

NOTE: This disposition is nonprecedential.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’s 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

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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.*

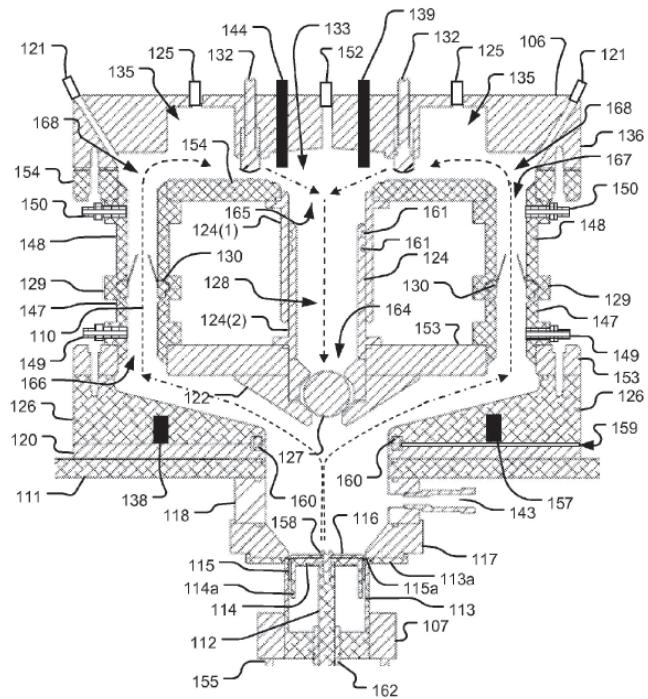
The specification describes the excess volume area in terms of its relationship to a compliance¹ chamber.

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.

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.



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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 Dynatek² anticipates claims 1, 2, 8, and 13 of the '935 patent and that the combination of Dynatek and Xi³ 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.

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).

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