

No. 2023-2393

IN THE
United States Court Of Appeals
FOR THE FEDERAL CIRCUIT

BIOMEDICAL DEVICE CONSULTANTS & LABORATORIES OF
COLORADO, LLC,

Plaintiff-Appellant,

v.

VIVITRO LABS, INC.,

Defendant-Appellee.

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

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

APPELLANT'S REPLY BRIEF

Gregory S. Tamkin
tamkin.greg@dorsey.com
DORSEY & WHITNEY LLP
1400 Wewatta Street, Suite 400
Denver, CO 80202-5549
Telephone: (303) 629-3400

Shannon L. Bjorklund
bjorklund.shannon@dorsey.com
DORSEY & WHITNEY LLP
50 South Sixth Street, Suite 1500
Minneapolis, MN 55402-1498
Telephone: (612) 340-2600

Counsel for Plaintiff-Appellant

December 4, 2023

Petitioner's Exhibit 1026
VIVITRO v. BDC
IPR2024-00320

TABLE OF CONTENTS

INTRODUCTION	1
ARGUMENT	2
I. ViVitro Fundamentally Misinterprets the District Court’s Opinion.....	2
II. The District Court Erroneously Construed the Claims	5
A. In Requiring a “Compliance Chamber,” the District Court Erroneously Read a Limitation Into the Claims and Violated the Principle of Claim Differentiation	6
B. ViVitro Concedes That the Fluid and Gas Need Not Be “Touching,” and the Court’s Construction Otherwise Is Now Undisputed Error.....	8
C. The Excess Volume Area Need Not Be “Separate from” and Outside of the Return Chamber	8
D. ViVitro’s Belated “Means-Plus-Function” Construction Is Both Waived and Unavailing.....	10
III. When the Court’s Undisputedly Incorrect Construction Is Stripped Away, BDC Has Shown a Substantial Likelihood of Infringement	12
A. Under a Proper Construction of “Excess Volume Area,” the Accused Product Unquestionably Infringes	13
B. Even If Only One Portion of the Court’s Construction Is Removed—That the Gas and Fluid Must Touch, Which Is Conceded Error—BDC Has Shown a Substantial Likelihood of Success on Infringement.....	14
C. BDC’s Statement in an Unrelated IPR Does Not Somehow Negate Infringement	15
D. Even If ViVitro’s Waived “Means-Plus-Function” Construction Were Applied, BDC Has Still Shown a Likelihood of Infringement.....	16
IV. ViVitro Has Not Raised a “Substantial Question” as to Validity	16
A. ViVitro Has Not Demonstrated That Dynatek Anticipates	16
1. The Dynatek Capacitance Tank Is Not “In Fluid Communication” with the Return Chamber.....	17
2. The Dynatek Capacitance Tank Is Not “Under Compression”	19

3.	The Dynatek Capacitance Tank Is Not an Excess Volume Area Operating an Accelerated Rate	21
4.	The Dynatek Anticipation Defense Resolves Only Four of Eight Claims	22
V.	ViVitro Has Failed to Meet Its Burden to Show Obviousness	23
A.	ViVitro Has Failed to Show That All Elements Exist in the Prior Art	23
B.	The District Court Correctly Concluded That ViVitro Had Failed to Demonstrate a Motivation to Combine	26
CONCLUSION		27

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>AK Steel Corp. v. Sollac</i> , 344 F.3d 1234 (Fed. Cir. 2003)	9
<i>In re Berger</i> , 279 F.3d 975 (Fed. Cir. 2002)	10
<i>Genuine Enabling Tech. LLC v. Nintendo Co.</i> , 29 F.4th 1365 (Fed. Cir. 2022)	8
<i>Interactive Gift Express, Inc. v. CompuServe Inc.</i> , 256 F.3d 1323 (Fed. Cir. 2001)	10
<i>Kinetic Concepts, Inc. v. Smith & Nephew, Inc.</i> , 688 F.3d 1342 (Fed. Cir. 2012)	26
<i>Mylan Pharms., Inc. v. Thompson</i> , 268 F.3d 1323 (Fed. Cir. 2001)	12
<i>N. Telecom Ltd. v. Samsung Elecs. Co.</i> , 215 F.3d 1281 (Fed. Cir. 2000)	16
<i>RF Del., Inc. v. Pac. Keystone Techs., Inc.</i> , 326 F.3d 1255 (Fed. Cir. 2003)	6, 7
<i>Sage Prods., Inc. v. Devon Indus., Inc.</i> , 126 F.3d 1420 (Fed. Cir. 1997)	10, 25
<i>SciMed Life Sys. v. Advanced Cardiovascular Sys.</i> , 242 F.3d 1337 (Fed. Cir. 2001)	6
<i>Trebro Mfg. v. FireFly Equip., LLC</i> , 748 F.3d 1159 (Fed. Cir. 2014)	5, 6
<i>In re Watts</i> , 354 F.3d 1362 (Fed. Cir. 2004)	10
<i>Williamson v. Citrix Online, LLC</i> , 792 F.3d 1339 (Fed. Cir. 2015)	11

Statutes

35 U.S.C. §112.....	9
---------------------	---

INTRODUCTION

The district court’s analysis is premised on what it described as an application of the plain and ordinary meaning of the claim term that was the focus of the briefing below. But on appeal, both parties acknowledge that the district court did *not* apply the plain and ordinary meaning. App. Br. at 28-29; App’ee Br. at 23. BDC asks this Court to apply the actual plain and ordinary meaning; by contrast, ViVidro seeks to import limitations from the specification into its construction. Ordinary principles of claim construction, when applied in any reasonable way, lead to the conclusion that BDC has demonstrated a likelihood of infringement. Because the district court’s claim construction is flawed as a matter of law, and because the construction is dispositive of infringement, this Court effectively reviews both claim construction and infringement *de novo*. Further, even reversing only that portion of the construction that both parties agree is incorrect—the requirement that the gas touch the fluid—results in reversal, as BDC has therefore shown a likelihood of infringement. *See* Part III.B.

The district court was equally off base in assessing invalidity. For example, it found that ViVidro met its burden of invalidating all claims based on anticipation, when the alleged anticipating reference was only asserted against half the claims. Even as to those claims, ViVidro failed to show the claimed “excess volume area” and ViVidro’s own expert acknowledges the absence of that element in the reference.

Perhaps recognizing this weakness, ViVidro asserts a new reference in its statement of facts, Lu, that was never asserted as a primary or even secondary reference below and raises several new arguments with no record factual support. Ultimately, ViVidro wholly fails to meet its “substantial question” burden on obviousness as it failed to show a motivation to combine nor did it make any showing to rebut the objective indicia of non-obviousness.

That ViVidro found it necessary to submit 68 pages of briefing and introduce a series of new arguments demonstrates the weakness of its position. None of ViVidro’s arguments, new or old, change the fundamental point: the district court erred in ruling that BDC did not demonstrate a likelihood of infringement, and erred in ruling that ViVidro had showed a substantial question of invalidity.

ARGUMENT

I. VIVITRO FUNDAMENTALLY MISINTERPRETS THE DISTRICT COURT’S OPINION

The core of this appeal is the district court’s 10.5-page order denying BDC’s request for a preliminary injunction. To justify that order, ViVidro misinterprets and misconstrues it. *See, e.g.*, App’ee Br. at 15. Before considering ViVidro’s arguments, it is critical to understand what the district court held and what it did not.

The court stated: “[t]he plain and ordinary meaning of ‘excess volume area,’ as used in Claim 1 and as supported by the teachings of the specification, is a compliance chamber that is *separate* and *needs to be fluidly connected*.” APPX0010

(emphasis in original). Both parties agree, however, that the court did not apply a “plain and ordinary meaning.” It limited the term “excess volume area” to be the “compliance chamber” disclosed in the specification. App. Br. at 28-29; App’ee Br. at 23. To further understand the scope of this construction, it is instructive to examine the district court’s numbered paragraphs on non-infringement. “First,” the district court determined that the “excess volume area” requires a compliance chamber that is separate from the fluid return chamber, relying upon the preferred embodiment described in the specification. APPX0007-08. “The claim language suggests that the excess fluid is going somewhere, and the specification implies it is the [compliance] *chamber* where the fluid is moving into.” APPX0007 (emphasis in original). “Second,” the district court determined that if there is material deformation, there cannot be an excess volume area, (mis)citing BDC’s statement in an IPR proceeding for a different patent.¹ APPX0007-08. “Third,” the district court determined that the accused excess volume area was not in fluid communication with the return chamber, because the “closed” compliance rings separated the air from the gas. APPX0008 (“[T]he area within the tubes’ is a closed chamber. No ‘fluid communication’ exists between the tubes and any other part of the device.”). “And

¹ This conclusion is plainly wrong. Material deformation and use of an excess volume area are not mutually exclusive. The specification itself provides examples of an excess volume area co-existing with a membrane or elastomeric material that materially deforms. Dependent Claim 7 specifically claims that very concept. APPX0029 at 12:33-39; APPX0032 at 18:19-24.

fourth,” the district court determined that the excess volume area in Claim 1 could not be located within the fluid return chamber. “If BDC’s interpretation of ‘excess volume area’ in Claim 1 always contemplated ‘within the fluid return chamber,’ then Claim 9 would not add anything.” APPX0009.²

The district court next turned to invalidity, stating that ViVistro’s expert “declaration supports the view that Dynatek discloses every element of Claim 1 and thus anticipates Claim 1 and other dependent claims,” presumably (but not explicitly) adopting the view that there is a substantial question of anticipation of Claims 1, 2, 8 and 13, which were the claims asserted as anticipated by ViVistro. APPX0011; APPX1186 (ViVistro expert). As to obviousness, however, the court was unable to conclude that there was a motivation to combine: “[s]imilar doubts remain for the concept of obviousness, and the Court will benefit from future briefing to determine whether the teachings of Xi, Dynatek and Lu could have been combined.” APPX0011-12. The district court did *not* rule that ViVistro had met its burden to show substantial question, based on the ultimate clear-and-convincing standard, that there was a motivation to combine Dynatek and Xi, as ViVistro now claims. App’ee Br. at 53. Instead, the district court reserved judgment on the issue of motivation to combine, leaving Claims 3, 4, 9 and 12 unrebutted as to validity.³

² The district court apparently believed, incorrectly, that a dependent claim must add a new feature not existing in the independent claim. *See* Part II.C.

³ ViVistro has never contended that Xi or Lu anticipate the ’935 Patent, and has never contended that Claims 3, 4, 9 or 12 are anticipated by Dynatek. APPX0324-25

II. THE DISTRICT COURT ERRONEOUSLY CONSTRUED THE CLAIMS

The district court construed “excess volume area” to require (1) a compliance chamber, (2) that is “separate from” and not within the fluid return chamber, and (3) in which the fluid and gas are not separated by a membrane. App. Br. at 23-37. All aspects of this interpretation are wrong, and should be reversed.⁴

As described in Claim 1 of the '935 Patent, an “excess volume area” is an area “capable of operating at the accelerated pulsed rate” that provides a “volume for storing a volume of a test system fluid when the test system fluid is under compression.” APPX0032 at 17:45-50. During compression, the area filled with gas is compressed, and fluid can flow into the volume formerly occupied by the uncompressed gas. APPX0029 at 12:5-39. The excess volume area is the area that can be filled with fluid during the compression stroke, and filled with gas when the system is not under compression.

¶45; APPX1183 ¶45; APPX1690; APPX1186. The district court never considered any dependent claim other than to erroneously note that Claim 9 should be adding to the independent claim, instead of narrowing it.

⁴ ViVitro overstates the standard of review, by claiming that “even a clearly erroneous factual finding is not itself sufficient to reverse,” citing a non-patent case. App’ee Br. at 18. As this Court has noted, in applying Ninth Circuit law, a district court abuses its discretion when it applies the wrong law (including wrong construction of a claim term), a question that is reviewed *de novo*. See *Trebro Mfg. v. FireFly Equip., LLC*, 748 F.3d 1159, 1166-68 (Fed. Cir. 2014) (reversing denial of preliminary injunction); App’ee Br. at 18, citing *Trebro*.

A. In Requiring a “Compliance Chamber,” the District Court Erroneously Read a Limitation Into the Claims and Violated the Principle of Claim Differentiation

In construing that the “excess volume area” is a “compliance chamber,” the district court committed a “cardinal sin” of claim interpretation: it limited the claim language based on two figures depicting a preferred embodiment, and it also construed the terms in such a way as to render a dependent claim meaningless. *SciMed Life Sys. v. Advanced Cardiovascular Sys.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001); *Trebro Mfg.*, 748 F.3d at 1167; App. Br. 30-34. This construction must be reversed.

ViVitro now argues that the description of the preferred embodiments shows that the compliance chamber is the only possible embodiment: “The compliance chambers are the *only* structures identified in the patent that perform the compliance function, or the functions recited in claim 1 for the ‘excess volume area’ term.” App’ee Br. at 26. But, failing to describe other examples does not limit the claims to the preferred embodiment. *RF Del., Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1264 (Fed. Cir. 2003) (“An independent claim usually covers a scope broader than the preferred embodiment, especially if the dependent claims recite the precise scope of the preferred embodiment.”). If that were the case, an inventor would be required to describe all possible examples in the specification, as opposed to only a preferred embodiment. In any event, here, the inventor specifically acknowledged

additional embodiments, such as those separated/created by a membrane or elastomeric material. *Id.*; APPX0032 at 18:19-24.

Perhaps recognizing that the inventors did not indicate in the specification any intention to limit “excess volume area” to a “compliance chamber,” ViVitro argues that the meaning of “excess volume area” was dramatically limited and redefined by BDC’s use of “i.e.” *one time* in the file history. App’ee Br. at 27.⁵ This alone demonstrates the weakness of ViVitro’s argument. In that passage, BDC explains the purpose of the excess volume area by referencing back to a feature of the preferred embodiment.

The purpose of the excess volume areas (i.e., compliance chamber(s)) as claimed in the method of independent claim 1 [not at issue in this lawsuit] is “to act as a resilient spring force to dampen the effects of large, quickly changing pressure gradients within the test chamber” in the test system during the accelerated frequency testing. (*See* Specification ¶0046.)

APPX1391. By using “i.e.,” BDC was referring with more specificity to the aspect to which it pointed in this particular example; it was not attempting to indirectly define the full scope of the preceding word. This use is consistent with how BDC uses “i.e.” the six other times it appears in that 7-page set of remarks. *See, e.g.*, APPX1386 (“the industry (i.e., a person of ordinary skill in the art)”); APPX1391 (“causes flow by moving the test system with respect to the fluid within the system

⁵ Even the sources cited by ViVitro note that “i.e.” *may* be definitional, but they do not assert that every use of i.e. is definitional. *See* App’ee Br. at 27-28.

(i.e., it uses a ‘swashplate’ or a ‘shaker table’)). Just as one cannot reasonably suggest that BDC attempted to define the broad term “industry” as meaning only a “person of ordinary skill in the art,” one cannot reasonably read BDC’s reference to a particular preferred embodiment as rewriting the scope of its claim. Such an ambiguous and passing reference cannot support prosecution history estoppel, nor can it re-define a claim term as ViVitro contends. In short, the inventors in no way made the clear and unmistakable disavowal of claims scope necessary for ViVitro’s or the course construction. *Genuine Enabling Tech. LLC v. Nintendo Co.*, 29 F.4th 1365, 1374 (Fed. Cir. 2022) (disavowal must be “clear and unmistakable,” a high burden).

B. ViVitro Concedes That the Fluid and Gas Need Not Be “Touching,” and the Court’s Construction Otherwise Is Now Undisputed Error

In ViVitro’s words: “It is undisputed that the patent discloses a membrane may ‘separate the air or gas from the working fluid.’” App’ee Br. at 28. BDC agrees. This fatally undermines the district court’s determination that to be “fluidly connected” the gas and fluid must not be separated by a membrane. The court’s claim construction finding that the membrane of the compliance rings precludes infringement is reversible error as a matter of law.

C. The Excess Volume Area Need Not Be “Separate from” and Outside of the Return Chamber

ViVitro does not try to defend the district court’s determination that Claim 1 requires an excess volume area to be outside of the fluid return chamber. App’ee Br.

at 29-30. ViVitro instead argues that there was no such finding, and the district court only “questioned” the applicability of this feature to the Accused Product. *Id.* But since the limitation was a basis for a finding of non-infringement, it was undoubtedly part of the claim construction. APPX0009.

The language of Claim 1 does not restrict location. By contrast, dependent Claim 9 recites a compliance chamber “within” the fluid return chamber. By definition, a dependent claim is narrower than an independent claim. 35 U.S.C. §112, ¶4; *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1242 (Fed. Cir. 2003). The court fundamentally misunderstood the nature of a dependent claim and how claim differentiation works when it read Claim 1 as something not inclusive of Claim 9. APPX009. If Claim 9 provides that a compliance chamber can be within a fluid return chamber, not only is a compliance chamber not intended to be the only excess volume area, but the excess volume area can certainly be within a return chamber. *AK Steel Corp.*, 344 F.3d at 1242 (“[T]he independent claims [] must be at least as broad as the claims that depend from them....”). Claim 1 can only be reasonably interpreted to cover excess volume areas both inside and not inside the fluid return chamber, such that Claim 9 narrows this scope. Thus, the Accused Product—which contains an excess volume area that is undisputedly within the fluid return chamber—would meet this aspect of both Claim 1 and Claim 9, and any suggestion otherwise by the district court must be reversed.

D. ViVistro’s Belated “Means-Plus-Function” Construction Is Both Waived and Unavailing

In an attempt to justify the district court’s decision, ViVistro raises a new proposed construction never raised below: “§112 ¶6 applies to the ‘excess volume area’ limitation, and it should be construed to cover, at most, the structure (and equivalents) in the specification—the compliance chambers.” App’ee Br. at 35.

As an initial matter, this new proffered claim construction is waived, because it was not presented below or considered by the district court. *In re Watts*, 354 F.3d 1362, 1368 n.3 (Fed. Cir. 2004). “With a few notable exceptions, such as some jurisdictional matters, appellate courts do not consider a party’s new theories, lodged first on appeal.” *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1426 (Fed. Cir. 1997). This is because “it is [this Court’s] place to review judicial decisions—including claim interpretations and grants of summary judgment—reached by trial courts.” *Id.* If an issue was not presented to the district court, it necessarily was not reached by that court, and cannot now be “reviewed.” *See, e.g., In re Berger*, 279 F.3d 975, 984 (Fed. Cir. 2002). While this Court may consider additional arguments “clarifying or defending the original scope of [the] claim construction,” it will not consider new constructions first offered on appeal. *Interactive Gift Express, Inc. v. CompuServe Inc.*, 256 F.3d 1323, 1347 (Fed. Cir. 2001). Thus, this argument should be disregarded.

Even if it were considered, it should be rejected. The primary case upon which ViVitro relies, *Williamson v. Citrix Online, LLC*, 792 F.3d 1339 (Fed. Cir. 2015), is so different as to be inapplicable. As ViVitro admits, it must overcome a presumption that “excess volume area” is *not* a means-plus-function term. App’ee Br. at 32. ViVitro cannot meet that burden. Indeed, the reasoning of *Williamson* undermines—not supports—ViVitro’s argument. The *Williamson* court construed a computer-based patent that claimed “a *distributed learning control module* for receiving communications....” *Williamson*, 792 F.3d at 1344 (emphasis in original). After observing that “[m]odule’ is a well-known nonce word,” *id.* at 1350, the court concluded that the limitation, described solely in functional terms, should be construed as means-plus-function. That ruling makes sense in the context of a computer program patent, where there is no physical or spatial area that “module” could refer to. But the facts of this case are entirely different. ViVitro has not cited, and BDC has not located, any case indicating the words “area,” “location” or “space” are recognized nonce words. And unlike *Williamson*, the ’935 Patent specification describes what may constitute an excess volume area, providing examples of a volume of “compressible air,” a volume separated by an “elastomeric material,” and “porous material.” APPX0032 at 18:19-24. For these reasons alone, ViVitro’s argument fails.

Even if the Court were to consider ViVistro's argument, and even if it were to adopt a means-plus-function construction, ViVistro's proposed construction is unduly narrow; it does not address even the various disclosures in the specification, which include use of membranes, elastomeric material, and compressible air.

III. WHEN THE COURT'S UNDISPUTEDLY INCORRECT CONSTRUCTION IS STRIPPED AWAY, BDC HAS SHOWN A SUBSTANTIAL LIKELIHOOD OF INFRINGEMENT

The issue of infringement is a pure matter of claim construction, and is thus decided *de novo* by this Court. *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1329 (Fed. Cir. 2001) (“[T]o the extent that a district court’s decision to grant [or deny] a preliminary injunction hinges on questions of law, [this Court’s] review is *de novo*.”). There is no dispute as to the operation of ViVistro’s Accused Product, nor is there any dispute that the Accused Product meets every limitation of claim 1 apart from the “excess volume area” limitation. The only question for this Court is whether the Accused Product has an “excess volume area ... in fluid communication with the fluid return chamber providing a volume for storing a volume of a test system fluid when the test system fluid is under compression.” App’ee Br. at 23-37 (raising “excess volume area” as sole non-infringement defense); App. Br. at 41; APPX1205 ¶91 (ViVistro’s expert); APPX0006-10 (court order addressing only “excess volume area”).

To conclude there is no likely infringement, the district court used a very narrow and flawed construction with a number of non-existent limitations. This

construction cannot stand; even ViVidro admits there can be no reasonable requirement that the gas touch the fluid. *See* App’ee Br. at 28. Even if the other two portions of the district court’s construction remain (a compliance chamber that is separate from the return chamber), BDC has demonstrated a likelihood of success of infringement. Because any reasonable interpretation of “excess volume area” leads to the conclusion that the Accused Product meets this limitation, BDC has demonstrated (more than) a likelihood of success on infringement.

A. Under a Proper Construction of “Excess Volume Area,” the Accused Product Unquestionably Infringes

ViVidro offers no non-infringement argument that applies to BDC’s construction. App’ee Br. at 37-38. Instead, it argues only that there is a “failure of proof” that there is “compression” in ViVidro’s system. App’ee Br. at 37. This strained argument ignores the record evidence. All sources—ViVidro’s product materials, ViVidro’s expert, and BDC’s expert—recognize that the test fluid of the Accused Product is “under compression.”

In the words of ViVidro’s expert: “A POSA understands that ‘compliance’ is the ability of a system with a fluid to absorb pressure changes, and that ‘providing compliance’ refers to providing a feature that absorbs pressure changes.” APPX1117-18 at ¶27. ViVidro itself describes its rings as “annular compliance rings [that] optimize differential pressure waveforms.” *See* APPX0964. These “compliance” rings therefore absorb pressure changes to the test system fluid.

APPX0925 ¶33 (BDC expert). BDC has shown a substantial likelihood of infringement.

B. Even If Only One Portion of the Court's Construction Is Removed—That the Gas and Fluid Must Touch, Which Is Conceded Error—BDC Has Shown a Substantial Likelihood of Success on Infringement

Both parties agree that the '935 Patent does not require that the gas and the fluid be directly touching; they may be separated by a membrane. App'ee Br. at 28. Thus, the fact that the compliance rings are “closed” is irrelevant, and the court's ruling that the separation between gas and fluid demonstrates that there is no “fluid communication” must be reversed. *See* APPX0008 (“[T]he area within the tubes’ is a closed chamber. No ‘fluid communication exists’ between the tubes and any other part of the device. The ‘fluid communication’ requirement of Claim 1 is not met.”).

Even reversal of this one portion leads to the conclusion that BDC has demonstrated a likelihood of success on infringement. ViVitro erroneously asserts there is undisputed non-infringement under any construction of “excess volume area” that requires a compliance chamber. *See* App'ee Br. at 36 (“There is no dispute that the ADC tester does not infringe under a construction requiring a separate compliance chamber (or equivalent) structure.”); *see also id.* at 20. This is incorrect. BDC asserts infringement of dependent Claim 9, and has pointed to the Accused Product's “compliance rings” as the “compliance chamber defining a cavity within

the fluid return chamber.” APPX0921 (BDC expert); APPX0007 (district court recognizing this argument). The compliance chamber is the area occupied by the compliance rings. Those compliance rings provide an excess volume area by containing gas (separated by a membrane) that compresses when under pressure such that the fluid flows into the volume or space occupied by the compliance rings when not under compression. APPX0924-25 ¶¶29-33. Thus, even if the district court’s other limiting constructions were accepted—the requirement of a physical structure that is separate from the return chamber—BDC has shown a likelihood of success on infringement of dependent Claim 9.⁶ Of course, Claim 1 is also infringed as those rings provide the required excess volume area, irrespective of the rings being compliance chambers.

C. BDC’s Statement in an Unrelated IPR Does Not Somehow Negate Infringement

As explained in BDC’s opening brief, the statement ViVitro and the district court relied upon does not limit the claim nor impact infringement. BDC stated in its IPR response that material deformation *alone*, without a volume to hold excess test fluid (created by, for example, compressible gas), does not meet the “excess volume” limitation of the ’935 Patent. App. Br. at 38. Elizondo’s straw-shaped vascular grafts were filled with fluid, App. Br. at 38 n.3; for this reason, they lacked

⁶ ViVitro does not allege that Claim 9 is anticipated. Since the district court did not make a finding of motivation to combine necessary to support obviousness, a showing of likelihood of success of infringement as to Claim 9, standing alone, is sufficient to require reversal of the district court’s order.

the compressible gas that would have allowed for an excess volume area. The district court erred in stating that the Accused Product “works like” Elizondo. Naming only one difference, ViVitro would need to fill its “compliance rings” with fluid to “work like” Elizondo. Of course, ViVitro cannot do so, because filling them with fluid would eliminate their ability to provide “compliance” as defined by ViVitro’s own expert. ViVitro has never argued that it operates as Elizondo and has failed to show any intention to exclude from the claims the compression of a volume of air separated by a membrane. *See, e.g., N. Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1294 (Fed. Cir. 2000) (one statement in the prosecution history was “far too slender a reed to support the judicial narrowing of a clear claim term”).

D. Even If ViVitro’s Waived “Means-Plus-Function” Construction Were Applied, BDC Has Still Shown a Likelihood of Infringement

If “excess volume area” means compliance chamber or equivalents, as ViVitro now contends, its product infringes. The compliance rings are a compliance chamber or, at the very least, an equivalent thereof. APPX0921.

IV. VIVITRO HAS NOT RAISED A “SUBSTANTIAL QUESTION” AS TO VALIDITY

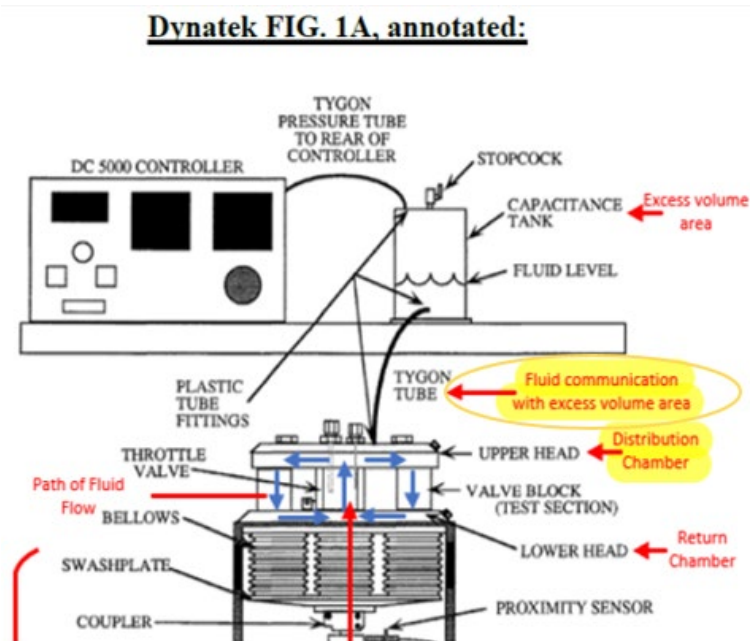
A. ViVitro Has Not Demonstrated That Dynatek Anticipates

Dynatek does not anticipate the asserted claims of the ’935 Patent for four independent reasons: (1) the claimed “excess volume area” is connected on the wrong side of the valve, (2) the test fluid is not “under compression” and thus there is no excess volume area that operates “when the test system fluid is under

compression,” (3) the claimed “excess volume area” does not operate at an accelerated rate, and (4) even if all of ViVistro’s arguments were accepted, four of the eight asserted claims remain unchallenged. App. Br. 46-49.⁷ ViVistro does not effectively rebut any of these four arguments.

1. The Dynatek Capacitance Tank Is Not “In Fluid Communication” with the Return Chamber

ViVistro’s own expert labeled the Dynatek capacitance tank as in “fluid communication” with the distribution chamber, *not* the return chamber as required by Claim 1.



APPX1187-88 ¶59 (ViVistro’s annotation of Dynatek) (yellow highlighting added by

⁷ ViVistro incorrectly states that Mr. Girard fails to “rebut” Dr. Dasi. As explained in BDC’s opening brief, BDC was forced to brief this preliminary injunction motion twice. In the first set of briefing, BDC submitted a reply expert declaration from Mr. Girard rebutting Dr. Dasi. In the second set of briefing, Mr. Girard included both his initial and rebuttal statements in one declaration filed with the opening brief. Mr. Girard had no need to further rebut Dr. Dasi’s recycled assertions; he had already addressed them.

BDC); APPX0930 ¶49. Moreover, ViVitro’s expert then acknowledges this missing element by explaining that Xi provides a backstop argument (APPX1195 ¶74) and by rephrasing the element to reference being in fluid communication with “the test chamber” or the “system” (APPX1187-91 ¶¶58-66). In its opposition brief, ViVitro doubles-down on this misdirection, arguing that the capacitance tank is “in fluid communication with” the return chamber because they are both part of the same fluid system. ViVitro’s construction would render the term meaningless in the ’935 Patent.⁸

The structure of Claim 1 of the ’935 Patent demonstrates that “in fluid communication” connotes the flow path of fluid, its plain meaning:

a pressurizable test chamber...comprising
 a fluid distribution chamber...*in fluid communication with the pressure source*;
 a fluid return chamber positioned on the second side of the valved prosthetic device;
 a fluid return conduit both structurally and *fluidly connecting the fluid distribution chamber to the fluid return chamber*; and
 an excess volume area...*in fluid communication with the fluid return chamber*.

APPX0032 at 17:35-50 (emphasis added). If “fluid communication” merely meant each portion was fluidly connected to some part of the test chamber, none of this

⁸ ViVitro appears to request a construction of “fluid communication” that was never requested below: “In other words, ‘fluid communication’ simply means that fluid can flow from one place to another, whether indirectly or directly.” App’ee Br. at 42.

language would exist. Further, the claims would not identify *different* components—pressure source, distribution chamber, return chamber—after each recitation of “fluid communication.”

ViVitro raises a straw-man argument, claiming that BDC argues “that components ‘in fluid communication’ must ‘touch each other.’” App’ee Br. at 42, citing APPX1767. BDC’s oral statement was not a proffered construction of “fluid communication” as “touching”; it was merely providing an example of the operation of the system in simple terms. ViVitro’s approach uses the extremes: either everything in a system is “in fluid communication”—for example, the Indian Ocean is “in fluid communication with” the Potomac River—or two areas are “in fluid communication” only if the molecules of fluid in the first area directly abut the molecules of fluid in the second area. Neither extreme makes sense, and ViVitro’s argument should be rejected.

2. The Dynatek Capacitance Tank Is Not “Under Compression”

As BDC explained in its opening brief, the “excess volume area” limitation requires that the overall test system fluid be “under compression.” For example, a linear drive motor, used in both the ’935 Patent preferred embodiment and in the Accused Product, would place the system fluid “under compression.” That drive motor would act like adding additional fluid to a closed system by using a syringe. By contrast, the see-saw action of the swashplate in the Dynatek system moves the

fluid through equal and concurrent movement of contracting and expanding bellows. While the “swashplate drive is used to compress six bellows,” *it does not compress them all at the same time*. Half of the bellows are moving in one direction and the other half are moving in the opposite direction. The overall effect is a constant level of pressure.

ViVitro’s argument that the Dynatek system is “under compression” fundamentally misunderstands the claimed excess volume area. Consider the words of ViVitro’s own expert:

When a sudden pressure change occurs in a sealed system with fluid, the incompressible fluid cannot absorb the pressure change, causing stress on the system holding the fluid as the pressure change passes through the system. ... This problem can be solved by adding *an excess volume of air* to the sealed fluid system *so the air can compress or expand* to absorb the shocks to the fluid.

APX1175 ¶21 (emphasis added). As ViVitro’s expert explained, the test fluid is incompressible, but the gas (“air”) is compressible and can “compress or expand to absorb the shocks.”⁹ Within this closed system, the volume of gas takes up more or less space, depending upon whether there is an overall increase in pressure on the test fluid. In the Dynatek system, there is simply no overall increase in pressure for any excess volume area to address.

⁹ ViVitro inexplicably argues that “Dynatek plainly discloses a system that can compress the test fluid.” App’ee Br. at 46. Experts for both parties agree that the test fluid is incompressible.

3. The Dynatek Capacitance Tank Is Not an Excess Volume Area Operating an Accelerated Rate

In arguing that the Dynatek capacitance tank—connected by a five foot tube the size of an iPhone charger—cannot and does not convey fluid back and forth to the test chamber at 200+ bpm, BDC’s expert relies upon ordinary physics and common sense. APPX1020; APPX1025 ¶6. He supports this conclusion with the description in the Dynatek manual, which discloses that the capacitance tank buffers small variations *due to long-term effects* like transient leaks or thermal expansion. APPX1032. This is not a description of storing a volume of fluid when under pressure at an accelerated rate. ViVitro relies solely upon its own *hope* of what its expert *might* have seen (but did not document in his declaration), though it never asked him:

[ViVitro’s expert] saw fluid move in and out of the tank. BDC says...well, [ViVitro’s expert] doesn’t say at what speed it was operating. Was it operating at an accelerated rate? To be frank, looking at the testimony, and I can tell you based -- you know, *I didn’t ask him that question before we submitted his declaration.*

APPX1745 at 103:15-21 (emphasis added). This is particularly striking, because BDC raised this argument *twice* before ViVitro’s expert submitted his declaration. Compare APPX0678 (first reply brief) (“This thin, long tube cannot accommodate passage of fluid at a rate of 200 times per minute or greater.”); APPX 0855-56 (second motion) (raising same argument) with APPX1191 ¶67 (ViVitro second opposition declaration). This failure of proof defeats ViVitro’s position.

Further, ViVistro’s position that the capacitance tank provides the function of the claimed excess volume area is contradicted by the Dynatek manual. The manual repeatedly instructs users to remove air bubbles from the testing chamber, yet add air to the capacitance tank at the end. If Dynatek were designed to use a volume of air to absorb pressure changes at an accelerated rate, there would be no need to remove the air from the test chamber. It is precisely because Dynatek creators did *not* want the air to absorb pressure at that rate that it repeatedly emphasized the need to de-bubble, and then placed a five-foot long, thin tube between the capacitance tank and the test chamber.¹⁰

4. The Dynatek Anticipation Defense Resolves Only Four of Eight Claims

ViVistro does not, and cannot, dispute that it offered an invalidity argument as to only four of the eight asserted claims based on the Dynatek reference. Because the Accused Product infringes four more claims, as described in Section III above, and because the court correctly determined ViVistro failed to demonstrate an adequate motivation to combine, these four claims are infringed and valid.

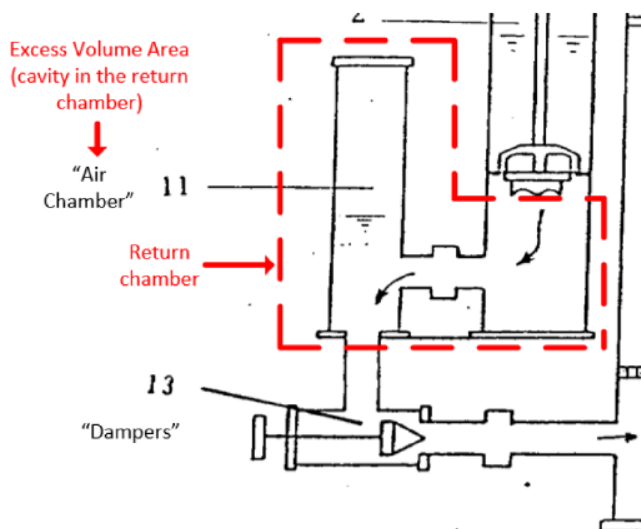
¹⁰ ViVistro attempts to ignore this instruction by arguing that “teaching away is irrelevant to anticipation.” App’ee Br. at 49. But this instruction is highly relevant. Not only does Dynatek not disclose the use of an excess volume area; it instructs users to take steps that go in the exact opposite direction. For that reason, it cannot anticipate.

V. VIVITRO HAS FAILED TO MEET ITS BURDEN TO SHOW OBVIOUSNESS

A. ViVitro Has Failed to Show That All Elements Exist in the Prior Art

ViVitro wrongly claims that BDC has “admitted” that the claimed excess volume area exists in prior art, because at least one prior art reference has a “compliance chamber.” App’ee Br. at 52. Not so. The question is not whether some compliance chamber existed anywhere before the ’935 Patent; the question is whether the excess volume area *with all of the elements claimed* in the ’935 Patent existed. It did not. Neither Dynatek nor Xi discloses “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.” ’935 Patent at claim 1. In fact, all the references are missing multiple elements of the claims.

First, the alleged excess volume area in Xi is connected to the wrong chamber. The Xi pressure source is the valve itself; thus, the “fluid distribution chamber” that is “in fluid communication with” the pressure source is on the left side of the valve in the following diagram.

Xi FIG. 4, annotated (APPX1198)

App'ee Br. at 58. ViVitro now argues that the fluid distribution chamber must be “upstream” of the valve and the fluid return chamber must be “downstream.” This has no basis in the '935 Patent claims, and in fact contradicts them.¹¹ Claim 1 does not describe the chambers as “upstream” or “downstream” of the valve; it defines them in reference to the pressure source. The fluid distribution chamber is “in fluid communication with” the pressure source, and the fluid return chamber is on the opposite side of the valve as the fluid return chamber. Thus, air chamber 11 is in fluid communication with the *distribution* chamber, and does not meet the excess volume limitation.

In its opposition, ViVitro raises a new argument pointing to a new portion of the reference: it now argues that “Large Air Chamber 12” is the claimed excess

¹¹ The fact that BDC used the term “downstream” once in its Opening Brief to describe BDC’s tester, App. Br. at 6, does not somehow alter or narrow the meaning of the patent claims.

volume area. *See* App’ee Br. at 55. This new argument contradicts ViVistro’s expert declaration, wherein the expert’s claim charts rely solely upon “Air Chamber 11” for disclosure of this feature:

Claim 9 - Obvious	Dynatek in view of Xi
9. The device of claim 1, wherein the excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber.	<i>See</i> Claim 1 above Xi discloses that the “excess volume area” or “compliance chamber” is a “cavity within the fluid return chamber.” <u>Xi FIG. 4, annotated:</u>

APPX1220.¹² Again, BDC had argued against Air Chamber 11 ***twice*** before ViVistro submitted this declaration continuing to rely upon Air Chamber 11 alone. *Compare* APPX0682-83 (first reply); APPX0931 ¶54 (BDC expert declaration) *with* APPX1220 (ViVistro’s second expert declaration). ViVistro’s attempt to rely upon a new feature of prior art is untimely and waived. *See, e.g., Sage Prods.*, 126 F.3d at 1426 (declining to consider “novel infringement arguments”).

¹² ViVistro wrongly accuses BDC of “crop[ping] each picture of Xi so that the reference number ‘12’....is omitted.” App’ee Br. at 54 n.19. BDC’s figures are cropped in the same way *ViVistro’s own expert* cropped them to illustrate the alleged excess volume area.

B. The District Court Correctly Concluded That ViVitro Had Failed to Demonstrate a Motivation to Combine

It is not enough to identify the existence of all features in the prior art (which ViVitro has not done); the patent challenger must also present specific evidence of a motivation to combine. *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012). This burden of showing motivation to combine rests with ViVitro, the patent challenger. *Id.* The fact that the district court stated it needed further briefing to assess “whether” there was a motivation to combine demonstrates a failure of proof by the ViVitro.¹³ APPX0011. ViVitro does not, and cannot, plausibly explain why a POSITA would take one (but only one) feature of Xi (and alleged compliance chamber), and add it to Dynatek, when the Dynatek system does not experience the problems caused by a linear drive motor changing the overall internal volume of the system during operation.

Nor does ViVitro rebut the objective indicia of non-obviousness (nor did the district court find that ViVitro met its burden in that respect—it did not even consider the question). ViVitro’s President admits that BDC achieved “substantial commercial success” with its new tester. APPX1158-59 ¶16. That ViVitro’s own system became obsolete, along with the Dynatek system ViVitro claims to be

¹³ ViVitro’s statement that the district court found a motivation to combine is directly contradicted by the language used by the district court. ViVitro bore the burden of proving a motivation to combine. The district court’s only statement as to the motivation to combine was that it needs further briefing. APPX0011. That is, there was no suggestion that the district court confirmed a motivation to combine, but rather thought that the matter required further consideration. That certainly does not show that ViVitro met its burden.

invalidating, is strong evidence of nonobviousness. For the first time in this appeal, ViVitro argues that there is no objective indicia of non-obviousness because there is insufficient nexus between the indicia and the patented invention.¹⁴ In addition to being untimely and waived, this argument is inadequately supported. ViVitro relies solely upon the self-serving declaration of its own president, who opines on what features he believes are most important to BDC's customers, although he also admits that BDC has been commercially successful. This tenuous, and newly-raised argument, is insufficient to overcome indicia of non-obviousness.

CONCLUSION

BDC respectfully asks this Court to reverse the denial of its Motion, hold that BDC has shown a likelihood of success on the merits, that ViVitro has not raised substantial questions as to validity and remand to the district court for consideration of the remaining factors.

Respectfully submitted this 4th day of December, 2023.

¹⁴ ViVitro previously argued there was no nexus for irreparable harm, but never argued a requirement (or lack) of nexus for objective indicia of non-obviousness.

DORSEY & WHITNEY LLP

By: /s/ Shannon L. Bjorklund
Shannon L. Bjorklund
bjorklund.shannon@dorsey.com
50 South Sixth Street, Suite 1500
Minneapolis, MN 55402-1498
Telephone: (612) 340-2600

Gregory S. Tamkin
tamkin.greg@dorsey.com
DORSEY & WHITNEY LLP
1400 Wewatta Street, Suite 400
Denver, CO 80202-5549
Telephone: (303) 629-3400

*Attorneys for Plaintiff-Appellant
Biomedical Device Consultants &
Laboratories of Colorado, LLC*

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

This motion complies with the relevant type-volume limitations of the Federal Rules of Appellate Procedure and the Federal Circuit Rules. According to the word-processing system used to prepare this document, excluding portions exempted by the Rules, this motion contains 6,432 words.

/s/ Shannon L. Bjorklund
Shannon L. Bjorklund
Dorsey & Whitney LLP

CERTIFICATE OF SERVICE

The undersigned counsel of record for Plaintiff/Counterclaim Defendant/Appellant Biomedical Device Consultants & Laboratories of Colorado, LLC, certifies that the foregoing document was filed with this Court via CM/ECF and thereby served on all parties on December 4, 2023.

/s/ Shannon L. Bjorklund
Shannon L. Bjorklund
Dorsey & Whitney LLP