NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

BIOMEDICAL DEVICE CONSULTANTS & LABORATORIES OF COLORADO, LLC,
Plaintiff-Appellant

v.

VIVITRO LABS, INC.,
Defendant-Appellee

2023-2393

Appeal from the United States District Court for the Central District of California in No. 2:23-cv-04291-HDV-E, Judge Hernan D. Vera.

Decided: March 28, 2024

GREGORY S. TAMKIN, Dorsey & Whitney LLP, Denver, CO, argued for plaintiff-appellant. Also represented by SHANNON L. BJORKLUND, Minneapolis, MN.

WARREN JAMES THOMAS, Meunier Carlin & Curfman LLC, Atlanta, GA, argued for defendant-appellee. Also represented by JOHN W. HARBIN.

Before LOURIE, DYK, and STARK, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Biomedical Device Consultants & Laboratories of Colorado, LLC ("BDC") appeals from the decision of the United States District Court for the Central District of California denying its motion for a preliminary injunction. *See Biomedical Device Consultants & Lab'ys of Colo., LLC v. Vivitro Labs, Inc.*, No. 2:23-CV-04291-HDV, 2023 WL 6783296 (C.D. Cal. Aug. 29, 2023) ("*Decision*"). We *affirm*.

BACKGROUND

BDC and ViVitro Labs, Inc. ("ViVitro") manufacture and sell competing heart valve durability testing devices. *Decision* at *1. BDC sued ViVitro in district court accusing ViVitro's "AD[C] Heart Valve Durability Tester" of infringing U.S. Patent 9,237,935 ("the '935 patent") and moved for a preliminary injunction. *Id.* The '935 patent is directed toward accelerated rate fatigue testing devices for prosthetic valves. '935 patent, abstract, col. 17 ll. 29–50. BDC asserted eight claims of the '935 patent with claim 1 as the only independent claim. Relevant to this appeal is the "excess volume area" limitation of claim 1. Claim 1 recites, in part:

> 1. A device for accelerated cyclic testing of a valved prosthetic device comprising . . .
>
> > an excess volume area capable of operating at the accelerated pulsed rate, wherein the 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.

Id. col. 17 ll. 29–50.

All three properties of an excess volume area described in that limitation are in dispute: (1) that it is "capable of

operating at the accelerated pulsed rate," (2) that it is "in fluid communication with the fluid return chamber," and (3) that it "provid[es] a volume for storing a volume of a test system fluid when the test system fluid is under compression." *Id.*

The specification describes the excess volume area in terms of its relationship to a compliance[1] chamber.

> The compliance chambers 135 provide *excess volume area* for fluid to move into when the piston 114 performs a compression stroke. As the pressure of the gas in the compliance chamber 135 increases, the volume occupied by the gas decreases to provide additional volume for displacement of the liquid working fluid within the test chamber 106.

Id. col. 12 ll. 4–9 (emphasis added).

The specification does not provide a more detailed description of the excess volume area; however, Figure 3 provides a cross-sectional view showing the return chamber 136, the compliance chamber 135, test valve sample 130, and the fluid flow path as described in an embodiment of the invention. *Id.* col. 9 ll. 5–9.

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[1] "Compliance" is a term of art that is also expressly defined in the '935 patent. '935 patent, col. 9 ll. 11–16 ("'compliance' refers to the ability of the cavities forming the compliance chambers 135 to absorb some of the pressure placed upon the fluid in the test chamber 106 and further to control recoil toward the original volume dimensions upon removal of the compressive force."). ViVitro agrees that this definition is consistent with the understanding of the term by a person of ordinary skill in the art. J.A. 1177–78.

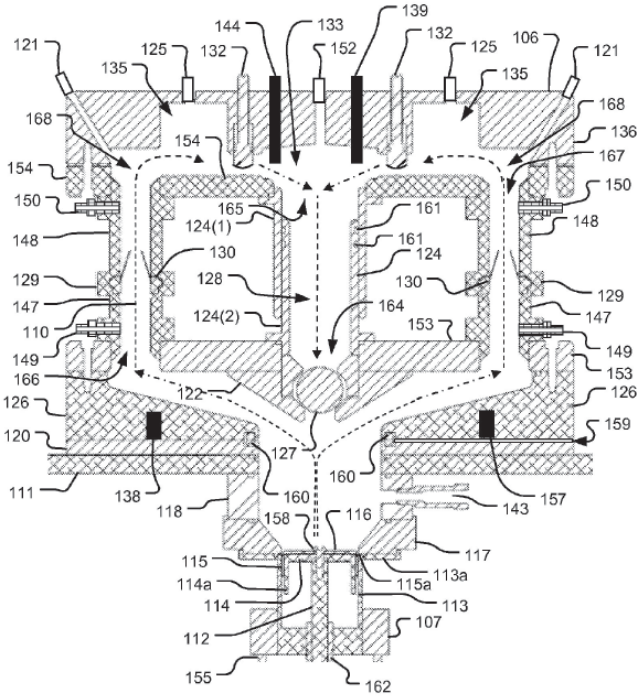

Fig. 3

Id. at Fig. 3.

The district court denied BDC's request for a preliminary injunction, finding that it failed to establish a likelihood of success on the merits for two independent reasons. The court first found a substantial question concerning infringement. To reach this conclusion, it adopted a preliminary construction of the term excess volume area. While at one point the court said it was adopting the plain and ordinary meaning of the phrase, at another point it seemed to give weight to the preferred embodiments and statements from an *inter partes* review proceeding for a related patent. *Decision* at *4–5 ("BDC's prior position in the IPR proceeding supports this view, as 'material deformation'

does not meet the excess volume area limitation"); *Id*. at *5 ("The 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*."). It then applied that limited preliminary construction and determined that ViVitro's accused product lacked the claimed excess volume area. *Id.* at *5.

The district court also found that "Vivitro has presented evidence of invalidity, and BDC has not demonstrated at this point that Vivitro's assertions lack substantial merit." *Id.* at *6. Using the expert declaration of Lakshmi Dasi ("the Dasi declaration"), ViVitro presented arguments that Dynatek[2] anticipates claims 1, 2, 8, and 13 of the '935 patent and that the combination of Dynatek and Xi[3] renders obvious all asserted claims of the '935 patent. Dynatek is a user manual for Dynatek Laboratories, Inc.'s, M6 accelerated rate heart valve durability testing device. J.A. 1014. That manual describes a device containing a partially air-filled capacitance tank connected to a test chamber. *Id.* at 1018. It uses a rotating swashplate and bellows as a drive mechanism. *Id.* Xi is a Chinese patent that discloses an accelerated rate heart valve durability testing device that contains a partially air-filled compliance chamber within a test chamber. *Id.* at 988–89. It uses a reciprocating shaft to drive a sample valve through test fluid. *Id.* at 986. The district court determined that Dynatek's annotated Figure 1A disclosed the "excess volume area" as a capacitance tank. *Decision* at *6.

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[2] DYNATEK LABORATORIES, INC., OPERATING INSTRUCTIONS M6 SIX-POSITION HEART VALVE DURABILITY TESTING DEVICE. J.A. 1014, 1018, 1020, 1022–29, 1032, 1036, 1039 (excerpts of Dynatek).

[3] Chinese Patent CN 1035153C. J.A. 981–96 (translation of Xi).

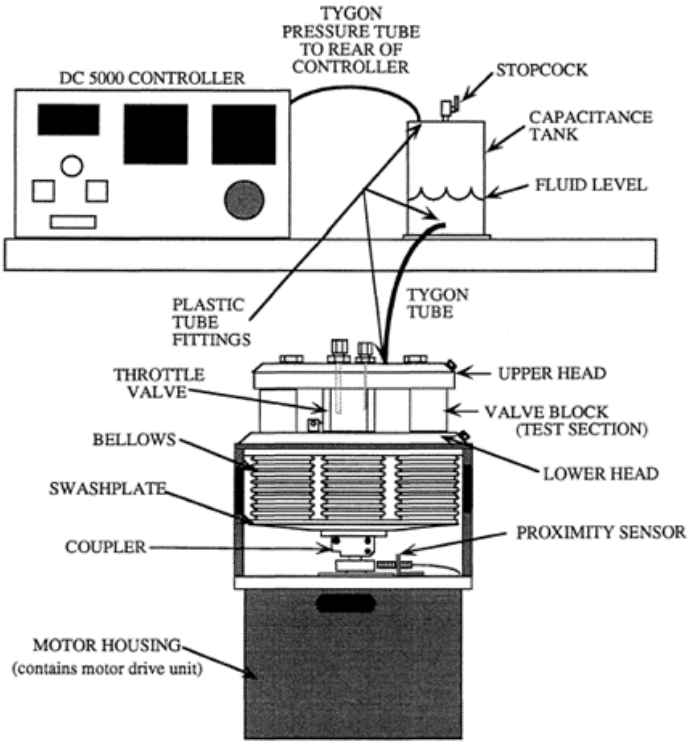

FIGURE 1A

J.A. 1020.

It also determined that the Dasi declaration "supports the view that Dynatek discloses every element of Claim 1 and thus anticipates Claim 1" and three dependent claims. *Decision* at *6. For the remainder of the asserted claims, it determined that the Dasi declaration raised questions regarding the obviousness of all the asserted claims over Dynatek and Xi and that BDC's argument attempting to distinguish those references lacked merit. *Id.*

In view of the resulting lack of a likelihood of success on the merits, the district court denied BDC's motion for a

preliminary injunction. BDC timely appealed, and we have jurisdiction to review the district court's order under 28 U.S.C. § 1292(c)(1).

DISCUSSION

The grant or denial of a preliminary injunction is within the sound discretion of a district court, and we will not reverse its judgment absent an abuse of that discretion. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). Accordingly, we will only overturn a preliminary injunction decision on appeal if "the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings." *Id.*

A movant seeking a preliminary injunction must establish that "(1) it is 'likely to succeed on the merits,' (2) it is 'likely to suffer irreparable harm in the absence of preliminary relief,' (3) the 'balance of equities tips in [its] favor,' and (4) 'an injunction is in the public interest.'" *BlephEx, LLC v. Myco Indus., Inc.*, 24 F.4th 1391, 1398 (Fed. Cir. 2022) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). The burden is on the patent owner to show that it is likely to succeed on the merits with respect to infringement and validity. *Id.* at 1398–99; *Amazon.com*, 239 F.3d at 1350. If the accused infringer "raises a substantial question concerning either infringement or validity, *i.e.*, asserts an infringement or invalidity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary injunction should not issue." *Amazon.com*, 239 F.3d at 1350–51 (quoting *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1364, (Fed. Cir. 1997)).

The district court found that ViVitro raised a substantial question with respect to both validity and infringement. If BDC cannot show that the district court abused its discretion with regard to both of those findings, we must affirm the denial of the preliminary injunction. *See id.* As we affirm the district court in finding a substantial

question of validity, we need not consider infringement. We will therefore begin and end with the court's finding of a substantial question of validity.

At the preliminary injunction stage, a defendant may raise a substantial question of validity "on evidence that would not suffice to support a judgment of invalidity at trial." *Amazon.com*, 239 F.3d at 1358. The question here is one of "vulnerability," which "requires less proof than the clear and convincing showing necessary to establish invalidity itself." *Id.* Furthermore, the district court's assessment of prior art references is an issue of fact reviewed for clear error. *Id.*; *BlephEx*, 24 F.4th at 1400 ("We review the underlying issue of whether the patent challenger's asserted prior art raises a substantial question of validity, a factual issue, for clear error.").

I

BDC argues that Dynatek does not anticipate any claims of the '935 patent for three reasons: (1) its capacitance tank is in fluid communication with the distribution chamber, not the return chamber, (2) its capacitance tank cannot store test fluid when "the test system fluid is under compression" because the test system as a whole is not under compression, and (3) its capacitance tank is not physically capable of "operating at the accelerated pulsed rate." App. Br. at 44–49. However, as we explain below, none of those arguments demonstrates clear error by the district court in evaluating Dynatek and the evidence presented in the Dasi declaration. BDC therefore fails to demonstrate that the district court abused its discretion by finding a substantial question of validity with respect to anticipation.

BDC makes the assertion that Dynatek's capacitance tank is not in fluid communication with the return chamber because "it is connected to the wrong side of the valve." App. Br. at 46. But BDC did not explain why the test valve, sitting in between the distribution chamber and the return

chamber, would cut off fluid communication between the capacitance tank and the return chamber other than to say that the district court abused its discretion by not considering that argument.

The Dasi declaration states that a person of skill in the art would understand "fluid communication" to only require that "fluid can move from a point inside a first volume to a point inside a second volume." J.A. 1195. It also explains that fluid flows from Dynatek's distribution chamber through the test valve, into the return chamber, and then back to the distribution chamber through the central return reservoir. J.A. 1188 (Dynatek Fig. 1A annotated).

The '935 patent specification supports Dasi's understanding of fluid communication—that intermediate structures do not prevent two components from being in fluid communication. For example, the specification describes the pressure source as in fluid communication with the distribution chamber. '935 patent col. 3 ll. 3–5. Yet, all the cross-sectional drawings in the '935 specification show a number of structures in between the pressure source and the distribution chamber. *See e.g.*, '935 patent Fig. 3, col. 6 l. 61–col. 7 l. 50 (showing at least an adapter 117 and a plenum 118 as intermediate structures between the pressure source and the distribution chamber 126). Neither the Dasi declaration, relied on by the district court, nor the specification supports BDC's argument that two components must be directly connected to be in fluid communication.

BDC alleges that Dynatek does not disclose "an excess volume area . . . providing a volume for storing a volume of test system fluid when the test system fluid is under compression" because Dynatek's "test system is never 'under compression.'" App. Br. at 47–48. That assertion fails because it does not conform with the language of the claim. The plain language of the claim merely requires that "the test system fluid is under compression," not that the test

system is under compression. '935 patent col. 17 ll. 45–50. That is an important distinction because BDC admits that Dynatek's drive mechanism subjects at least a portion of the test fluid to compression. App. Br. at 48 ("fluid in the test chamber on the upper end of the swashplate is subject to some positive force"). The Dasi declaration also explains that Dynatek's bellows compress the fluid to actuate the test value. J.A. 1187.

Finally, BDC alleges that Dynatek's capacitance tank cannot operate at the accelerated pulsed rate. Specifically, it alleges that the capacitance tank is designed to address only small variations in volume over longer periods of time and that the tube connecting the capacitance tank to the test system is, "as a matter of ordinary physics," too narrow to allow fluid to transfer back and forth at an accelerated rate. App. Br. at 48–49. However, the claim does not require fluid to transfer to and from the excess volume area at an accelerated rate; it requires that the excess volume area is "capable of operating at the accelerated pulsed rate." '935 patent col. 17 ll. 29–50. BDC does not dispute that Dynatek discloses a system capable of operating at an accelerated rate, App. Br. at 45 (Dynatek discloses "an accelerated tester") and that the capacitance tank is connected to the test system, *id.* at 46 ("the Dynatek capacitance tank is in fluid communication with the distribution chamber"). The claim language and BDC's own admissions rebut its allegations with respect to the capacitance tank being "capable of operating at the accelerated pulsed rate."

For the foregoing reasons, the district court did not make a clear error in its assessment of the prior art. It therefore did not abuse its discretion in finding that BDC failed to demonstrate that ViVitro's anticipation defense lacked substantial merit. *See Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1377 (Fed. Cir. 2009) ("[I]t is the patentee, the movant, who must persuade the court that, despite the challenge presented to validity, the

patentee nevertheless is likely to succeed at trial on the validity issue.").

II

BDC also argues that the district court's ruling on anticipation is not adequate to deny the preliminary injunction because it addresses only four of the eight asserted claims. It argues that the district court did not find a substantial question of obviousness because the decision states that "the Court will benefit from further briefing to determine whether the teachings of Xi, Dynatek and Lu[4] could have been combined." App. Br. at 50 (quoting *Decision* at *6). That argument fails because the district court expressly recognized ViVitro's argument that the asserted claims were "all obvious variations of Dynatek and Xi." *Decision* at *6. It rejected BDC's attempt to distinguish Dynatek and Xi based on their drive mechanisms, noting that "the '935 patent does not specify the 'pressure source' that moves the fluid," and stated that "[s]imilar doubts remain for the concept of obviousness." *Id.* It is clear from those statements that the district court found a substantial question of obviousness with respect to Dynatek and Xi. The court's statement that it would benefit from future "briefing to determine whether the teachings of Xi, Dynatek, and Lu could have been combined," does nothing more than acknowledge that it will benefit from additional briefing when it needs to evaluate obviousness under the more rigorous clear and convincing standard.

BDC goes on to argue that to the extent that the district court's ruling can be interpreted as finding a substantial question of obviousness, it was an abuse of discretion.

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[4] Lu is a publication that the Dasi declaration alleges describes the system of Xi but was not relied on by ViVitro as a basis for its invalidity arguments. *See* J.A. 1184, 1255–1261.

BDC argues that the combination of Dynatek and Xi fails to establish obviousness for three reasons: (1) neither Dynatek nor Xi discloses an "excess volume area," (2) ViVitro failed to articulate why a person of ordinary skill in the art would have been motivated to combine Dynatek and Xi, and (3) ViVitro and the district court failed to address secondary considerations. Again, none of those arguments demonstrates that the district court abused its discretion by finding a substantial question of validity with respect to obviousness based on the Dasi declaration.

For example, BDC repeats the allegation that the air chamber of Xi fails to meet the excess volume area limitation because "it is connected on the wrong side of the valve." App. Br. at 51. That allegation fails for at least similar reasons as the Dynatek argument discussed above. *See also* J.A. 1195 (The Dasi declaration explaining that "fluid can flow from either side of the valve (i.e., any of the return chamber, distribution chamber, or return conduit) in Xi's system into any of the air chambers of Xi, the air chambers of Xi are in fluid communication with both the fluid return chamber and fluid distribution chamber of Xi.").

BDC also argues that ViVitro failed to explain why a person of ordinary skill in the art would have been motivated to combine Dynatek and Xi. It alleges that the two systems "operate in completely different ways," and thus, that there would have been no motivation to combine the two references' teachings. App. Br. at 53. However, the district court expressly rejected that argument in the context of distinguishing Dynatek and Xi from the claimed invention. *Decision* at *6. And the Dasi declaration explains that a skilled artisan would have understood that the different disclosed drive mechanisms would have required only a simple substation. J.A. 1202 (a person of ordinary skill in the art "would know that [Xi's] linear motor would move a bellows up and down in the same way as [Dynatek's] rotating motor with a swashplate."). Additionally, the declaration contains a variety of other reasons why a

skilled artisan would have been motivated to combine Dynatek and Xi. *See, e.g.*, J.A. 1200 ("Both Xi and Dynatek disclose accelerated testing systems for implantable valves."); *id.* (A person of ordinary skill in the art "would be motivated to use Xi's air chambers in place of Dynatek's capacitance tank and tygon tube. This simple substitution would result in a tester with fewer parts that would be easier for an end user to assemble, setup, and transport."). These arguments fail to demonstrate that ViVitro's obviousness defense lacks substantial merit.

BDC's remaining arguments do not disturb that conclusion. For example, it alleges that Dynatek teaches away from combining these references because it "repeatedly warns users that all air must be removed from the test chamber." App. Br. at 53. But Dynatek also teaches users to add air to the system to pressurize the capacitance tank. *See, e.g.*, J.A. 1028 ("Open the stopcock, add air and close the stopcock to refill the syringe with air."). A reference does not teach away if it "does not 'criticize, discredit, or otherwise discourage' investigation into the invention claimed." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) (citation omitted).

Finally, BDC argues that both ViVitro and the district court failed to address secondary considerations of non-obviousness. App. Br. at 54. It claims that its evidence of non-obviousness "is substantial and compelling," yet, in making that argument, the only evidence that BDC points to in support of that assertion is a single statement by ViVitro's President that "BDC achieved 'substantial commercial success' with its new tester." App. Br. at 55. At the preliminary injunction stage, after the accused infringer successfully raises a substantial question of invalidity, the burden shifts to the patentee to demonstrate that the accused infringers' invalidity defenses lack substantial merit. *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1006 (Fed. Cir. 2009). That single

statement fails to demonstrate that the district court abused its discretion by finding that BDC failed to meet its burden.

Furthermore, BDC's argument is incomplete because ViVitro did address secondary considerations below. BDC first raised its secondary considerations argument in its reply memorandum. As ViVitro explained at oral arguments before this court, its first opportunity to rebut BDC's secondary consideration arguments was therefore at the preliminary injunction hearing. Oral Arg. at 16:15–17:55, available at https://oralarguments.cafc.uscourts.gov/default.aspx?fl=23-2393_02072024.mp3. At the hearing, ViVitro addressed secondary considerations by arguing that BDC failed to establish a nexus between the success of its product and the features claimed in the '935 patent. Hearing Transcript 115–17, ECF No. 92. BDC's argument that the court erred by not considering secondary considerations is therefore uncompelling.

In view of the arguments before us and the evidence presented to the district court, we cannot conclude that the district court abused its discretion in finding a substantial question of validity and in denying BDC's request for a preliminary injunction. However, that does not resolve the ultimate question of invalidity, which the district court will need to determine under the higher clear and convincing standard rather than the substantial questions standard applicable to a preliminary injunction. *See Amazon.com*, 239 F.3d at 1358–59.

We need not consider the district court's claim construction because its determinations on invalidity are equally applicable to a broader construction of an "excess volume area" or the narrower one applied by the court. However, we caution that claim terms are generally not limited to the preferred embodiments. *See Laryngeal Mask Co. v. Ambu*, 618 F.3d 1367, 1372 (Fed. Cir. 2010).

CONCLUSION

We have considered BDC's remaining arguments and find them unpersuasive. For the foregoing reasons, we *affirm*.

AFFIRMED