

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VIVITRO LABS INC.,
Petitioner,

v.

BIOMEDICAL DEVICE CONSULTANTS & LABORATORIES OF
COLORADO, LLC,
Patent Owner.

IPR2024-00320
Patent 9,237,935 B2

Before JOHN F. HORVATH, JOHN A. HUDALLA, and
DONALD E. DAYBELL, *Administrative Patent Judges*.

PER CURIAM.

Opinion Concurring filed by HUDALLA, *Administrative Patent Judge*.

Opinion Concurring filed by DAYBELL, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

ViVidro Labs, Inc. (“Petitioner”) filed a Petition requesting *inter partes* review of claims 1–4, 7–10, 12, and 13 (“challenged claims”) of U.S.

Patent No. 9,237,935 B2 (Ex. 1001, “the ’935 Patent”) pursuant to 35 U.S.C. §§ 311–319. Paper 1 (“Pet.”). Biomedical Device Consultants & Laboratories of Colorado, LLC (“Patent Owner”) filed a Preliminary Response. Paper 11 (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 314 and 37 C.F.R. § 42.4 to determine whether to institute review. Upon consideration of the arguments and evidence before us, we conclude that Petitioner has shown a reasonable likelihood that it would prevail in establishing unpatentability of at least one challenged claim of the ’935 Patent.

The Petition is *granted*, and *inter partes* review is instituted. A scheduling order will follow this decision.

A. Real Parties in Interest

Petitioner identifies itself (ViVitro Labs, Inc.) and Starfish Holdings Inc. as real parties in interest. Pet. 76. Patent Owner identifies itself (Biomedical Device Consultants & Laboratories of Colorado, LLC) as real party in interest. Paper 5, 2 (Mandatory Notices).

B. Related Matters

Each party identifies the following related matters:

Biomedical Device Consultants & Laboratories of Colorado, LLC v. ViVitro Labs., Inc. No. 1:23-cv-867 (D. Colo.), subsequently transferred to the Central District of California as No. 2:23-cv-04291-HDV (C.D. Cal.) (“the underlying litigation”). Pet. 76; Paper 5, 2 (Mandatory Notices). The underlying litigation has been stayed pending the outcome of this proceeding. *Biomedical Device Consultants & Laboratories of Colorado, LLC v. ViVitro Labs., Inc.*, No. 2:23-cv-04291-HDV, Dkt. No. 101 (C.D. Cal. Apr. 11, 2024).

The parties further identify an appeal of a denial of Patent Owner's preliminary injunction motion in the underlying litigation, No. 2023-2393 (Fed. Cir. 2023). The Court of Appeals for the Federal Circuit affirmed this denial. *Biomedical Device Consultants & Laboratories of Colorado, LLC v. ViVitro Labs., Inc.*, No. 2023-2393, 2024 WL 1318251, at *1 (Fed. Cir. Mar. 28, 2024). The Federal Circuit did not reach any of the issues we address herein.

C. The '935 Patent¹

The '935 Patent is directed to a fatigue testing system for prosthetic heart valves. Ex. 1001, code (57). An illustrative embodiment is depicted in Figure 3, reproduced below.

¹ The '935 Patent issued from Application No. 14/137,313, filed Dec. 20, 2013, which is a continuation of Application No. 12/718,316, filed Mar. 5, 2010, now Pat. No. 8,627,708. Ex. 1001, codes (21), (22), (63). The '935 Patent also claims the benefit of priority to Provisional Patent Application No. 61/158,185, filed Mar. 6, 2009. *Id.* at code (60).

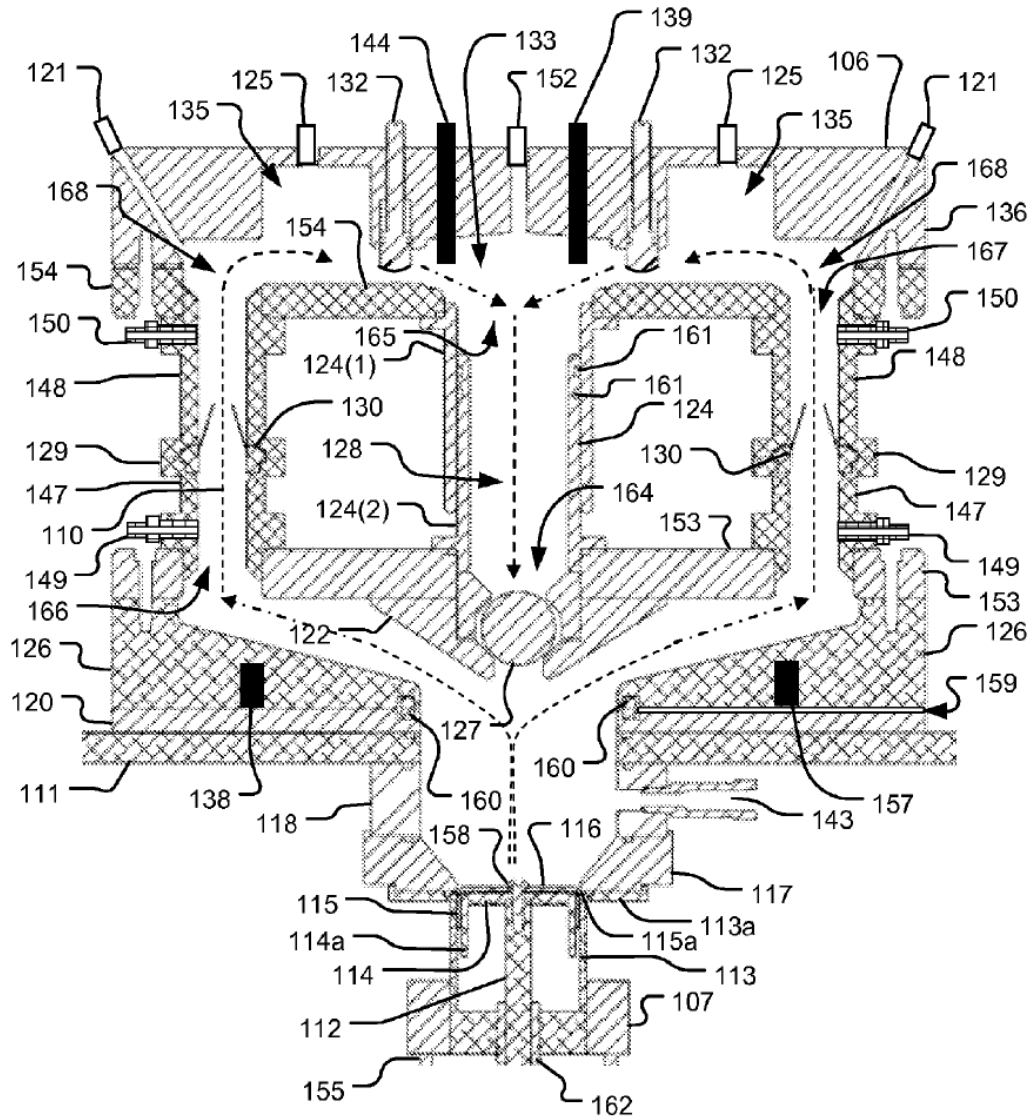


Figure 3 depicts a test chamber of a fatigue testing system. Ex. 1001, 3:38–39. The fatigue testing system includes a drive mechanism that moves piston 114 and diaphragm 115 up and down to pump test system fluid through the system. *Id.* at 11:43–59. On an upstroke, the piston forces test fluid upward, applying a fluid pressure that forces one-way valve 127 to close, heart valves 130 mounted in test chambers 148 to open, and fluid flow from lower distribution chamber 126 into return chamber 136 and

compliance chamber 135. *Id.* at 11:60–12:3, 12:4–9. As the fluid flows into compliance chamber 135, its air volume decreases and air pressure increases until the air pressure equals the increased fluid pressure in the return chamber, at which point the fluid flow stops. *Id.* at 12:4–9. On a downstroke, the piston no longer pushes test fluid up against heart valves 130 and one-way valve 127, but gravity and the air pressure in compliance chamber 135 push test fluid down against them, forcing one-way valve 127 to open, heart valves 130 to close, and fluid to flow from upper return chamber 136 and compliance chambers 135 into lower fluid distribution chamber 126. *Id.* at 12:25–33. As the test fluid drains from compliance chambers 135, its air volume increases and air pressure decreases until it reaches the reduced test fluid pressure of the residual test fluid in the return chamber. *Id.* This behavior continuously and cyclically repeats as the piston cycles through its up and down strokes.

D. Illustrative Claims

Claim 1 is independent and reproduced below.²

[1pre] A device for accelerated cyclic testing of a valved prosthetic device comprising:

[1a] a pressure source configured to drive a test system fluid cyclically within the device above a normal physiological rate, at an accelerated pulsed rate of greater than 200 beats per minute within the device; and

² The headings with bracketed letters identifying each of the claim elements correspond to those used by Petitioner to reference the claim elements. *See* Pet. 78. We use them here for ease of reference, understanding, and consistency.

- [1b] a pressurizable test chamber for containing the test system fluid and further comprising
- [1c] a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source;
- [1d] a fluid return chamber positioned on a second side of the valved prosthetic device;
- [1e] a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and
- [1f] an excess volume area capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid communication with the fluid return chamber providing a volume for storing a volume of a test system fluid when the test system fluid is under compression.

E. Evidence relied on by Petitioner and Patent Owner

Petitioner relies on the following references.

Name	Reference	Exhibit
Xi	Chinese Patent CN 1035153C to Baoshu Xi, Zhaohong Pei, Peizhen Zu & Shouyan Li (June 18, 1997) with certified translation ³	1004
Lu	Po-Chien Lu, Jia-shing Liu, Baoshu Xi, Shawyan Li, Jia Wu & Ned H.C. Hwang, <i>On Accelerated Fatigue Testing of Prosthetic Heart Valves</i> , in FRONTIERS IN BIOMEDICAL ENGINEERING 185–196 (Ned H.C. Hwang & Savio L-Y. Woo eds., 2003)	1005
Dynatek	Operating Instructions for M6 Six-Position Heart Valve Durability Testing Device, Dynatek Dalta Scientific Instruments (1993)	1006
Goldstein	U.S. Patent 5,899,937	1007

³ All citations herein to Xi are to the certified translation.

Petitioner also relies on the Declaration of Lakshmi Dasi, Ph.D. (Ex. 1002). In its Preliminary Response, Patent Owner relies on the declarations of Michael J. Girard (Ex. 2003), Craig Weinberg, Ph.D. (Ex. 2005), and a dictionary definition of “communicate” (Ex. 2004).

F. Asserted Grounds

Petitioner asserts that claims 1–4, 7–10, 12, and 13 are unpatentable on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §⁴	Reference(s)/Basis
A	1–4, 8, 9, 12	102(a)	Xi
A1	13	103(a) ⁵	Xi
B	1–4, 8, 9, 12, 13	103(a)	Dynatek, Xi ⁶
C	1–4, 7–10, 12, 13	103(a)	Goldstein, Lu
D	7, 10	103(a)	Xi, Goldstein
E	7, 10	103(a)	Dynatek, Xi, Goldstein ⁷

⁴ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102 and 103. Because the ’935 patent was filed before March 16, 2013 (the effective date of the relevant amendments), the pre-AIA versions of §§ 102 and 103 apply.

⁵ Claim 13 only. Pet. 27.

⁶ Although Petitioner alleges obviousness over Dynatek and Xi, Petitioner argues that Dynatek alone teaches or suggests all of the limitations of claims 1, 2, 8, 9, 12, and 13. *See* Pet. 50–58. For this reason, as discussed below, we consider the obviousness of these claims over Dynatek alone. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019).

⁷ Although Petitioner alleges obviousness over Dynatek, Xi, and Goldstein, Petitioner argues that Dynatek and Goldstein alone teach or suggest all of the limitations of claims 7 and 10. *See* Pet. 70–71. For this reason, as discussed below, we consider the obviousness of these claims over Dynatek and Goldstein. *See Realtime Data*, 912 F.3d at 1373.

II. ANALYSIS

A. *Level of Ordinary Skill in the Art*

Petitioner asserts that a person of ordinary skill in the art (“POSITA”) as of the time of the invention of the ’935 Patent “would have had at least (i) a bachelor’s degree in biomedical engineering, or a related field, such as mechanical engineering, biomechanical engineering, or bioengineering, who also has at least 3 years of experience with cardiovascular devices; or (ii) an advanced degree in the same areas of academic study with at least 1 years [sic] of experience with cardiovascular devices.” Pet. 17.

Patent Owner disputes Petitioner’s contention that a POSITA need only have experience with “cardiovascular devices,” which could include, according to Patent Owner, devices such as stents or pacemakers that are unrelated to heart valves. Prelim. Resp. 18; *see also* Ex. 2003 ¶ 10 (Mr. Girard’s testimony regarding same). Patent Owner contends that a POSITA would have had experience with “flow-based test systems for evaluating heart valves or valve repair devices.” Prelim. Resp. 18; *see also* Ex. 2003 ¶¶ 9–10 (Mr. Girard’s testimony regarding same). Patent Owner otherwise contends that a POSITA would have had an additional year of experience beyond Petitioner’s proposed definition. Prelim. Resp. 18; *see also* Ex. 2003 ¶ 10 (Mr. Girard’s testimony regarding same). Lastly, Patent Owner proposes that a POSITA could have had degrees in “engineering, such as biomedical, mechanical, aerospace or civil engineering.” Prelim. Resp. 18; *see also* Ex. 2003 ¶ 9 (Mr. Girard’s testimony regarding same).

At this juncture, we adopt Patent Owner’s definition, though we note that our analysis would be the same under either party’s definition. We find persuasive the testimony of Mr. Girard that a POSITA would have had experience with flow-based test systems for evaluating heart valves or valve

repair devices. Ex. 2003 ¶ 10. We observe that both declarants have a civil engineering degree, and agree on this record that such a degree, with the other accompanying qualifications, would have been sufficient to make someone a POSITA. This definition appears to be consistent with what is reflected by the content of the applied prior art references as well. *Cf. Okajima v. Bourdeau*, 261 F.3d 1350, 1354–55 (Fed. Cir. 2001) (the applied prior art may reflect an appropriate level of skill).

B. Claim Construction

We use “the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b) (2023). The claim construction standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc) is applicable.⁸

Claim terms are generally given their ordinary and customary meaning as would be understood by one with ordinary skill in the art in the context of the specification, the prosecution history, other claims, and extrinsic evidence including declarant and inventor testimony, dictionaries, and learned treatises, although extrinsic evidence is less significant than the intrinsic record. *Phillips*, 415 F.3d at 1312–17. Usually, the specification is

⁸ Patent Owner incorrectly recites the law on claim construction, contending that “[t]he claims at issue must be given their broadest reasonable interpretation consistent with the specification.” Prelim. Resp. 18. The broadest reasonable interpretation standard does not apply to petitions filed on or after November 13, 2018. 37 C.F.R. § 42.100(b) (2019) (amended October 2018).

dispositive, and “it is the single best guide to the meaning of a disputed term.” *Id.* at 1315.

The specification may reveal a special definition given to a claim term by the patentee, or the specification or prosecution history may reveal an intentional disclaimer or disavowal of claim scope by the inventor. *Id.* at 1316. If an inventor acts as his or her own lexicographer, the definition must be set forth in the specification with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). A disavowal of claim scope, if any, can be effectuated by language in the specification or the prosecution history. *Poly-America, L.P. v. API Indus., Inc.*, 839 F.3d 1131, 1136 (Fed. Cir. 2016).

Only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Realtime Data*, 912 F.3d at 1375.

Petitioner identifies three terms it contends require construction: (a) “fluid communication”; (b) “excess volume area”; and (c) “under compression.” Pet. 18–27. Patent Owner agrees that an express construction of these three terms “would clarify the issues” in this matter. Prelim. Resp. 19 n.4.

1. “in fluid communication”

Claim 1 recites “a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source,” and “an excess volume area . . . in fluid communication with the fluid return chamber.” Ex. 1001, 17:37–39, 17:45–50. Petitioner contends that the plain and ordinary meaning of “in fluid communication” is that “fluid can flow from one referenced element to another.” Pet. 18 (citing Ex. 1002 ¶¶ 94–95).

Patent Owner contends that “in fluid communication” means that “fluid can move from one area to another *unimpeded*.” Prelim. Resp. 20 (emphasis added). In support of this construction, Patent Owner cites various places in the Specification of the ’935 patent where the phrase is used. *Id.* at 20–22 (citing Ex. 1001, code (57), 2:13–16, 2:44–46, 3:3–5, 3:9–12, 4:20–27, 9:13–19, 9:29–32). Patent Owner further notes that the Specification and claims of the ’935 patent do *not* describe the fluid distribution chamber and fluid return chamber as being “in fluid communication,” a difference that Patent Owner ascribes to the presence of an intervening valve. *Id.* at 22–24 (citing Ex. 1001, 4:20–27, 9:29–32, 17:37–41). Patent Owner additionally argues that the term “fluidly connecting” is broader than “in fluid communication” based on the usage of “fluidly connecting” in conjunction with a valved flow of fluid. *Id.* at 24 n.7 (citing Ex. 1001, 2:51–53, 12:25–29, 13:59–62).

The parties agree that “in fluid communication” connotes that fluid can flow from one referenced element (or area) to another, which we find to be consistent with the plain and ordinary meaning of “in fluid communication.” The crux of the parties’ dispute is whether the flow must be “unimpeded,” as Patent Owner asserts. At this juncture, we decline to impose an “unimpeded” restriction because Patent Owner’s construction is based on a negative implication from an instance in the Specification where “in fluid communication” is *not* used in conjunction with valved flow. *See* Prelim. Resp. 22–24. We find the evidence from the Specification to be inconclusive and, in our view, insufficient to demonstrate the patentees’ intention to depart from the term’s plain and ordinary meaning “with reasonable clarity, deliberateness, and precision.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Finally, we have considered Patent Owner’s argument that “fluidly connecting” is broader than “in fluid communication.” *See* Prelim. Resp. 24 n.7. Based on the present record, we do not agree with this premise for reasons similar to those discussed above. Indeed, “fluidly connecting” and “in fluid communication” seem to have the same meaning in the context of the ’935 patent, i.e., that fluid can flow from one place to another. For example, the ’935 patent discloses “a single fluid reservoir in fluid flow communication with each of [a] plurality of sample holders.” Ex. 1001, 4:22–25. Yet fluid flow from the reservoir or fluid distribution chamber is through “a first manifold defining a plurality of ports configured to receive and fluidicly [sic, fluidly] couple with a first end of each of a respective plurality of sample holders.” *Id.* at 2:40–44, 8:29–37. The ports necessarily have a smaller cross-sectional area than the fluid distribution chamber because they “are defined at a uniform radial distance from the center and are equiangularly spaced apart.” *Id.* at 8:29–32. Thus, they necessarily impede the flow of fluid from the fluid distribution chamber to each of the sample holders. Nonetheless, the fluid distribution chamber is “in fluid flow communication” with the sample holders because it is “fluidly connected” to them via the plurality of flow-impeding ports.

2. “*excess volume area*”

Claim 1 recites that the test chamber comprises “an excess volume area.” Ex. 1001, 17:45–47. Petitioner contends that an “excess volume area” should be construed to mean a “compliance chamber,” or at a minimum encompass a compliance chamber. Pet. 23. Patent Owner contends that not all excess volume areas are compliance chambers, and that not all compliance chambers provide excess volume areas. Prelim. Resp. 26. Instead, Patent Owner contends that an “excess volume area” should be

construed to mean “a space for storing pressurized fluid displaced by the driving of fluid by the pressure source that opens the valved prosthetic device.” *Id.* at 23.

The term “excess volume area” also appears in dependent claim 9, which recites “the excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber.” Ex. 1001, 18:30–32. Because claim 9 recites that the excess volume area of claim 1 *includes* a compliance chamber and Petitioner relies on prior art compliance chambers to meet this limitation, we need not precisely define the metes and bounds of this term. Rather, on this record, we construe the term to include, but not necessarily be limited to, a compliance chamber.

3. “*under compression*”

Claim 1 recites that the excess volume area provides a volume for storing test system fluid when the test system fluid is “under compression.” Ex. 1001, 17:45–50. The parties and their declarants agree that the test system fluid is incompressible, and thus agree that a POSITA would have understood a test fluid “under compression” means a test fluid to which pressure is applied. *See* Pet. 26; Ex. 1002 ¶ 110; Prelim. Resp. 28–29; Ex. 2003 ¶ 68. On this record, we agree with the parties.

Both parties additionally contend that this pressure must be applied by the claimed “pressure source,” which “drives” the fluid through the device. Pet. 26 (citing Ex. 1002 ¶ 111); Prelim. Resp. 29. This is so, according to the parties, because the pressure source is the only element positively recited in claim 1 that can apply pressure to the system. Pet. 26; Prelim. Resp. 29.

We agree that the only element affirmatively recited in claim 1 that can place the test system fluid under pressure/compression is the claimed “pressure source.” However, claim 1 is an open-ended “comprising” claim,

which does not rule out the presence of other elements that could provide the pressure needed to put some or all of the test system fluid under pressure. *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1235 (Fed. Cir. 2005). We see nothing in claim 1 that limits the excess volume area to storing a volume of test system fluid under compression *only* when pressure is supplied by the claimed “pressure source.” The claim does require a “pressurizable test chamber” (Ex. 1001, 17:35), but the claim does not require the claimed pressure source to be the only entity that pressurizes the test chamber. Indeed, the Specification discloses the chamber can be pressurized via an external air supply. Ex. 1001, 11:21–27, 12:43–49. Thus, on this record, we do not agree that the “under compression” limitation requires the claimed pressure source to be the source of the claimed test fluid “compression.” Therefore, we determine that a test fluid “under compression” means that the test fluid has pressure applied to it.

C. Legal Principles

Petitioner bears the burden to demonstrate unpatentability, and that burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious to a person having ordinary skill in the art to which said subject matter pertains. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations, including commercial success, long-felt but

unsolved needs, failure of others, and unexpected results. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

D. Dynatek and Xi – Obviousness

1. Analysis based on Dynatek Alone

As noted above, although Petitioner alleges obviousness over Dynatek and Xi, Petitioner argues that Dynatek alone teaches or suggests all of the limitations of claims 1, 2, 8, 9, 12, and 13. *See* Pet. 50–58 (arguing, *inter alia*, that both Dynatek and Xi teach a compliance chamber). This is sufficient to discharge Petitioner’s burden of identifying “the grounds on which the challenge to each claim is based.” 35 U.S.C. § 312(a)(3).

As the Federal Circuit has found, when a petition “identifie[s] [a single reference] as disclosing every element of claim 1” and relies on a secondary reference only in the alternative, the Board does “not violate § 312(a)(3) or other notice requirements” by relying on the single reference alone, even though the petitioner’s asserted ground formally recites both references. *Realtime Data*, 912 F.3d at 1373. Indeed, the Federal Circuit has found that when a petitioner “set[s] forth an obviousness group containing and requiring three references” but “explicitly argued that [a single reference] alone teaches every element of the challenged claims . . . [t]he Board erred when it refused to consider those arguments.” *Polygroup Ltd. MCO v. Willis Elec. Co., Ltd*, 759 F. App’x 934, 942–43 (Fed. Cir. 2019).

The concurrence expresses concerns that it is not proper for the Board to deviate from the grounds raised in the petition and to raise its own theory of obviousness. *See infra*, Hudalla Concurrence, 2 (citing *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 138 S. Ct. 1348, 1356 (2018); *Sirona Dental Sys. GmbH v. Institut Straumann AG*, 892 F.3d 1349, 1356 (Fed. Cir. 2018)). We agree that it would not be proper for the Board to craft a theory that was not

articulated in the Petition. Here, however, we find Petitioner has sufficiently articulated and raised a theory of obviousness over Dynatek alone (*see* Pet. 50–58), even though Petitioner failed to expressly list an asserted ground under § 103(a) based on Dynatek alone (*see* Pet. 27).

a) Dynatek

Dynatek is a manual for a heart valve durability testing device. Ex. 1006, 5.⁹ Petitioner contends that this manual was publicly available at least as early as 1993. Pet. 28. Patent Owner does not dispute this at this time.

Figure 1A of Dynatek is reproduced below.

⁹ Exhibit 1006 has two sets of page numbers, i.e., the original page numbers and a set of page numbers applied by Petitioner to the PDF file. The parties cite to the page numbers applied by Petitioner. For consistency, we do as well.

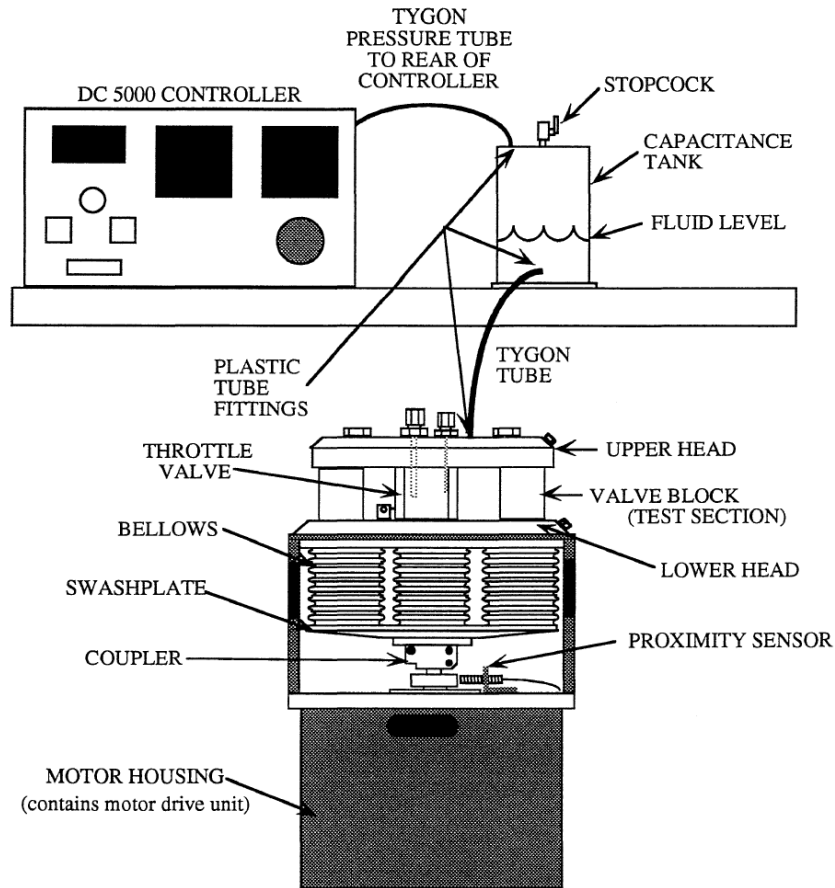


Figure 1A depicts Dynatek's heart valve durability testing device connected to a capacitance tank and to a voltage controller. Ex. 1006, 5. The device consists of a motor housing attached to a coupler and a swashplate. *Id.* The swashplate supports a plurality of bellows, each of which is associated with a test section. *Id.* at 17–18. The test sections contain heart valves. *Id.* at 18–19. The device includes an upper head above the test sections and a lower head below the test sections. *Id.* at 18. There is also a central return column located between the heads. *Id.* at 5, 18–19, 28. As discussed in further detail below, fluid flows between the upper and lower heads, and through the test sections and the central return column, based on the actions of the swashplate.

The device relies on a swashplate and bellows to drive fluid through the system. Ex. 1006, 5. In operation, the swashplate is angled such that at any given time one of the bellows is fully compressed, the bellows on the other side of the device is fully extended, and bellows in between are partially compressed/extended. *Id.* As the swashplate rotates, it fully compresses each bellows in turn, allows the corresponding opposing bellows to fully expand, and partially compresses the bellows in between. *Id.* Compressing a given bellows drives fluid from the bellows into the lower head. *Id.* The force of the fluid being expelled from the bellows closes the heart valve in the test section immediately above the bellows. *Id.* The fluid from the lower head is driven upwards through the central column and into the upper head. *Id.* From there, the fluid flows into and through the test sections corresponding to the expanding bellows. *Id.* In this manner, the combination of the positive pressure differential created by the full or partial compression of some of the bellows and the full or partial expansion of the remaining bellows causes fluid to flow through the device from the compressing bellows to the expanding bellows. *Id.* As the swashplate rotates, each pair of opposing bellows is sequentially fully compressed and expanded. *Id.*

Dynatek further teaches the use of a capacitance tank, which is connected to the upper head of the device via a flexible Tygon tube. Ex. 1006, 19. This capacitance tank is used to “buffer small variations in the systemic pressure,” for example to compensate for leakage in the system, or for changes in fluid temperature that cause the fluid to expand or contract. *Id.*

b) Analysis of Claim 1

Petitioner relies on disclosures in Dynatek alone for its contention that claims 1, 2, 8, 9, 12, and 13 would have been obvious. Pet. 50–58.

(1) Preamble [1pre] A device for accelerated cyclic testing of a valved prosthetic device

Petitioner does not address whether the preamble is limiting, but contends that Dynatek teaches the preamble, noting that Dynatek discloses a “heart valve durability/fatigue testing machine.” Pet. 50 (citing Ex. 1006, 5, 23).

Patent Owner does not dispute this contention at this time. We have reviewed the evidence cited by Petitioner, and find Dynatek teaches the subject matter of the preamble sufficiently to meet Petitioner’s burden on institution, and thus need not determine whether the preamble is limiting.

(2) Limitation [1a]: a pressure source configured to drive a test system fluid cyclically within the device above a normal physiological rate, at an accelerated rate of greater than 200 beats per minute within the device;

Petitioner relies on Dynatek for teaching this limitation, noting that Dynatek discloses that “a swashplate drive is used to compress six bellows” to cycle fluid through the system. Pet. 50 (citing Ex. 1006, 5). Petitioner further notes that Dynatek is “capable of speeds [up] to 2000 cpm” (cycles per minute). *Id.* (citing Ex. 1006, 23).

Patent Owner does not dispute this contention at this time. We have reviewed the evidence cited by Petitioner, and find Dynatek teaches the subject matter of this limitation sufficiently to meet Petitioner’s burden on institution.

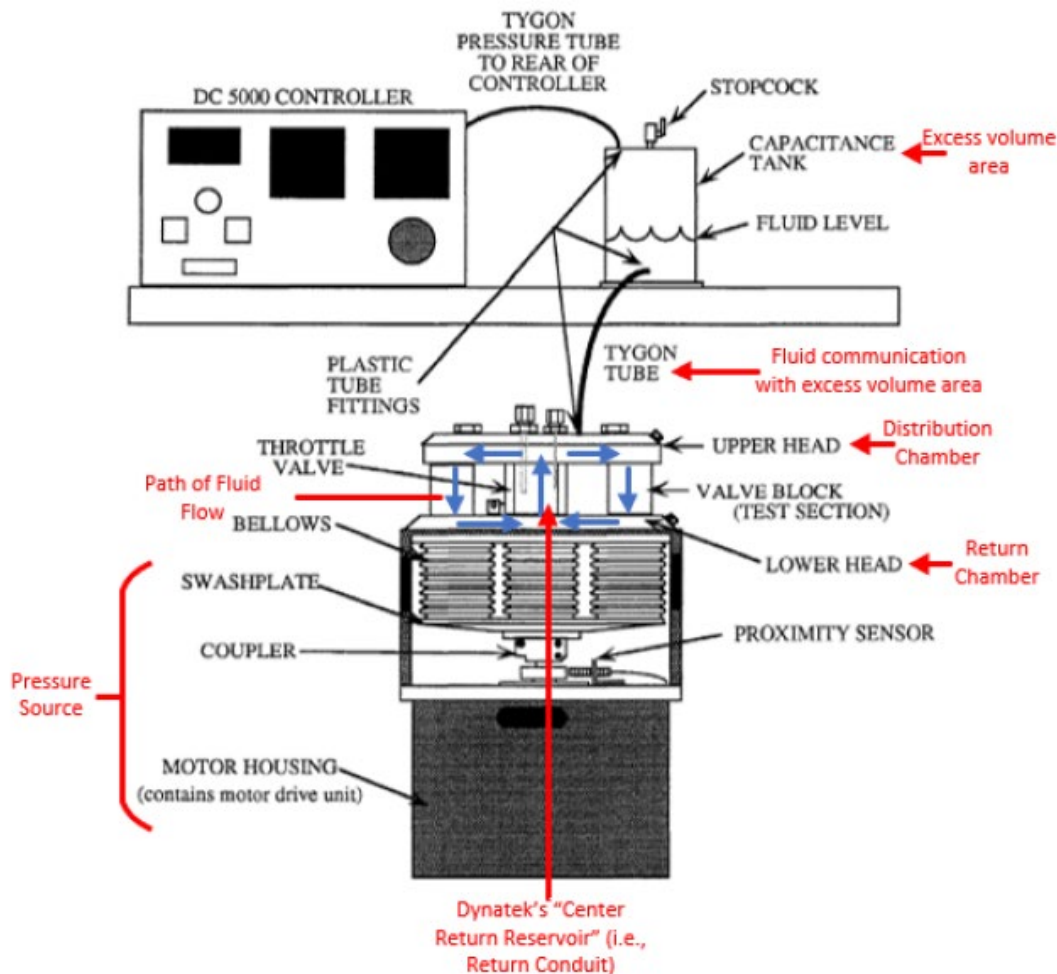
(3) Limitation [1b]: a pressurizable test chamber for containing the test system fluid and further comprising

Petitioner relies on Dynatek for this limitation, noting that Dynatek discloses a “Testing Chamber” comprising “upper and lower heads, throttle valve, valve blocks and capacitance tank.” Pet. 51 (citing Ex. 1006, 5, 18, Fig. 1A). Petitioner further notes that Dynatek’s system has a “systemic operating pressure” that can be adjusted by “pressurizing the capacitance tank.” We note that this is similar to how the ’935 patent is capable of pressurizing its system, using an air supply. Ex. 1001, 11:21–27, 12:43–49.

Patent Owner does not dispute this contention at this time. We have reviewed the evidence cited by Petitioner, and find Dynatek teaches the subject matter of this limitation sufficiently to meet Petitioner’s burden on institution.

(4) Limitation [1c]: a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source;

Petitioner relies on Dynatek for this limitation, noting that Dynatek has an “upper head above the valves,” which includes “inlet flow passages.” Pet. 52 (citing Ex. 1002 ¶ 173; Ex. 1006, 5, 7, 18, Fig. 1A). These passages are in fluid communication with the pressure source (the bellows driven by the swashplate) as shown by the annotated Figure 1A of Dynatek provided by Petitioner’s declarant, Dr. Dasi, which is reproduced below. Ex. 1002 ¶ 169.



The figure above is an annotated version of Figure 1A of Dynatek, illustrating the flow of fluid through the system. *Id.* In Dynatek's system, when a given bellows is compressed by the swashplate, fluid flows from the bellows through the lower head, into the "Center return reservoir" and into the upper head, as shown by the blue arrows in Dr. Dasi's annotated Figure 1A. When the opposing bellows is expanded by the swashplate, fluid flows from the upper head through the test section and into the lower head and the expanded bellows, again as shown by the blue arrows in Dr. Dasi's annotated Figure 1A.

Patent Owner disputes Petitioner's contentions. Patent Owner first contends that Petitioner relies on Dynatek's swashplate as the claimed pressure source. Prelim. Resp. 46. This contention is incorrect. Petitioner relies on the combination of the "swashplate drive" and the "bellows" as the claimed pressure source. Pet. 50 (citing Ex. 1006, 5); *see also* Pet. 52. Thus, Patent Owner's contention (Prelim. Resp. 46) that the swashplate is not in fluid communication with the fluid distribution chamber (upper head) is misplaced. The proper analysis is whether the swashplate and bellows (not the swashplate alone as contended by Patent Owner) is in fluid communication with the fluid distribution chamber.

Patent Owner further contends that Dynatek's pressure source is not in fluid communication with the fluid distribution chamber (upper head) because the pressure source (which includes Dynatek's bellows) is in fluid communication with the return chamber (lower head), and at certain times in Dynatek's cycle the closed test valve impedes fluid flow from the distribution chamber (upper head) to the return chamber. Prelim. Resp. 46–47. We disagree for two reasons. First, and most significantly, our construction of "in fluid communication" does not require unimpeded fluid flows. Second, fluid can flow unimpeded when pushed from Dynatek's swashplate through its lower head and central reservoir to its upper head (fluid distribution chamber).

Thus, Petitioner shows sufficiently on this record that Dynatek teaches this limitation.

(5) *Limitation [1d]: a fluid return chamber positioned on a second side of the valved prosthetic device;*

Petitioner contends that Dynatek teaches this limitation. Petitioner notes that Dynatek discloses that "a lower head is ported from the valve

discharge region into the center return reservoir.” Pet. 52 (citing Ex. 1006, 7, 18, Fig. 1A). The lower head is on the opposite side of the “valve block” from the upper head. Ex. 1006, Fig. 1A.

Patent Owner does not dispute this contention at this time. We have reviewed the evidence cited by Petitioner, and find Dynatek teaches the subject matter of this limitation sufficiently to meet Petitioner’s burden on institution.

(6) *Limitation [1e]: a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber;*

Petitioner relies on Dynatek for this limitation. Petitioner points to Dynatek’s “lower head” and observes that Dynatek teaches that after fluid passes through the test valve, it “escapes through the bypass port, through the throttle valve and into the central reservoir where it is then available to the upper head above the valves for another cycle.” Pet. 52 (citing Ex. 1006, 5).¹⁰

Patent Owner does not dispute this contention at this time. We have reviewed the evidence cited by Petitioner, and find Dynatek teaches the subject matter of this limitation sufficiently to meet Petitioner’s burden on institution.

(7) *Limitation [1f]: an excess volume area capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid communication with the fluid return chamber providing a volume for*

¹⁰ We understand Petitioner’s contention to mean that fluid that has passed through an open test section valve during a bellows expansion cycle escapes from the test section via the bypass port when the valve closes during a bellows compression cycle. See Ex. 1006, 5.

storing a volume of a test system fluid when the test system is under compression

Petitioner relies on Dynatek for rendering this limitation obvious. Petitioner identifies Dynatek's capacitance tank as a compliance chamber. Pet. 53 (citing Ex. 1006, 16, 19; Ex. 1002 ¶ 176).¹¹ Petitioner contends that it would have been obvious to attach Dynatek's compliance chamber "downstream of the valve (e.g., to the lower head of Dynatek)." Pet. 54 (citing Ex. 1002 ¶¶ 160–161, 182). Petitioner identifies several references that demonstrate placing a compliance chamber downstream of the valve being tested was a known configuration. Pet. 54 (citing Ex. 1002 ¶¶ 179–181; Ex. 1004, 7–8, 13, Fig. 4; Ex. 1005, 190–91; Ex. 1007, 10:25–35, Fig. 3; Ex. 1018, 22:15–19; Ex. 1015, 37–38, Fig. 3.2). Moreover, Petitioner contends a compliance chamber can be placed anywhere in a valve test system, including upstream or downstream of the test valves. *Id.* n.16 (citing Ex. 1027, 10:15–34, Ex. 1002 ¶¶ 181–182). Thus, Petitioner contends it would have been obvious to modify Dynatek to locate its compliance chamber immediately "downstream of the valve" and "in fluid communication with the return chamber." *Id.* (citing Ex. 1002 ¶¶ 161–162, 182). We understand Petitioner's contention to be modifying Dynatek so that the compliance chamber would be attached directly to Dynatek's lower head, which is what Petitioner contends is the "return chamber" in Dynatek. Pet. 54. We agree on this record that such a structure would lead to an excess volume area in fluid communication with the fluid return chamber. We find on this record that Petitioner has sufficiently shown that it would have been

¹¹ Petitioner relies on Xi's compliance chamber in the *alternative*. See Pet. 53 ("*Even if Dynatek's capacitance tank were not a compliance chamber, Xi also teaches using a compliance chamber.*" (emphases added)).

obvious to locate Dynatek's compliance chamber downstream of the valve because doing so was a known or obvious configuration, thus making the location a matter of design choice. *See* Ex. 1002 ¶¶ 161–162, 179–182; Ex. 1004, 7–8, 13, Fig. 4; Ex. 1005, 190–91; Ex. 1007, 10:25–35, Fig. 3; Ex. 1018, 22:15–19; Ex. 1015, 37–38, Fig. 3.2; *see also KSR*, 550 U.S. at 417 (“When a work is available in one field of endeavor, design incentives . . . can prompt variations of it. . . . If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.”)

Petitioner contends that Dynatek's compliance chamber is capable of operating at the accelerated pulse rate (i.e., greater than 200 beats per minute), because it is part of a testing system that operates at the accelerated pulse rate. Pet. 53. Petitioner sufficiently shows that Dynatek's compliance chamber is capable of performing the functions of an excess volume area (e.g., receiving a volume of test system fluid when the test system fluid is placed under pressure), when Dynatek's compliance chamber is used in a system that operates at the accelerated pulsed rate. Pet. 53; Ex. 1006, 16, 19; Ex. 1002 ¶ 176. For example, when Dynatek's system pressure increases due to “thermal effects,” excess fluid flows into Dynatek's capacitance tank. Ex. 1006, 15. Furthermore, as Dr. Dasi testifies, fluid flows into and out of Dynatek's capacitance tank when Dynatek's system is operated at accelerated rates. Ex. 1002 ¶ 176 n.21. On this record, we find Dr. Dasi's testimony persuasive. His personal observations of the Dynatek device in operation support the understanding a POSITA would have had regarding the teachings of Dynatek. *See, e.g.*, Ex. 1006, 19.

Lastly, Petitioner proposes that Dynatek's compliance chamber, connected to the lower head, would provide a space to store excess volume of test fluid when the fluid is under compression. Pet. 54–55; Ex. 1006, 5.

Patent Owner contends that Dynatek's "capacitance tank" is not in fluid communication with the fluid return chamber, because it is connected to Dynatek's distribution chamber (upper head) and not Dynatek's return chamber (lower head). Prelim. Resp. 47. As discussed above, Petitioner sufficiently shows that it would have been obvious to connect Dynatek's capacitance tank to the return chamber (lower head). Thus, this contention is unavailing.

Patent Owner similarly contends that Petitioner fails to establish that Dynatek's capacitance tank is an excess volume area as claimed. Prelim. Resp. 48. Patent Owner identifies three alleged deficiencies with Dynatek's capacitance tank. First, this tank allegedly "does not provide space for storing fluid under compression (displaced by the driving of fluid by the pressure source that opens the valved prosthetic device)." *Id.* at 48–49. We have determined that the fluid need only be placed under pressure, without regard to the specific source of that pressure. *Supra*, Section II.B.3. Thus, the fluid in Dynatek's system can be placed under pressure due to thermal effects. Ex. 1006, 19. Such thermal effects cause fluid to flow into and be drawn out of the capacitance tank even during system operation as observed by Dr. Dasi (Ex. 1002 ¶ 176 n.21). Accordingly, we do not agree with Patent Owner's contention that Dynatek's capacitance tank is not an excess volume area for storing fluid under compression.

Second, Patent Owner contends that Dynatek's capacitance tank is incapable of performing as an excess volume area because it is located on the inflow side of the valve. Prelim. Resp. 48–49. As we have already addressed, Petitioner has adequately shown that it would have been obvious to locate the capacitance tank on the outflow side of the valve. Therefore, we do not agree with Patent Owner's contention.

Third, Patent Owner contends that Dynatek's capacitance tank is connected via a long tube that prevents it from operating as an excess volume area. Prelim. Resp. 48, 50. This contention largely relies on Patent Owner's contention that the excess volume area must be capable of "storing an entire stroke of the test system fluid when under compression." *Id.* at 51. This in turn relies on Patent Owner's proposed construction for "under compression" that imports the concept that the claimed "pressure source" must be the entity that places the system "under compression." We have rejected this construction. For purposes of this Decision, we determine that "under compression" merely requires that some form of pressure be applied to the test system fluid. *Supra*, Section II.B.3. There is nothing in the claims that requires the excess volume area be able to store an entire stroke's worth of test system fluid. Furthermore, Dr. Dasi testifies that he has observed Dynatek's system in operation, and that fluid flows into and out of Dynatek's capacitance tank when that system is operating. Ex. 1002 ¶ 176 & n.21. As noted above, we find Dr. Dasi's testimony persuasive on this record. Thus, on this record, we agree with Petitioner that Dynatek's capacitance tank operates as an excess volume area.

Accordingly, we determine on this record that Petitioner has met its burden on institution for this limitation.

(8) *Conclusion Regarding Claim 1*

Because Petitioner has met its burden on institution for all limitations of claim 1, we determine that Petitioner has shown a reasonable likelihood of success in establishing that claim 1 would have been obvious over Dynatek and Xi, based on its theory described above regarding the teachings of Dynatek alone.

c) *Analysis of Claims 2, 8, 9, 12, and 13*¹²

We have reviewed Petitioner’s evidence for dependent claims 2, 8, 9, 12, and 13. We need not opine in detail on these dependent claims, but we write to express our preliminary views. We are preliminarily persuaded that Dynatek teaches the limitations of claims 2, 8, and 13 for the reasons expressed in the Petition. Pet. 56–58. Claim 9, however, recites that the excess volume area comprises a compliance chamber “defining a cavity within the fluid return chamber.” Ex. 1001, 18:31–32. Petitioner merely alleges that “it would have been obvious to locate the air compliance chamber downstream of the test valve to be ‘a cavity within the fluid return chamber’ as recited in claim 9.” Pet. 58. The only evidence Petitioner cites to is the testimony of its declarant, Dr. Dasi. *Id.* (citing Ex. 1002 ¶¶ 195–197). Dr. Dasi’s testimony largely parrots the Petition, with a further cite to another section of his testimony. Ex. 1002 ¶ 197 (citing *id.* ¶¶ 161, 179–182). These paragraphs discuss Dr. Dasi’s views on locating the compliance chamber downstream of the valve, but they do not address the additional limitation of claim 9, requiring that the compliance chamber “defin[e] a cavity within the fluid return chamber” as claimed. Thus, we are not persuaded on this record that Petitioner has established a reasonable likelihood of showing that Dynatek renders dependent claim 9 or further dependent claim 12 obvious.

2. *Analysis based on Dynatek and Xi*

Because we determine that Petitioner has established a reasonable likelihood of showing at least 1 claim is unpatentable over Dynatek alone,

¹² We note Petitioner does not present any theory that Dynatek alone renders claims 3 or 4 obvious. *See* Pet. 56–57.

we need not address in detail Petitioner's contention that claims 1–4, 8, 9, 12, and 13 are unpatentable over Dynatek in view of Xi. However, we write to provide guidance to the parties as to our preliminary views of this combination to assist them in further briefing during the trial.

a) Xi

Xi is a Chinese patent directed to a testing system for prosthetic heart valves. Ex. 1004, 1. Petitioner provides a certified translation of Xi, which we rely upon herein. Figure 4 of Xi is reproduced below.

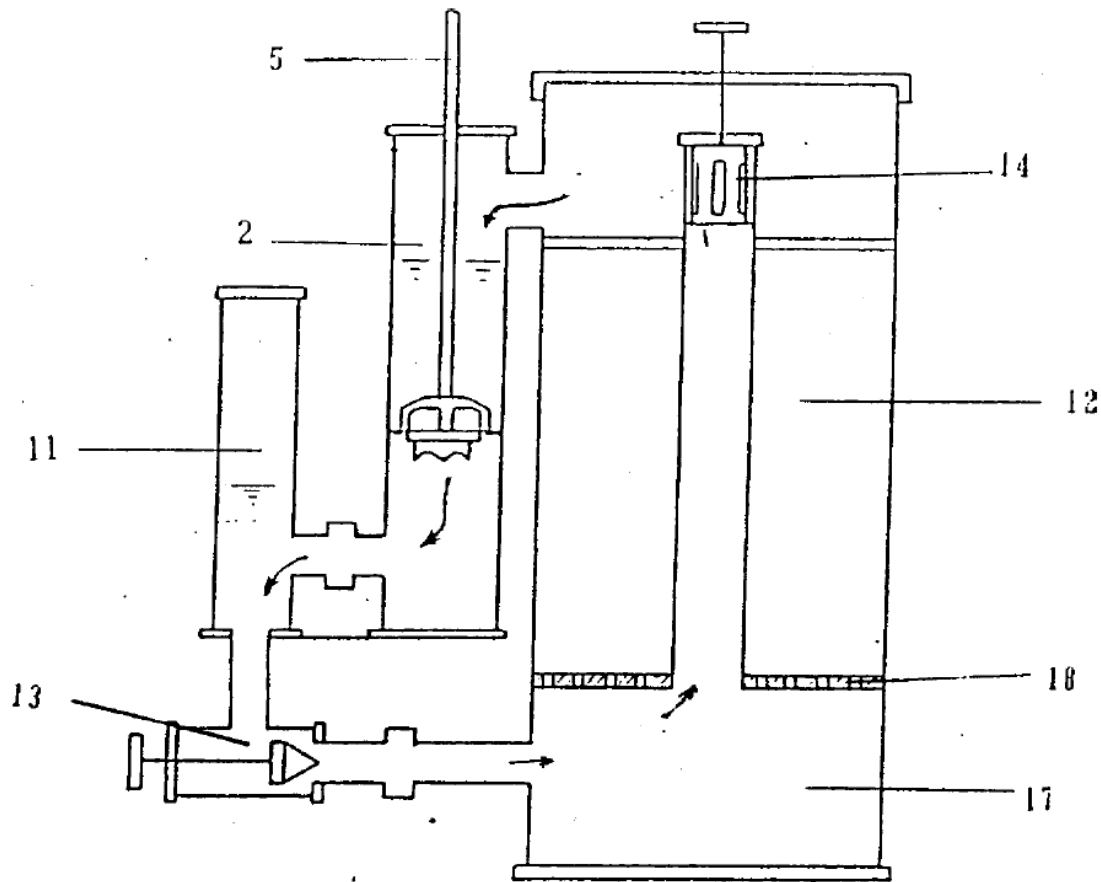


Fig. 4

Figure 4 depicts the circulation loop of Xi's system showing one of six test sections 2 connected to liquid storage tank 17. Ex. 1004, 6–8. Test section 2 includes link rod 5 connected to a linear motor. *Id.* at 5. Link rod 5 propels up and down within test section 2 a valve frame containing a

prosthetic heart valve being tested. *Id.* When the valve frame and valve is propelled upward, the valve opens and passes through the fluid. *Id.* at 7. When the valve frame and valve are propelled downward, the valve closes and forces fluid through circulation loop 30 consisting of air chambers C₁ 11 and C₂ 12, dampers R₁ 13 and R₂ 14, test section 2, and liquid storage tank 17. *Id.* at 7–8. Xi adjusts the “compliance and impedance of the circulation loop” to adjust the differential pressure across the heart valve to replicate “normal physiological conditions.” *Id.* at 7. As fluid is forced to flow from test section 2 to fluid chamber 17, damper R₁ 13 impedes its flow to create a 0 to 100 mm Hg pressure-differential across the heart valve. *Id.* at 8. The increased pressure below the heart valve forces some fluid to flow into air chamber C₁ 11, compressing the air in that chamber and increasing the air pressure until it equals the increased fluid pressure below the heart valve. *Id.* at 8, Fig. 4.

The decreased fluid pressure above the heart valve occurs because the volume of air in the upper portion of chamber 2 increases as fluid is forced into the lower portion of chamber 2. *Id.* This decreases the air and fluid pressure in the upper chamber. *Id.* The fluid from storage tank 17 is then forced to flow into the upper portion of chamber 2 by the expansion of pressurized air in air chamber C₂ 12. *Id.* at 8–9, Fig. 4. This expansion decreases the air pressure in chamber C₂ 12 and the fluid pressure in storage tank 17. *Id.* The flow of fluid from storage tank 17 into the upper portion of chamber 2 decreases the volume of air in the upper portion, thereby increasing the air and fluid pressure in the upper portion. *Id.* When the decreasing fluid pressure in storage tank 17 equals the increasing fluid

pressure in the upper portion of chamber 2, fluid flow from storage tank 17 into the upper portion of chamber 2 ceases.¹³ *Id.*

b) Analysis of claim 1

Petitioner relies on Dynatek alone to meet limitations [1pre]–[1e] as discussed above. *See* Pet. 50–52. However, for limitation [1f], Petitioner contends that a POSITA would have found it obvious to modify Dynatek by placing Xi’s air compliance chamber downstream of Dynatek’s test valves to, for example, help control undesirable back-pressure. Pet. 46–47, 53–54 (citing, *inter alia*, Ex. 1002 ¶ 161; Ex. 1004, 6). But Xi and Dynatek operate differently. In Xi, the test valves in the parallel test chambers simultaneously force fluid through the system, causing relative changes in the volume of fluid held in the areas before and after the test valves. Ex. 1004, 8, Fig. 4. Xi’s air chambers C₁ 11, C₂ 12 accommodate these volume changes by absorbing or releasing fluid as a function of the test cycle. *Id.*

As Patent Owner observes, Dynatek operates differently. Prelim. Resp. 45. As one bellows is collapsed, another (typically opposing) bellows is expanded, and whatever fluid is drained from the collapsing bellows is accepted into the expanding bellows. Ex. 1006, 5. Thus, the relative volume of fluid before and after the test valves does not change and there is no need for a Xi-style compliance chamber to temporarily store or release fluid due to changes in volume before and after the test valves. Prelim. Resp. 45 (citing Ex. 2003 ¶¶ 90–93). For this reason, we are not persuaded on this record that a POSITA would have combined Xi with Dynatek in the manner suggested by Petitioner.

¹³ Should either party disagree with our understanding of Xi’s principle of operation, as explained herein, it should correct, elaborate on, or provide an alternative explanation of Xi’s principle of operation.

Because Patent Owner's argument is applicable to all challenged claims for this proposed combination, we find Petitioner has not established a reasonable likelihood of showing any claim unpatentable over the combination of Dynatek and Xi, based on its theory described above regarding the combined teachings of both references.

E. Xi – Anticipation and Obviousness (Grounds A, A1, and D)¹⁴

Having found that Petitioner has demonstrated a reasonable likelihood of success in showing that claim 1 is unpatentable over Dynatek and Xi, based on its theory regarding the teachings of Dynatek alone, we need not address Grounds A, A1, and D in detail. However, we write to provide guidance to the parties as to our preliminary views of Grounds A, A1, and D to assist them in further briefing during the trial.

To show anticipation under 35 U.S.C. § 102, each and every claim element, arranged as in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008). The prior art need not, however, use the same words as the claims. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). The anticipation inquiry takes into account the literal teachings of the prior art reference and inferences the ordinarily skilled person would draw from it. *Eli Lilly and Co. v. Los Angeles Biomedical Res. Inst. at Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017).

We are not persuaded that the Petition adequately demonstrates that Xi discloses limitation [1a]. This limitation recites:

¹⁴ Petitioner alleges obviousness for Ground A1, but the only obviousness argument advanced by Petitioner is for dependent claim 13. Thus, we understand Petitioner to argue that Xi anticipates the remaining claims set forth for this ground.

a pressure source configured to drive a test system fluid cyclically within the device above a normal physiological rate, at an accelerated rate of greater than 200 beats per minute within the device;

Petitioner contends that Xi's valve frame and link rod constitute a pressure source that can operate at up to 2,000 beats per minute. Pet. 32–33 (citing Ex. 1004, 5–8; Ex. 1002 ¶¶ 115–117). Xi's linear motor drives the link rod and the valve frame. Ex. 1004, 7. The valve frame is attached to the valve, which closes when the rod is pushed down. *Id.* at 7–8. The closed valve pushes the test fluid down and ultimately causes the fluid to be circulated through the system “back to each test section.” *Id.*

Patent Owner contends that Petitioner improperly relies on Xi's test valve to satisfy two separate elements of claim 1, namely the “pressure source” of this limitation and the “valved prosthetic device” recited in the preamble and limitations [1b1] and [1b2]. Prelim. Resp. 35. According to Patent Owner, Petitioner “requires the test valve to satisfy two elements and be in two locations simultaneously.” *Id.* We disagree with Patent Owner's characterization of Petitioner's argument, but Patent Owner does highlight a fundamental problem with Petitioner's position for this limitation.

Petitioner does not rely on Xi's valve to satisfy the “pressure source” limitation. Pet. 33. Instead, Petitioner relies only on Xi's “valve frame and rod” as being the pressure source. *Id.* (“Thus, Xi's valve frame and rod teach a pressure source to drive fluid cyclically through the device.”) Therefore, Petitioner does not rely on the same structure (Xi's valve) as meeting both the “pressure source” and “valved prosthetic device” limitations.

The problem Petitioner faces, however, is that without the valve, Xi's system has no way of driving the test fluid cyclically within the device, as

required by claim 1. Xi's teachings are clear: it is not the valve frame that drives the fluid, it is the valve itself:

The valve (16) closes due to fluid resistance as the valve frame (6) moves down. This also pushes the liquid down. The liquid flows from each test section (2) to its respective corresponding air chamber C1 (11) and needle valve damper R1 (13) and then flows together into the liquid storage tank (17). The liquid storage tank (17) has a large air chamber C2 (12), and there is a perforated separator (18) below it to prevent water waves. The liquid is divided and diverted back to each test section through the adjustable damper R2 (14).

Ex. 1004, 7–8 (emphasis added). Since Petitioner does not identify Xi's valve as part of what Petitioner contends is the claimed pressure source, Petitioner fails to show sufficiently that Xi discloses the claimed pressure source, which must “drive the test fluid cyclically within the device.”

Ex. 1001, 17:31–32. Therefore, Petitioner fails to show that Xi discloses all of the limitations of claim 1 and, thus, that Xi anticipates any of claims 1–4, 8, 9, and 12 (Ground A), or renders claims 7 or 10 (in combination with Goldstein, Ground D) or 13 (Ground A1) obvious.

F. Goldstein and Lu – Obviousness (Ground C)

1. Goldstein

Goldstein is a U.S. patent that discloses a “closed, sterile pulsatile flow loop for studying tissue valves.” Ex. 1007, code (57). This type of valve testing device is known as a “bioreactor.” *Id.* 1:47, 2:51, 9:46. Figure 3 of Goldstein, which is illustrative of Goldstein's system, is reproduced below:

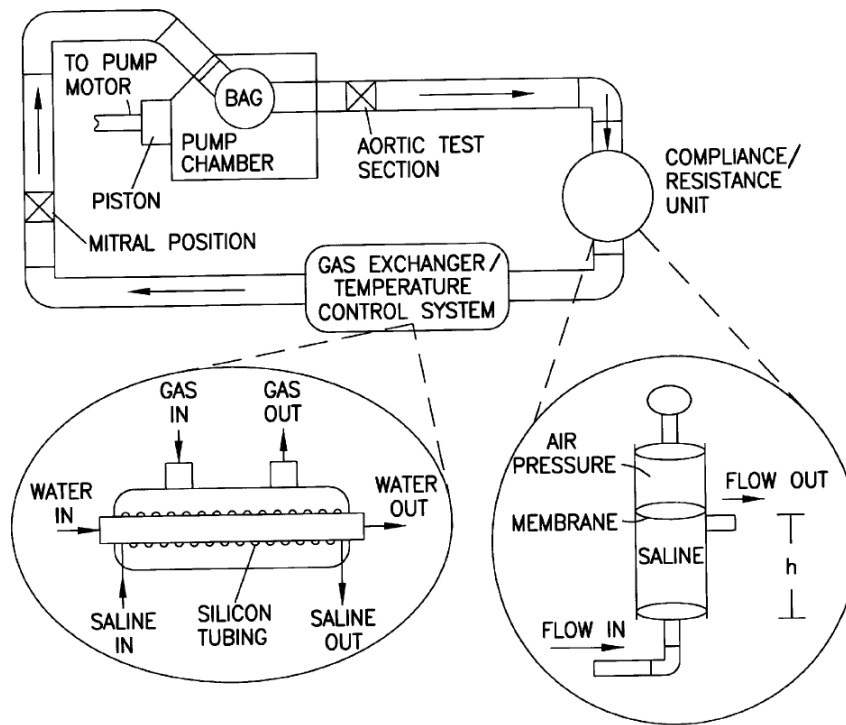


FIG. 3

Figure 3 depicts an in vitro flow loop for analyzing aortic valve function. Ex. 1007, 5:5–6. The system includes a pump chamber with a bag-style pumping device, intended to simulate the human heart. *Id.* at 9:52–67. This bag-style pump is driven by a piston attached to a pump motor. *Id.* The piston pressurizes a fluid which compresses the bag, causing fluid within the bag to be expelled. *Id.* The expelled fluid flows through an aortic test section, where the heart valve being tested is located. *Id.* Once through the valve, the fluid flows into a compliance/resistance unit. *Id.* at 10:30–40. The compliance/resistance unit includes a fluid reservoir and an air-filled chamber above the fluid. *Id.* Fluid entering the unit causes the air in the chamber to be compressed. *Id.* Fluid then exits the unit and flows back through a gas exchanger/temperature control system, through a mitral valve simulator, and then back around to the pump chamber for recirculation. *Id.* at 9:52–67, 10:25–27.

Goldstein teaches that its system is used for the development of living tissue heart valves, in particular to recellularize a xenograft (e.g., pig) valve such that it can be implanted in a human patient with reduced risks of rejection. Ex. 1007, 1:42–48. Goldstein operates at no more than 120 beats per minute (bpm). *Id.* at 10:1–4.

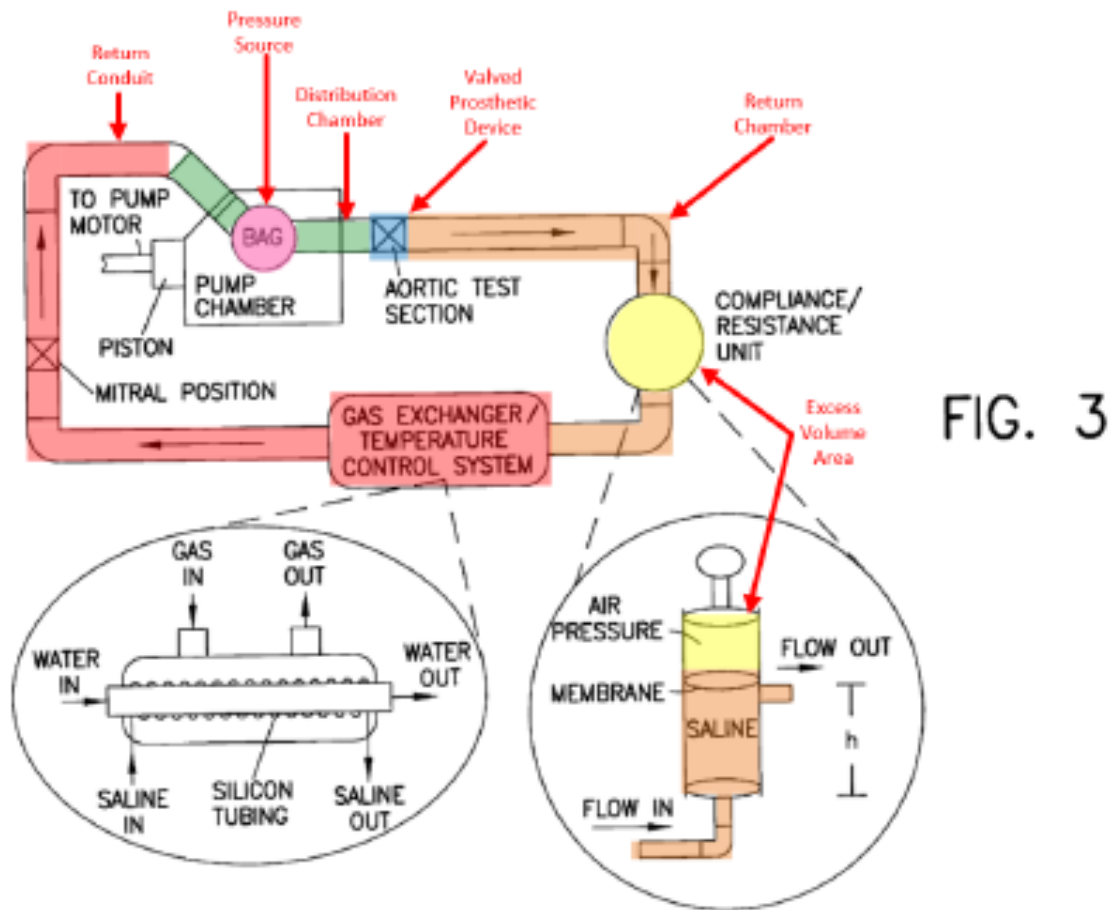
2. *Lu*

Lu is a book chapter that Petitioner alleges was publicly available as of 2003. Pet. 28. Patent Owner does not dispute this contention at this time. Lu discusses accelerated testing of artificial heart valves, and discusses the benefits and potential pitfalls of accelerated testing. Ex. 1005, 185 (predicting valve durability in a short period of time), 189 (finding that significant valve loading causes valve damage at high pulse rates). Lu further discusses a solution to the valve loading problem—adjusting the pulse amplitude and loading force with increasing pulse frequency. *Id.* at 189–90; *see also id.* at 196 (“As the heart rate or frequency (ω) increases, the amplitude and afterload should be decreased to maintain constant loading.”). Implementing these conditions allows an accelerated tester “to more accurately reflect the lifetime of the artificial valve under normal physiological usage.” *Id.* at 190; *see also id.* at 196 (“At constant loading, the artificial valves can undergo accelerated testing while simulating physiological conditions.”).

3. *Analysis of Claim 1*

Petitioner contends a combination of Goldstein and Lu renders claims 1–4, 7–9, 12, and 13 unpatentable as obvious. Pet. 59. Petitioner generally relies on Goldstein for teaching all limitations of these claims, except for the use of the system at “an accelerated pulsed rate of greater than 200 [bpm].” *Id.* at 60. Petitioner relies on Lu for teaching that accelerated testing of heart

valves is beneficial, and for teaching the relationships between flow velocities and forces that a POSITA would have known in order to effectively accelerate a testing system such as Goldstein's.¹⁵ *Id.* In support of its analysis, Petitioner provides an annotated version of Goldstein's Figure 3, which is reproduced below.



Pet. 62. Figure 3 of Goldstein schematically illustrates an in vitro flow loop for analyzing aortic valve function. Ex. 1007, 5:5–6. In particular, “[t]he left ventricular model is shown, and the inset figures illustrate the compliance/resistance element and the gas exchange/temperature control unit.” *Id.* at 5:6–9. In this annotated version of Goldstein’s Figure 1,

¹⁵ Patent Owner also relies on Lu for aspects of the configuration of the drive motor as set forth in dependent claim 3. Pet. 66–67.

Petitioner has indicated with red arrows the return conduit, the pressure source, the distribution chamber, the valved prosthetic device, the return chamber, and the excess volume area. Pet. 62.

a) *Preamble [1pre] A device for accelerated cyclic testing of a valved prosthetic device*

Petitioner does not address whether the preamble is limiting, but contends that Goldstein teaches a “closed . . . flow loop for studying tissue valves.” Pet. 63 (quoting Ex. 1007, code (56)). Petitioner further cites Lu’s teaching that “accelerated testing of heart valves” allows for faster development of heart valves. *Id.* (citing Ex. 1005, Abstr.). Thus, Petitioner contends it would have been obvious “to use an accelerated cycle rate with Goldstein’s device for testing heart valves.” *Id.* (citing Ex. 1002 ¶¶ 210–212).

Patent Owner does not dispute Petitioner’s contentions regarding the preamble at this time. We have reviewed the evidence cited by Petitioner, and we are persuaded preliminarily that the combination of Goldstein and Lu teaches the subject matter of the preamble. Thus, we need not determine whether the preamble is limiting. We further address Petitioner’s rationale for the combination below.

b) *Limitation [1a]: a pressure source configured to drive a test system fluid cyclically within the device above a normal physiological rate, at an accelerated rate of greater than 200 beats per minute within the device;*

Petitioner relies on Goldstein’s teaching of “[a] piston pump . . . used to drive the pulsatile flow.” Pet. 63 (citing Ex. 1007, 9:57–58). Petitioner further cites Goldstein’s teaching that a “flexible rubber bladder” is “mounte[d] inside of a Lexan chamber filled with water.” *Id.* (quoting Ex. 1007, 9:61–62). The piston displaces the water, which “squeeze[s] the

flexible bladder and propel[s] the blood analog fluid out through the aortic valve test section.” *Id.* (quoting Ex. 1007, 9:63–65). Petitioner acknowledges that Goldstein does not teach a rate of greater than 200 bpm, but notes Goldstein’s teaching that the “waveform could be varied in frequency.” *Id.* (quoting Ex. 1007, 7:63–64).

Petitioner contends that a POSITA would have been motivated by Lu and Elizondo¹⁶ “to operate Goldstein at accelerated rates, using an appropriately programmed waveform generator.” Pet. 63 (citing Ex. 1002 ¶¶ 211–212; Ex. 1007, 9:58–60); *see also id.* at 60–62 (discussing Petitioner’s rationale for the combination). According to Petitioner, “Lu shows that designers as early as 2003 thoroughly understood how accelerated test systems operated and how to use compliance in the test systems.” *Id.* at 60 (citing Ex. 1002 ¶¶ 38–43). As such, Petitioner contends that a POSITA “would have been able [to] select and configure a waveform generator and pump to achieve the desired accelerated rate—at minimum over 200 bpm recited by claim 1.” *Id.* at 61 (citing Ex. 1002 ¶¶ 205–206). Petitioner further contends that a POSITA “would have understood from Elizondo¹⁷—a bioreactor capable of accelerated testing—that the benefits of accelerated testing could similarly be applied to a bioreactor like Goldstein with a reasonable expectation of success.” *Id.* (citing Ex. 1002 ¶ 207; Ex. 1007, 1:41–49; Ex. 1027, 1:1–10, 11:33–12:54).

¹⁶ U.S. Patent No. 5,916,800 to Elizondo et al. (Ex. 1027, “Elizondo”).

¹⁷ Elizondo is a U.S. Patent that teaches that a bioreactor-style valve testing system can be operated at an accelerated pulse rate. Ex. 1027, 10:63–12:35. This teaching would, according to Petitioner, inform a POSITA that bioreactors can operate properly at accelerated pulse rates such as those taught by Elizondo and Lu. Pet. 61.

Patent Owner does not dispute that Goldstein teaches a pressure source configured to cyclically drive a test system fluid. We are persuaded preliminarily by Petitioner's showing as discussed above. Instead, Patent Owner argues that it would not have been possible to operate Goldstein's system at accelerated rates, citing examples of the specific composition of the embodiment disclosed in Goldstein. Prelim. Resp. 57 (noting that Goldstein's compliance tank is raised above the rest of the loop, and that the system is a "large volume system and would not be able to function at accelerated rates"). These contentions largely focus on the particular implementation details of the embodiment in Goldstein, and not on what Goldstein would have taught a POSITA. Thus, these contentions are unavailing on this record.

Patent Owner then alleges that a POSITA would have encountered difficulties in 2009 in attempting to speed up a closed, real-time test system. Prelim. Resp. 58–59. Patent Owner contends that closed, real-time systems with compliance chambers have been known for many years yet nobody before Patent Owner had developed a similar but accelerated system. *Id.* at 60 (citing Ex. 2003 ¶ 112). To the extent that Patent Owner is advocating a secondary considerations argument against the combination of Goldstein and Lu, on this record we accord little weight to this argument because it is underdeveloped. This contention also is at least in tension with the disclosures in Lu of six different accelerated testing systems. Ex. 1005, 186. To the extent Patent Owner wishes to pursue this position at trial, Patent Owner is encouraged to fully develop this position, including an explanation of why none of the accelerated systems disclosed in Lu are closed systems.

We are persuaded preliminarily by Petitioner's rationale for accelerating Goldstein's system because Lu teaches that the benefits of

accelerated testing were known. Ex. 1002 ¶ 38; Ex. 1005, 185–86. In addition, Lu also describes the necessary fluid mechanics and mathematical principles behind designing accelerated testers with compliance in a way that accurately reflects the lifetime of tested valves under normal physiological conditions. Ex. 1002 ¶¶ 37, 39–43, 204, 206; Ex. 1005, 187, 189–90. Lastly, Elizondo teaches that bioreactors (like Goldstein) can be successfully operated at accelerated pulse rates. Ex. 1027, 10:63–12:35.

Lastly, Patent Owner contends that accelerating Goldstein to operate at above real-time rates would frustrate the purpose of Goldstein. Goldstein, according to Patent Owner, is intended to assist with the conversion of xenograft valves into autograft valves. Prelim. Resp. 62; Ex. 1007, 1:6–9. Goldstein therefore provides a system that optimizes recellularization and that maintains flow under tissue culture conditions to precondition a living heart valve prior to implantation. Prelim Resp. 62; Ex. 1007, 1:44–48, 4:51–54. Accelerating Goldstein, according to Patent Owner, would “prematurely wear down a heart valve being transformed in preparation for implantation.” Prelim. Resp. 62. Because of this, Patent Owner contends that a POSITA would not have been motivated to accelerate Goldstein’s system.

We do not agree with Patent Owner’s arguments. As discussed above, Lu’s teachings show that it was known to accelerate valve testers with compliance in a manner that does not prematurely damage the valve. *See* Ex. 1005, 189–90. In addition, Elizondo discloses a test chamber for testing non-human biological valves at rates ranging from physiological (70 bpm) to durability (up to 1000 bpm). *See* Ex. 1027, 1:18–22, 11:33–12:15. This supports Petitioner’s contention that a POSITA would have had a reasonable expectation of success in accelerating Goldstein’s system to greater than 200 beats per minute as claimed. We find this evidence sufficient for institution.

- c) *Limitation [1b]: a pressurizable test chamber for containing the test system fluid and further comprising*

Petitioner cites Goldstein's teaching of a closed flow loop for teaching the "pressurizable test chamber" and notes that "[p]ressures are formed in the chamber by clamping the tubing or by raising the compliance tank."

Pet. 64 (citing Ex. 1002 ¶ 213; Ex. 1007, 10:38–42). Patent Owner does not dispute Petitioner's showing at this time. We find Petitioner's evidence sufficient for institution.

- d) *Limitation [1c]: a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source;*

According to Petitioner, Goldstein discloses "a fluid conduit leading from the bladder to a test section" (shown in green in the annotated version of Figure 3 above) that is in fluid communication with the pressure source.

Pet. 64 (quoting Ex. 1007, 24:25–28) (citing Ex. 1002 ¶ 215). Patent Owner does not dispute Petitioner's showing at this time. We find Petitioner's evidence sufficient for institution.

- e) *Limitation [1d]: a fluid return chamber positioned on a second side of the valved prosthetic device;*

Petitioner cites a second fluid conduit in Goldstein for teaching the recited "fluid return chamber." Pet. 64. In particular, Petitioner cites Goldstein's "fluid conduit leading from the test section to a downstream compliance and resistance element," which is shown in orange in the annotated version of Figure 3 above. *Id.* (citing Ex. 1007, 24:28–30). Patent Owner does not dispute Petitioner's showing at this time. We find Petitioner's evidence sufficient for institution.

- f) *Limitation [1e]: a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and*

Petitioner cites a third fluid conduit in Goldstein for teaching the recited “fluid return conduit.” Pet. 64. In particular, Petitioner cites Goldstein’s “fluid conduit leading from the compliance and resistance element to the bladder,” which is shown in red in the annotated version of Figure 3 above. *Id.* (citing Ex. 1007, 24:29–37). Petitioner contends that “this portion of the ‘flow loop’ structurally and fluidly connects the fluid return chamber back to the fluid distribution chamber.” *Id.* at 65 (citing Ex. 1002 ¶ 215). Patent Owner does not dispute Petitioner’s showing at this time. We find Petitioner’s evidence sufficient for institution.

- g) *Limitation [1f]: an excess volume area capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid communication with the fluid return chamber providing a volume for storing a volume of a test system fluid when the test system is under compression*

Petitioner cites Goldstein’s teaching of an “adjustable resistance and compliance element” that is “placed downstream to simulate the peripheral resistance of the circulation.” Pet. 65 (quoting Ex. 1007, 10:27–30). Petitioner further cites Goldstein’s teaching that “[c]ompliance will be provided by allowing the fluid to collect in a Lexan tank and to push against a flexible membrane.” *Id.* (quoting Ex. 1007, 10:30–32). Petitioner contends that a POSITA would have recognized Goldstein’s “adjustable resistance and compliance element” to be a compliance chamber. *Id.* (citing Ex. 1002 ¶ 217). Petitioner also contends a POSITA would have known to adapt Goldstein for accelerated speeds. *Id.* at 65–66 (citing Ex. 1002 ¶ 217; Ex. 1007, 2:8–14). Petitioner additionally contends that a POSITA would have understood “that when Goldstein’s device is accelerated, the

compliance chamber would be capable of mitigating the water hammer effect by ‘allowing the fluid to collect’ in the chamber when the fluid is ‘under compression’—i.e., ‘under pressure’ from the piston and bladder pressure source, even when operated at an ‘accelerated pulsed rate.’” *Id.* at 66 (citing Ex. 1002 ¶ 218; Ex. 1007, 10:30–47).

Patent Owner relies on the same arguments discussed above in which it disputes that a POSITA would have known to accelerate Goldstein’s system. We find those arguments unavailing for the reasons discussed above. Otherwise, Patent Owner does not dispute Petitioner’s showing for this limitation. Thus, we find Petitioner’s evidence sufficient for institution.

h) Conclusion Regarding Claim 1

Because Petitioner has met its burden on institution for all limitations of claim 1, we determine that Petitioner has shown a reasonable likelihood of success in establishing that claim 1 would have been obvious over the combination of Goldstein and Lu.

4. Analysis of Claims 2–4, 7–10, 12, and 13

We have reviewed Petitioner’s evidence for dependent claims 2–4, 7–10, 12, and 13. We need not opine in detail on these dependent claims, but we write to express our preliminary views. We are preliminarily persuaded that the combination of Goldstein and Lu satisfies the limitations of these claims for the reasons expressed in the Petition. Pet. 66–70.

G. Dynatek and Goldstein – Obviousness (Ground E)

Having found that Petitioner has demonstrated a reasonable likelihood of success in showing that claim 1 is unpatentable over Dynatek and Xi, based on its theory regarding the teachings of Dynatek alone, we need not address Ground E in detail. However, we observe that Petitioner has identified the additional elements recited in claims 7 and 10 (a flexible

membrane) in Goldstein. Pet. 68–69. Petitioner further provides sufficient support on this record for why a POSITA would have been motivated to include this flexible membrane in Dynatek, i.e., to preserve the sterility of the test system fluid. Pet. 70–71.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing that at least one of the challenged claims of the '935 Patent is unpatentable. Accordingly, we institute an *inter partes* review on all of the challenged claims and all grounds presented in the Petition. At this stage of the proceeding, we have not made a final determination as to the patentability of any challenged claim.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is instituted as to claims 1–4, 7–10, 12, and 13 of the '935 Patent, with respect to all grounds of unpatentability presented in the Petition; and

FURTHER ORDERED that *inter partes* review is commenced on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of trial.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VIVITRO LABS INC.,
Petitioner,

v.

BIOMEDICAL DEVICE CONSULTANTS & LABORATORIES OF
COLORADO, LLC,
Patent Owner.

IPR2024-00320
Patent 9,237,935 B2

HUDALLA, *Administrative Patent Judge*, concurring.

I concur with my colleagues' decision to institute an *inter partes* review, and I agree with my colleagues' analysis in almost all respects. I write separately to express a difference of opinion regarding the majority's analysis of unpatentability over (1) Dynatek without Xi; and (2) the combination of Dynatek and Goldstein without Xi.

I agree with my colleagues that Petitioner does not put forth a sufficient rationale for combining Xi with Dynatek and, as such, Petitioner does not establish a reasonable likelihood of prevailing with respect to Ground B based on the combination of Dynatek and Xi. The majority also considers Ground B to recite an obviousness ground based on Dynatek

alone, but I find that Petitioner puts forth no such ground in the Petition. Specifically, the table of grounds lists only combinations of Dynatek with other references. Pet. 27–28. Moreover, Petitioner’s analysis of Dynatek specifically mentions combinations with at least Xi. *See, e.g.*, Pet. 50 (“As shown in the chart below, *the combination of Dynatek and Xi* renders claim 1 obvious” (emphasis added)), 53 (“A [POSITA] would have therefore found it obvious to use either of Dynatek or Xi’s air chambers as a compliance chamber (i.e., excess volume area) *in a combined system* to provide additional control of loading forces and address the well-known water hammer effect.” (emphasis added)), 55 (“Thus, obvious use of a compliance chamber *in the combined system* would meet the limitation of [1f.3] and perform the same function recited in the claim.” (emphasis added)).

I am mindful of the U.S. Supreme Court’s admonition that “[n]othing suggests the Director enjoys a license to depart from the petition and institute a different *inter partes* review of [her] own design.” *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 138 S. Ct. 1348, 1356 (2018); *see also Sirona Dental Sys. GmbH v. Institut Straumann AG*, 892 F.3d 1349, 1356 (Fed. Cir. 2018) (“It would . . . not be proper for the Board to deviate from the grounds in the petition and raise its own obviousness theory.”). The Petition undoubtedly contains some alternative language in Petitioner’s analysis of the Dynatek–Xi ground, but I do not believe that the Petition can be read fairly to advance an obviousness theory based on Dynatek alone. I also have considered the cases cited by the majority, including *Realtime Data LLC v. Iancu*, 912 F.3d 1368 (Fed. Cir. 2019), and *Polygroup Limited MCO v. Willis Electric Company, Ltd*, 759 Fed. App’x 934 (Fed. Cir. 2019), and I find them

distinguishable insofar as the petitions in those cases more clearly advanced alternate theories for an asserted ground.

Additionally, as a matter of policy, I do not think we should condone or encourage petitions that purport to include alternative grounds based on subtleties. To do so is antithetical to the rule that a petition must “[p]rovide a statement of the *precise* relief requested for each claim challenged.”

37 C.F.R. § 42.104(b) (2024) (emphasis added). The Board should not have to parse through the analysis in a clearly expressed ground and determine whether the analysis also includes the bare minimum to advance an alternative ground by implication. *Microsoft Corp. v. FG SRC, LLC*, 860 F. App’x 708, 713 (Fed. Cir. 2021) (“It is not the Board’s job to cobble together assertions from different sections of a petition or citations of various exhibits in order to infer every possible permutation of a petitioner’s arguments. Arguments in a petition must be made with particularity, not opacity”) Nor should a patent owner have to face such uncertainty when crafting its responses.

Accordingly, I would decline to consider an obviousness theory based on Dynatek without Xi. By extension, I also would not consider an obviousness theory based on the combination of Dynatek and Goldstein without Xi.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VIVITRO LABS INC.,
Petitioner,

v.

BIOMEDICAL DEVICE CONSULTANTS & LABORATORIES OF
COLORADO, LLC,
Patent Owner.

IPR2024-00320
Patent 9,237,935 B2

DAYBELL, *Administrative Patent Judge*, concurring.

I concur with my colleagues' decision to institute an *inter partes* review, and I agree with nearly all of my colleagues' analysis. I write separately to express a difference of opinion regarding the construction of the term "in fluid communication."

Claim 1 recites "a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source," and "an excess volume area . . . in fluid communication with the fluid return chamber." Ex. 1001, 17:37–39, 17:45–50. Petitioner contends that this term means "that fluid can flow from one referenced element to another." Pet. 18. Patent Owner disagrees, contending that this term means

that “fluid can move from one area to another unimpeded.” Prelim. Resp. 20. The parties agree that “in fluid communication” requires that fluid can flow from one referenced element (or area) to another. The crux of the dispute is whether “communication” requires the flow of fluid between two areas be “unimpeded,” or allows for both impeded and unimpeded fluid flows.

I turn first to the language of claim 1. Claim 1 recites a testing device having “a pressure source configured to drive a test system fluid cyclically within the device.” Ex. 1001, 17:31–32. The claim further recites a “fluid distribution chamber” that is “in fluid communication with the pressure source.” *Id.* at 17:37–39. In addition, it recites a “fluid return chamber” and a “fluid return conduit both structurally and fluidly connecting” the distribution chamber to the return chamber. *Id.* at 17:40–44. Finally, the claim recites an “excess volume area” that is “in fluid communication with the fluid return chamber.” *Id.* at 17:46–47.

Claim 1, therefore, recites two different fluid relationships that are present in the claimed system. Certain components are claimed as being “in fluid communication” with each other, whereas others components are described as being “fluidly connect[ed].” *Compare id.* at 17:37–39, 17:46–47, *with id.* at 17:40–44. Where a patentee uses different language to describe different elements of a claim, I may presume that the patentee intended to afford different meanings to that language. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1129–30 (Fed. Cir. 2004). Here, the difference in meaning between “connecting” and “in communication” supports Patent Owner’s position that “communication” requires an “unimpeded” flow of fluid. *Compare* Ex. 3001 (“connect: to join or fasten together usually by something intervening”), *with* Ex. 3002

(“communicate: to transmit information, thought or feeling so that it is satisfactorily received or understood”).¹⁸

The specification is consistent with this understanding of the term “in fluid communication.” The specification recites:

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.

Ex. 1001, 9:29–31 (emphasis added).

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.

Id. at 9:41–43 (emphasis added).

Figure 3 of the '935 Patent, reproduced at page 4 of the *per curiam* opinion, shows the relationships between the return conduits 168 and the sample holders 129 and compliance chambers 135. In both relationships, there is nothing depicted which would impede the flow of fluid between the conduits 168 and the regions defined by the sample holders 129. Similarly, there is nothing depicted which would impede the flow of fluids between the compliance chambers 135 and the conduits 168.

The specification further recites:

A temperature transducer 139 and a water level sensor 144 may be placed *in communication* with the central return basin 133

Id. at 9:63–65 (emphasis added).

In Figure 3, the temperature transducers 139 and water level sensors 144 are directly in contact with the central return basin 133, and thus there is

¹⁸ The term “communicate” as applied to fluids would be understood to mean that the fluids were “satisfactorily received,” i.e. that the flow was unimpeded.

nothing which would impede fluid flow between those components and the basin 133. Therefore, the structures in claim 1 that are recited as being “in fluid communication” with each other are described and depicted in the specification as having an unimpeded fluid flow between them.

Additionally, the specification consistently uses “in communication” to refer to relationships where nothing impedes the transfer of the relevant entity (be it fluid or heat).

By contrast, the claimed fluid return conduit “fluidly connects” the fluid distribution chamber to the fluid return chamber. Ex. 1001, 17:42–44. The structures which make up the fluid pathway between the fluid return conduits 168 and the cavity defined by the fluid distribution chamber 126, corresponding to the claimed fluid return conduit, include several structures that impede the flow of fluids. Turning again to Figure 3, the fluid flow out of the fluid return conduits 168 is depicted by dashed arrows. Ex. 1001, Fig. 3. First, this fluid flow passes from the fluid return conduits 168 into the central return basin 133. *Id.*, 9:41–43. This flow is regulated by a throttle valve 132. *Id.* at 9:32–40. Once the fluid passes through the throttle valves and into the central return basin 133, the fluid flows down into a center return conduit 124 and into a center bore 164. *Id.* at 8:23–26. The center bore 164 terminates in a one-way valve 127. *Id.* at 8:38–44. This one-way valve entirely blocks fluid from flowing upwards in the center conduit 124. *Id.* at 11:63–67. Fluid is only allowed to flow downwards, from the center conduit 124 into the cavity formed by the fluid distribution chamber 126. *Id.*, F11:64–67, Fig. 3. These impediments to fluid flow are consistent with the Patent Owner’s usage of different claim language (“in fluid communication” vs. “fluidly connecting”) where it intended to convey a difference in meaning. *Innova/Pure Water*, 381 F.3d at 1129–30.

Based on the intrinsic evidence discussed above, I would adopt Patent Owner's construction for the term "in fluid communication," as meaning "the relative position of two elements to permit fluid to pass unimpeded between the two elements."

Accordingly, to demonstrate unpatentability over Dynatek, I would require Petitioner to establish for limitation [1c] that the fluid distribution chamber and the pressure source have an unimpeded fluid flow between them. I would however find, as shown in Petitioner's annotated version of Figure 1A, that when the test valve is closed there is a flow of fluid from the lower head through the throttle valve to the upper head. Pet. 45. This fluid flow is affected only by the presence of the throttle valve. The Dynatek manual teaches that this valve is used to fine tune back pressure on the test valve. Ex. 1006, 18. This valve does not otherwise interfere with fluid flows from the lower head to the upper head. *Id.* at 18–19. Of course, when the test valve is open, fluid flows unimpeded from the upper head past the open valve to the lower head and into the bellows. Ex. 1006, 5. On this record, I thus would find that this flow of fluid is sufficient to place the lower head in fluid communication with the upper head, and thus place the pressure source (bellows) in fluid communication with the fluid distribution chamber (upper head) under the claim construction I believe is proper here.

Similarly, for limitation [1f], I would require Petitioner to establish that the excess volume area and the fluid return chamber have an unimpeded fluid flow between them. I would find on this record, however, that Petitioner's proposed modification of Dynatek to connect the capacitance tank to the lower head would satisfy such a requirement. Pet. 54 (citing Ex. 1002 ¶¶ 160–161, 182).

For Ground C, I would find that Petitioner has preliminarily demonstrated that Goldstein’s fluid conduit is in fluid communication with Goldstein’s bladder, as required by limitation [1c]. Pet. 64 (citing Ex. 1007, 24:25–28; Ex. 1002 ¶ 215. I would further find that Petitioner has preliminarily demonstrated that Goldstein’s adjustable resistance and compliance element is in fluid communication with Goldstein’s “fluid conduit leading from the test section to a downstream compliance and resistance element.” Pet. 64–65 (citing Ex. 1007, 10:27–30, 24:29–37).

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