IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action Number: 1:23-cv-867

BIOMEDICAL DEVICE CONSULTANTS &
LABORATORIES OF COLORADO, LLC

Plaintiff,

vs.

VIVITRO LABS, INC.

Defendant.

COMPLAINT AND JURY DEMAND

Plaintiff, Biomedical Device Consultants & Laboratories of Colorado, LLC ("BDC"), hereby states for its Complaint against ViVitro Labs, Inc. ("ViVitro" or "Defendant") as follows:

NATURE OF ACTION

1. BDC is the owner by assignment of United States Patent No. 9,237,935 (the "'935 Patent"), a copy of which is attached hereto as **Exhibit A** (the "Patent-In-Suit"). The Patent-in-Suit represents a significant advancement in the field of cardiac device durability testing systems.

2. Prior to this invention, heart valve durability testing systems had minimal control of the differential pressure rate and spikes associated with valve closure, which resulted in early deterioration of the test valves and potential false test failures. The '935 Patent developed a novel test system that placed an excess volume area on the outflow side of a test sample valve to reduce differential pressure spikes.

3. Based on BDC's inventions related to heart valve durability testing devices, BDC has become the market leader in its niche field. In doing so, over the last 10+ years BDC replaced ViVitro as a leading supplier and provider of testing services for prosthetic heart valve products. Seeking to re-capture the market and usurp the goodwill generated by BDC, ViVitro has recently launched a new heart valve durability tester that infringes at least one of BDC's patents. As set forth more fully below, Defendant has infringed the Patent-In-Suit without authorization by BDC.

4. BDC has repeatedly requested that ViVitro cease its infringing conduct and provided a detailed explanation of infringement, but ViVitro has refused.

5. Plaintiffs filed this Complaint to preliminarily and permanently enjoin Defendant's blatant and willful patent infringement pursuant to the Patent Act, 35 U.S.C. §§ 271, 283-285, and to recover all damages and monetary relief warranted by Defendant's acts of infringement.

THE PARTIES

6. BDC is a Colorado limited liability company with a principal place of business in Wheat Ridge, Colorado.

7. Defendant is a Canadian corporation, and upon information and belief, has a principal place of business located at 455 Boleskine Road, Victoria, BC, Canada V8Z 1E7.

8. BDC and Defendant are direct competitors in the field of cardiac-related medical device testing equipment and testing services.

JURISDICTION AND VENUE

9. This is an action for patent infringement arising under the Patent Laws of the United States. This Court has original jurisdiction over this patent infringement action under 28 U.S.C. §§ 1331 and 1338(a).

10. The Court has personal jurisdiction over Defendant pursuant to Fed. R. Civ. P. 4(k), because Defendant is a foreign corporation that has committed acts of infringement within the United States but Defendant is not subject to jurisdiction in any state's courts of general jurisdiction.

11. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

THE PATENT-IN-SUIT

12. This case concerns equipment used for durability or high cycle fatigue testing of heart valves. Before any medical device, such as a heart valve, is marketed, it must meet certain regulatory standards. International bodies, such as the International Organization for Standardization, set certain standards, such as those for testing the durability of medical devices, including heart valves.

13. Prosthetic heart valves must be tested to ensure that they will function for an adequate period of time. This testing is done by opening and closing the valve leaflets under flows and pressures that are present within the human vascular system. Testing systems use a test fluid to mimic blood and pressurize the fluid to mimic the blood pressure in the human body. In order to complete hundreds of millions of cycles in a commercially viable timeframe, as required by international standards, durability testing is done on an "accelerated" basis.

14. Before the Patent-in-Suit, heart valve durability testing systems on the commercial market used test system designs that resulted in minimal control of the differential pressure rate and spikes associated with valve closure that could result in unnecessary early deterioration of the test valves and potential false test failures. To better manage valve closing dynamics and differential pressure spikes, and thus better comply with the durability testing standards, the inventors of the '935 Patent developed a novel test system that placed an excess volume area on the outflow side of a test sample valve to reduce differential pressure spikes.

15. Generally, the Patent-in-Suit discloses a device for testing heart valves at a high rate of speed. That device includes, for example, a pressure source, a test chamber, fluid distribution and return chambers, and an excess volume area.

16. BDC is the owner of the Patent-in-Suit as original assignee, with full rights to pursue recovery of royalties or damages, including full rights to recover past and future damages, and injunctive relief for infringement of such patent.

17. BDC has complied with the requirements of 35 U.S.C. § 287 with respect to the Patent-in-Suit.

DEFENDANT'S INFRINGING PRODUCT

18. Defendant imports and offers to sell the ADC Heart Valve Durability Tester in the United States. *See generally* **Exhibit B** ("ADC Heart Valve Durability Tester" brochure).

19. Upon information and belief, Defendant has entered at least one agreement with a customer for sale of the ADC Heart Valve Durability Tester, but has not yet delivered the product to any customers.

20. Upon information and belief, the ADC Heart Valve Durability Tester is manufactured at one of Defendant's manufacturing facilities—all of which are outside of the United States. Defendant has imported at least one ADC Heart Valve Durability Tester, which it has displayed at trade shows in Boston, Massachusetts and Anaheim, California.

21. The ADC Heart Valve Durability Tester tests heart valve devices at a frequency of up to 70 Hz, well beyond the normal human physiological rate and exceeding 200 BPM. *See* Ex. B at 2.

22. Among the features that Defendant touts in the ADC Heart Valve Durability Tester are the "[i]nflow and outflow chamber annular compliance rings [that] optimize differential pressure waveforms." Ex. B at 2.

23. The infringing ADC Heart Valve Durability Tester satisfies every limitation of at least claims 1-4, 8, 9 and 12-13 of the '935 Patent and, therefore, infringes Plaintiff's patent rights. A claim chart further describing this infringement is attached as **Exhibit C**.

DEFENDANT'S INFRINGING PRODUCT

24. BDC notified Defendant of the Patent-In-Suit and the infringement by the ADC Heart Valve Durability Tester. In August 2022, BDC's counsel sent a letter to ViVitro alleging that the ADC Heart Valve Durability Tester infringed at least the '935 Patent and attaching a claim chart to demonstrate infringement. Over the next several months, BDC and ViVitro engaged in correspondence concerning BDC's allegations. At first, ViVitro claimed that BDC misunderstood its product. After BDC amended its descriptions, ViVitro stalled on its response. Ultimately, ViVitro offered a series of pieces of prior art that had little relationship to the

claimed invention. Unsurprisingly, ViVitro did not deny infringement of the claims of the '935 Patent.

25. Despite this notice, Defendant has continued to willfully infringe. Specifically, Defendant displayed and offered for sale the ADC Heart Valve Durability Tester at the TCT Conference in Boston on or around September 16-19, 2022. Defendant again displayed and offered for sale the ADC Heart Valve Durability Tester MD&M West conference in Anaheim, California on or around February 7-9, 2023. As of March 27, 2023, the ADC Heart Valve Durability Tester was still listed on Defendant's website. *See* **Exhibit D**.

FIRST CAUSE OF ACTION
DIRECT INFRINGEMENT OF THE '935 PATENT
35 U.S.C. § 271

26. BDC incorporates by reference each of the allegations in paragraphs 1-22 above.

27. On January 19, 2016, the '935 Patent, entitled a "Fatigue Testing System for Prosthetic Devices," was duly and legally issued by the United States Patent and Trademark Office.

28. Each claim of the '935 Patent is valid and enforceable.

29. Since at least as early as August 2023, Defendant has directly infringed at least one claim of the '935 Patent and, unless enjoined, will continue to do so, by offering for sale, selling and/or importing into the United States infringing products without authorization from BDC.

30. For example, and without limitation, the ADC Heart Valve Durability Tester meets every limitation of at least independent claim 1 and dependent claims 2-4, 8, 9 and 12-13 of the '935 Patent, either literally or under the doctrine of equivalents.

31. The ADC Heart Valve Durability Tester satisfies all the limitations of independent claim 1. *See* Ex. C (claim chart). It is a device for performing accelerated testing of valved prosthetic devices. *See* Ex. B at 1, 2. It has a pressure source to drive fluid within the device well above a normal physiological level, up to 70 Hz. *See id.* at 4. It has a pressurizable test chamber for containing the fluid. *See id.* at 2. On one side of the location for the prosthetic heart valve, it has a fluid distribution chamber, which is in fluid communication with the pressure source. *See id.* at 2. On another side, it has a fluid return chamber. *See id.* It has a fluid return conduit, which structurally and fluidly connects the fluid distribution chamber to the fluid return chamber. *See id.* It has an excess volume area, which is in fluid communication with the fluid return chamber and which can store fluid when under compression. *See id.*

32. The ADC Heart Valve Durability Tester satisfies the additional limitations of dependent claim 2. *See* Ex. C (claim chart). It has a drive motor. *See* Ex. B at 1 (uses "linear electromagnetic motor"). It has a fluid displacement member connected with and driven by the drive motor to provide the pressure source that increases and decreases a pressure on the test system fluid in the chamber. *See* Ex. B at 2.

33. The ADC Heart Valve Durability Tester satisfies the additional limitations of dependent claim 3. *See* Ex. C (claim chart). The linear electromagnetic motor drive system of the ADC tester is driven by the signal generator, which allows the waveform to be cyclical, acyclical or a combination of both.

34. The ADC Heart Valve Durability Tester satisfies the additional limitations of dependent claim 4. *See* Ex. C (claim chart). It uses a drive motor that comprises a linear motor. *See* Ex. B at 1 (uses "linear electromagnetic motor").

35. The ADC Heart Valve Durability Tester satisfies the additional limitations of dependent claim 8. *See* Ex. C (claim chart). The annular compliance rings optimize differential pressure by having gas adjacent to the membrane compress when under pressure.

36. The ADC Heart Valve Durability Tester satisfies the additional limitations of dependent claim 9. *See* Ex. C (claim chart). The compressible cavity defines the compliance chamber. The annular compliance ring on the "outflow" side of the valve is adjacent to the fluid return chamber.

37. The ADC Heart Valve Durability Tester satisfies the additional limitations of dependent claim 12. *See* Ex. C (claim chart). The annular compliance rings provide compliance by holding a compressible gas adjacent to the membrane that separates the gas from the fluid. When under pressure, the gas compresses.

38. The ADC Heart Valve Durability Tester satisfies the additional limitations of dependent claim 13. *See* Ex. C (claim chart). The test chamber has a first port on a first side of the valved prosthetic device and a second port on a second side of the valved prosthetic device. *See* Ex. B at 2. These first and second ports are configured to receive sensors. *See id.*

39. Defendant's direct infringement has and, continues to be, willful and egregious. Defendant knew of the '935 Patent and that it infringed the '935 Patent at least as of August 2022, through a letter from BDC notifying Defendant of infringement. Despite knowing of its infringement and that it had no reasonable defense, Defendant deliberately and in bad faith continued its infringing activities.

PRAYER FOR RELIEF

WHEREFORE, BDC prays for judgment as follows:

A. A decree preliminarily and permanently enjoining Defendant, its officers, directors, employees, agents, and all persons in active concert with it, from infringing, and inducing others to infringe, the Patent-In-Suit;

B. An award of BDC's damages caused by Defendant's infringement of the Patent-In-Suit;

C. Enhancement of BDC's damages pursuant to 35 U.S.C. § 284;

D. Costs of suit and attorneys' fees pursuant to 35 U.S.C. § 285;

E. Pre-judgment interest; and

F. Such other relief as justice requires.

JURY DEMAND

BDC demands a trial by jury on all issues so triable.

Respectfully submitted this 7th day of April, 2023.

DORSEY & WHITNEY LLP

s/ Gregory S. Tamkin
Gregory S. Tamkin
Maral J. Shoaei
tamkin.greg@dorsey.com
shoaei.maral@dorsey.com
1400 Wewatta Street, Suite 400
Denver, CO 80202
Telephone: (303) 629-3400

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

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