passes through restriction chamber 130. *Id.* at 14:4-10. Second compensation chamber 142 (yellow) can hold some of the excess fluid which eventually passes through second test chamber 128 (blue) and returns to the intake chamber, thus, completing one cycle. *Id.* at 9:38-45; 14:4-10.

B. Elizondo (St. Jude)⁴

Elizondo discloses a multi-functional system for culturing, monitoring, testing, and storing biological materials, such as heart valves within a single system. Ex. 1011 at 1:56-67. Petitioner relies upon pulse evaluation circuit 60 shown Figure 3 as allegedly invalidating prior art (reproduced below in colorized and labeled form without reference numerals).⁵ Pet. 24-25.

⁴ For consistency, U.S. Patent No. 5,916,800 is referred to herein by the first-named inventor, Elizondo. Petitioner referred to this reference by the assignee, St. Jude.

⁵ Unless otherwise noted, Patent Owner will accept Dr. Billiar's description of Elizondo, until it has the opportunity to submit its own expert declaration.

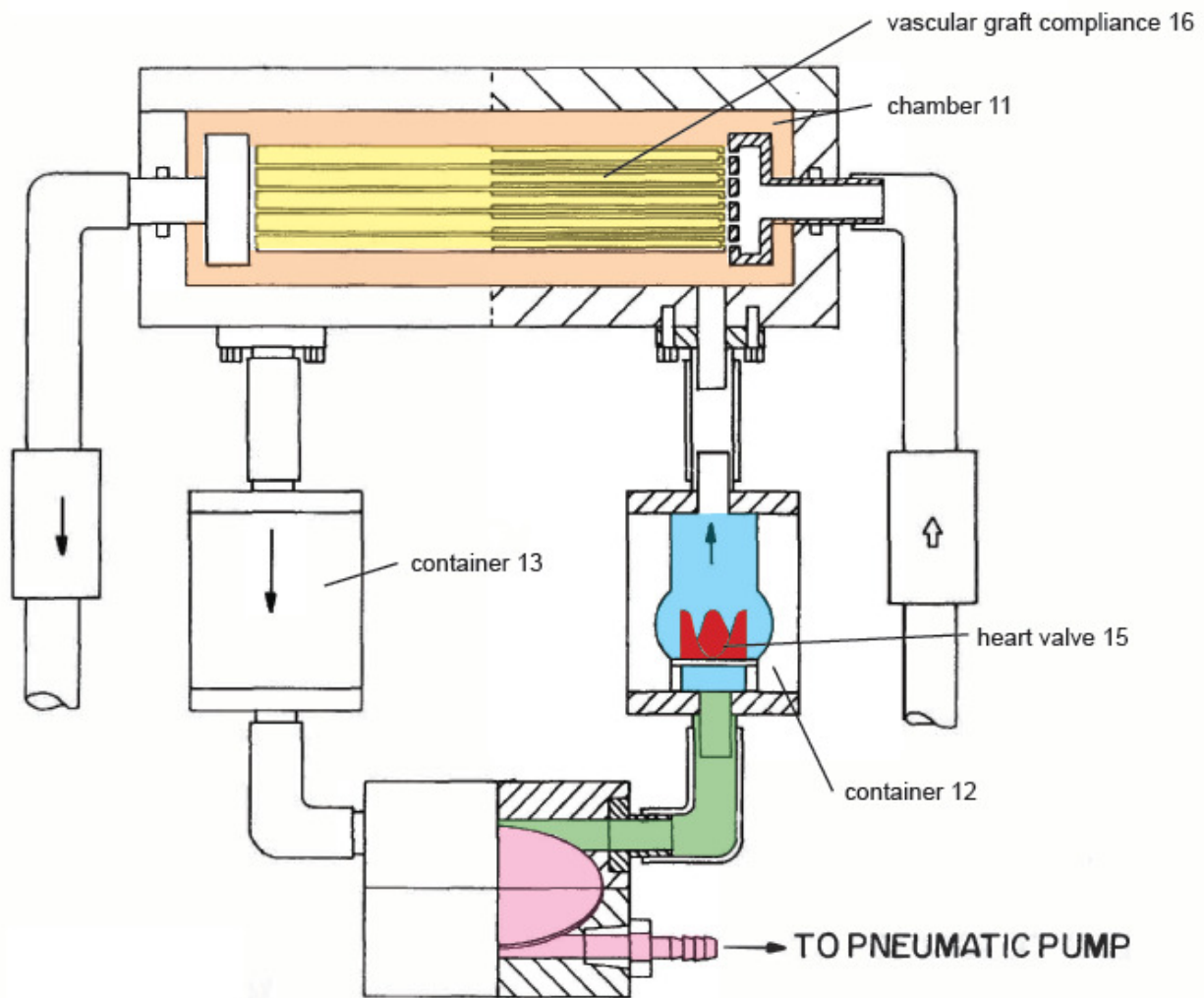


**Figure 3 of Elizondo
(colorized and labelled with reference numerals removed).**

Pneumatic pump 64 (not shown) pumps air into a balloon-like structure (pink) within the pump housing (depicted in green) which expands forcing fluid toward container 12 (depicted in blue) (container 13 contains a one-way valve, not shown, that blocks flow) and through heart valve 15 (red). Ex. 1011 at 10:48-59.

The flow will continue to chamber 11 (orange) containing vascular graft material 16 (yellow). *Id.* at 10:18-29. In place of vascular grafts, flexible bags or flexible containers may be used. *Id.* According to Dr. Billiar, the vascular grafts or flexible bags/containers act as compliance (Ex. 1003 ¶ 74), however, unlike compliance chamber 135 of the '224 Patent, the total volume of the channel remains constant. That is, any pressure being mitigated would presumably be through material deformation—not by providing a space in addition to the channel to store some of the excess introduced fluid. Therefore, Elizondo has no “excess volume area” for storing fluid in excess of that contained in the channel.

**VII. PETITIONER FAILS TO DEMONSTRATE A REASONABLE
LIKELIHOOD OF PREVAILING ON ANY OF ITS FIVE
ASSERTED GROUNDS**

A. GROUND 1a: Claims 1-7 in view of Pickard and Woodward

Pickard fails to disclose an “accelerated cyclic test system,” as required by claim 1. Pickard is a real-time system which operates at normal physiological rates, as opposed to an “accelerated” system operating above normal physiological rates. Similarly, Pickard fails to disclose “driving a test system fluid cyclically above the normal physiological rate,” as required by claim 1. Likewise, Pickard does not disclosed “driving a test system fluid . . . at an accelerated pulsed rate of greater than 200 beats per minute.”

Pickard is a hydrodynamic testing system for determining flow through a prosthetic heart valve. As such, the system is designed to mimic the human circulatory system. *See e.g.*, Ex. 1010 at 1:6-20. Unlike a durability testing system, a hydrodynamic system would be operated at normal physiological conditions and heart rates. In fact, Pickard distinguishes itself from durability testing systems. *Id.* at 1:36-51 (“In the past, most techniques for testing heart valves have been directed to durability or fatigue testing . . . However, . . . manufacturers desire to test each heart valve for reliability and integrity rather than simply durability.”) In contrast to the hundreds of millions of cycles required for durability testing, Pickard suggests that even 30 minutes of testing in its system is too long. *Id.* at 1:52-64 (“In the past, most circulatory simulating systems have . . . a complex flow channel, this procedure is extremely time consuming Indeed, prior art apparatus of the type just described requires a period of up to thirty minutes to test a heart valve.”).

Woodward does not make up for the deficiencies in Pickard. Woodward does not disclose an “accelerated cyclic test system,” “driving a test system fluid cyclically above the normal physiological rate,” nor “driving a test system fluid . . . at an accelerated pulsed rate of greater than 200 beats per minute”—all of which are required by claim 1. Like Pickard, Woodward is a real-time system which

operates at normal physiological rates for the purposes of serving as an artificial heart while a patient is undergoing open heart surgery (Ex. 1012 at 1:13-29), as opposed to an “accelerated” system operating above normal physiological rates. Petitioner never alleges otherwise. Pet. 29-34. Instead, Petitioner simply ignores the limitation “driving a test system fluid cyclically above the normal physiological rate,” and misstates that Patent Owner defined “accelerated” to mean above 200 bpm (an argument addressed above). As for the limitation “driving a test system fluid . . . at an accelerated pulsed rate of greater than 200 beats per minute,” Petition ignores the phrase “driving a test system fluid.”

Woodward does not disclose an “accelerated cyclic test system,” “driving a test system fluid cyclically above the normal physiological rate,” nor “driving a test system fluid . . . at an accelerated pulsed rate of greater than 200 beats per minute.” Woodward does disclose that a normal young adult’s heart rate may extend up to 240-270 bpm for short exhaustive work, however, Woodward does not disclose nor suggest that its system, or any other hydrodynamic test system, should be driven at such rates. Ex. 1012 at 13:43-47. In fact, Woodward operates its system below 200 bpm at all times. *Id.* at 10:4-6 (“70 to 190 or so cycles per minute”); 17:24-26 (“The upper limit depends on flow resistance. The upper limit has been raised to above 190 cycles per minute.”). Thus, while recognizing that

heart rates for “a young adult” may extend to 270 bpm “for short exhaustive work,” Woodward restricts its system to 200 bpm and does not disclose “driving a test system fluid . . . at an accelerated pulsed rate of greater than 200 beats per minute” nor “driving a test system fluid cyclically above the normal physiological rate.”

As mentioned earlier, ISO 5840 was updated in 2013. Ex. 2003. One revision is that the standard now explicitly addresses hydrodynamic testing for pediatric heart valves. The hydrodynamic testing guidelines are contained in Annex N (*id.* at 102-5), but refers to Annex H for pediatric test condition guidelines (*id.* at 104). The recommended testing frequencies for a heart valve designed for “a young adult” (in Woodward’s terminology) or an “adolescent” (in ISO terminology) is 45, 70, and 120 bpm. *Id.* at 70. Indeed the highest recommended cycle rates for any heart valve used in Annex H are for an infant at 60, 150, and 200 bpm. *Id.* To avoid any suggestion that the ISO is misinformed or unaware of the fact that an adolescent’s heart rate may exceed 120 bpm, Table 1 indicates that normal heart rates for adults (who typically have lower heart rates) range from 30 to 200 bpm. *Id.* at 24. However, hydrodynamic testing of adult heart valve rates is done at rates of 45, 70, and 120 bpm. *Id.* at 104. Thus, it is clear that while a person of ordinary skill understands that higher heart rates may

occur in transplant recipients, this does not provide a reasonable rationale for *testing* the heart valve at these higher rates. The ISO standards indicate that while an adult may experience heart rates of 200 bpm and an adolescent 270 bpm, hydrodynamic testing is carried out at 120 bpm and never more than 200 bpm. So, contrary to Petitioner's contention, a person of ordinary skill in the art reading Woodward's disclosure that a young adult's heart rate may peak at 270 bpm would not be motivated to *drive* Pickard's system at such rate. Woodward, and undoubtedly the ISO, knows that heart rates may peak at 270 bpm, yet both drive hydrodynamic systems at rates below 200 bpm. This is concrete evidence of how a person of ordinary skill in the art would reasonably use the information from Woodward with the hydrodynamic system of Pickard. Therefore, Pickard in combination with Woodward does not disclose an "accelerated cyclic test system," "driving a test system fluid cyclically above the normal physiological rate," nor "driving a test system fluid . . . at an accelerated pulsed rate of greater than 200 beats per minute," as required by claim 1.

Moreover, even *assuming* Woodward would have motivated a person of ordinary skill in the art to *drive* Pickard's system at 270 bpm, Petitioner admits that 270 bpm is still not "above a normal physiological rate." Pet. 29 (Woodward "discloses that a normal physiological range can go up to 270 bpm."). Thus, the

combination still fails to disclose an “accelerated cyclic test system” and “driving a test system fluid cyclically above the normal physiological rate.”

1. Claim 4

Claim 4 reads: “The method of claim 3 further comprising altering a spring factor of the spring force provided by the excess volume area through selection of a material forming at least a portion of a boundary of the excess volume area.”

Petitioner argues without explanation that because Pickard discloses using polyurethane diaphragm 518 it satisfies claim 4. Pet. 42. Nowhere in Pickard does it suggest “altering” the spring factor through the selection of the material composing the diaphragm or that spring factor is a consideration in selecting the diaphragm material.

B. GROUND 1b: Claims 1-7 in view of Pickard, Woodward, and Elizondo

While Petitioner entitles Ground 1b as a combination of three references, it only suggests combining Pickard with Elizondo. Pet. 46-49. Thus, Ground 1b is actually Pickard in view of Elizondo.

As described above, Elizondo is a multi-functional system for culturing, monitoring, testing, and storing biological materials, such as heart valves within a single system. Ex. 1011 at 1:56-67. Elizondo does disclose accelerated durability

testing at 1000 bpm. *Id.* at 11:8-11. Petitioner, however, fails to show a reasonable rationale for utilizing accelerated durability rates (e.g., 1000 bpm) with Pickard's real-time hydrodynamic system. Doing so would frustrate Pickard's purpose of his system—to mimic the human circulatory system for the purpose of evaluating flow conditions through a prosthetic heart valve. Pickard was not interested in testing the durability of the heart valve, so there is no reasonable rationale for a person of ordinary skill in the art to use Elizondo's accelerated rate of 1000 bpm. Moreover, Pickard's system is incapable of running durability tests.

Patent Owner recognized, during prosecution, that compliance chambers were used in hydrodynamic testing systems. The point is that they were not being used in accelerated durability test systems. Because the two types of systems are inherently at odds with one another (hydrodynamic mimics the circulatory system at physiological rates and accelerated durability operates above physiological rates) combining them is not obvious.

Thus, while the concept of using a compliance chamber to store excess volume of test fluid in a real-time, physiologically accurate, cardiac valve test system is well known for the purpose of substituting for the arteries of a human circulatory system (in fact, compliance is required by ISO 5840 in Annex L . . .), a method in an accelerated cyclic system that uses an excess volume area is entirely new.

Ex. 1007 at 8. The Patent Owner goes on to explain why Pickard would not function at accelerated rates for durability testing. *Id.*; *see also* Ex. 1009 ¶ 10.

To justify its hindsight reconstruction, Petitioner makes two related arguments for a reasonable rationale to combine Pickard with Elizondo. First, Petitioner argues that Elizondo operates “at 1000 bpm in order to test in 3 days the equivalent of 5 years use.” Pet. 47. This argument rests on the premise that Pickard was concerned with durability testing. On the contrary, Pickard suggests that even 30 minutes of testing in its system is too long. *Id.* at 1:52-64. Moreover, operating at 1000 bpm or above normal physiological rates is contrary to the stated goal of Pickard. Ex. 1010 at 1:9-14 (“the present invention is particularly useful for mimicking the human circulatory system so that a heart valve may be placed therein, tested and observed for determining the suitability of the heart valve for actual implantation into the body.”). In fact, Pickard distinguishes its system from durability testing systems. *Id.* at 1:36-51 (“In the past, most techniques for testing heart valves have been directed to durability or fatigue testing . . . However, . . . manufacturers desire to test each heart valve for reliability and integrity rather than simply durability.”) Thus, there is no reasonable rationale for converting Pickard into a durability testing system operating above normal physiological rates. *In re*

Ratti, 270 F.2d 810, 813 (CCPA 1959) (A proposed modification to a reference should not change the principle of operation of the reference).

Petitioner also argues that one “would naturally combine Pickard and [Elizondo] since both disclose systems that evaluate heart valves in circulatory loops.” Pet. 48. This ignores the fact that Pickard is concerned with flow (hydrodynamics) as experienced during normal physiological conditions and Elizondo is concerned with durability testing at above normal physiological conditions. The two are inherently incompatible. Furthermore, even if the two were both related to durability testing, that in and of itself, does not provide a motivation to combine them. *Nautilus Hyosung Inc. v. Diebold, Inc.*, IPR2016-00633, Paper 9 at 21-22 (emphasis in original) (Aug. 22, 2016) (denying institution for lack of evidence on rationale to combine because stating “something *could* be done” failed to “articulate a reason why something *would* be done by one of ordinary skill in the art at the time of the invention.”).

Lastly, Petitioner argues without any specific explanation or support (other than a conclusory statement by its expert) that Pickard could be easily modified to run at 1000 bpm. Pet. 47-48. Petitioner provides no details other than to say that Pickard’s switch piston pump could be swapped to the diaphragm pump of

Elizondo. Pet. 49. It should be obvious to anyone comparing Figure 3 of Pickard with Figure 3 of Elizondo that merely swapping out the pump would not convert Pickard from a hydrodynamic testing system to a durability testing system.

Hydrodynamic systems need to mimic the human circulatory system which is heavily dependent upon the geometry of the channel, the location of the various elements (e.g., test chamber, return channel, compliance, etc.). If one could simply swap pumps are convert a hydrodynamic testing system into a durability testing system, it would be done as doing so would save companies testing their heart valves millions of dollars. In fact, Waters' durability testing system, DuraPulse, only operates at 900-1800 bpm (Ex. 2001 at 10), and it does not provide a pump to convert it into a hydrodynamic testing system.

1. Claim 4

As stated in addressing Ground 1a, Pickard does not suggest “altering” the spring factor through the selection of the material composing the diaphragm.

Petitioner does not rely upon Elizondo to make up for this deficiency.

C. GROUND 2a: Claims 1-4 in view of Elizondo

Elizondo, unlike Pickard, includes a system for accelerated durability testing of heart valves. *See e.g.*, Fig. 3 (described above). Dr. Billiar contends that unlike most accelerated durability testing systems, Elizondo utilizes compliance, namely,

vascular grafts 16 or flexible bags/containers. Assuming these 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. Thus, Elizondo has no “excess volume area” for storing fluid in excess to that contained in the channel, as required by claim 1.⁶

1. Claim 2

According to Dr. Billiar, during the compression stroke, compliant structure 16 is compressed, releasing its fluid. Ex. 1003 ¶ 91. However, claim 2 requires that the “excess volume area enlarges . . . during the driving stroke and decreases during the return stroke.” Thus, even accepting Dr. Billiar’s contention that vascular grafts 16 constitute an “excess volume area,” claim 2 is still not satisfied because, according to Dr. Billiar, it decreases during the drive stroke and increases during the return stroke.

⁶ Petitioner also argues that Elizondo *must* have an excess volume area for storing fluid. Pet. 56. While the start of an inherency argument, Petitioner never develops it, so it not addressed. Further, Petitioner’s contention is wrong as a matter of fluid dynamics. A water hammer works precisely because there is no space for excess fluid which is the impetus for providing an excess volume area in the present invention. Through rapid compressions, the fluid standing in the channel can be caused to circulate or move.

2. Claim 4

Dr. Billiar does not explain how using a flexible bag instead of a vascular grafts alters the spring force, much less that the selection of compliance material is based on the spring force. Ex. 1003 ¶¶ 94-95. It is entirely possible that the flexible bag used to replace the vascular grafts was selected to provide the same spring force. Thus, Dr. Billiar's implicit reliance on inherent disclosure must fail.

D. GROUND 2b: Claims 3-7 in view of Elizondo and Pickard

Petitioner attempts to use Pickard to make up for deficiencies in Elizondo. More specifically, Petitioner argues that a person of ordinary skill in the art would be motivated to replace Elizondo's compliance chamber with Pickard's compliance chamber. Petitioner, however, fails to provide a reasonable rationale for making such a substitution.

Petitioner argues that if vascular grafts are not needed, Elizondo provides "an explicit motivation" to remove them which creates a need or motivation to substitute Pickard's compliance chamber. Pet. 61. Elizondo already provides for compliance in lieu of vascular grafts, namely, flexible bags or flexible containers. In point and fact, as described, these flexible bag/containers are the norm, the vascular grafts are the substitute. "Exemplary compliant structures include but are not limited to flexible bags or flexible containers, and may even include biological

material, such as vascular graft material.” Ex. 1011 at 10:21-24. Thus, Elizondo already provides for compliance when grafts are not desired. Petitioner makes no attempt to explain why a person of ordinary skill in the art would ignore the compliance disclosed by Elizondo (flexible bags or flexible containers) and substitute Pickard’s more complex compliance chamber which would require redesigning the chamber, as opposed to simply placing a bag or container inside of it. *Free-Flow Packaging Int’l, Inc. v. Automated Packaging Sys.*, IPR2016-00350, Paper 7 at 14 (June 27, 2016) (Institution denied because Petitioner did not explain “why a person of skill in the art would have considered it desirable to further modify” one reference which already addressed the problem).

E. GROUND 2c: Claims 6 and 7 in view of Elizondo and Iwasaki

Lastly, Petitioner proposes replacing Elizondo’s’ compliance (flexible bags/containers or vascular grafts) with Iwasaki’s air compliance chamber. Again, Petitioner fails to provide a reasonable rationale for making the substitution, offering only a conclusory statement that it would be a simple substitution. Pet. 68. Petitioner fails to explain what would motivate a person of skill in the art to make the alleged simple substitution, especially, since doing so would require complicating the design of the chamber. *InTouch Techs., Inc. v. VGO Commc’ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (assertions that one could combine

references, not that one would have been motivated to do so, reveals hindsight bias).

VIII. CONCLUSION

Based on the deficiencies identified above, Petitioner has not demonstrated a reasonable likelihood of prevailing on any of its proposed grounds for any claim. Thus, Patent Owner respectfully submits that the Board should decline to institute an IPR proceeding based on the Petition.

Respectfully submitted,

Date: April 27, 2018

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CERTIFICATION UNDER 37 CFR §42.24(d)

Under the provisions of 37 CFR §42.24(d), the undersigned hereby certifies that the word count for the foregoing Patent Owners' Preliminary Response is less than the 14,000 allowed under 37 CFR §42.24(b)(1).

Respectfully submitted,

Date: April 27, 2018

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4) and 42.205(b), the undersigned certifies that on April 27, 2018, a complete and entire copy of this Patent Owners' Preliminary Response was provided via electronic service to the Petitioner by serving the correspondence address of record as follows:

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/Kimberly C. Croft/
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