IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action Number: 1:23-cv-00867-SKC

BIOMEDICAL DEVICE CONSULTANTS &
LABORATORIES OF COLORADO, LLC

Plaintiff,

vs.

VIVITRO LABS, INC.

Defendant.

MOTION FOR PRELIMINARY INJUNCTION[1]

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[1] BDC's counsel communicated with Defendant's counsel on April 10, 11 and 12, 2023 concerning the relief requested. Defendant has not agreed to the relief requested herein.

TABLE OF CONTENTS

I. INTRODUCTION 1

II. FACTUAL BACKGROUND 2

A. Field of Technology and BDC's Role 2

B. BDC's Heart Valve Durability Test Equipment 3

C. Defendant's ADC Heart Valve Durability Tester Infringes the '935 Patent and Competes Against BDC's VDT-3600i 5

D. BDC Attempts to Stop the Irreparable Harm Through Negotiation, But is Unsuccessful 5

III. ARGUMENT 6

A. BDC is Likely to Succeed on the Merits 7

1. The '935 patent is Presumptively Valid 8

2. Defendant's ADC Heart Valve Durability Tester Infringes at Least Claims 1, 2-4, 8-9, 12 and 13 of the '935 patent 8

B. BDC Will Suffer Irreparable Harm If Defendant's Infringement Is Not Stopped 12

1. Loss of Market Share 13

2. Reputational Harm 15

3. BDC Will Lose Incalculable Sales of Related Products/Services as a Result of Defendant's Infringing Product 16

C. The Balance of Equities Favors Entry of a Preliminary Injunction. 17

D. The Public Interest Favors Entry of a Preliminary Injunction 18

E. Bond 19

IV. CONCLUSION 19

TABLE OF AUTHORITIES

Page(s)

Cases

Anderson v. TOL, Inc.,
927 F. Supp. 2d 475 (M.D. Tenn. 2013).....17, 18

Apple Inc. v. Samsung Elecs. Co.,
809 F.3d 633 (Fed. Cir. 2015).....13, 18

Aria Diagnostics v. Sequenom, Inc.,
726 F.3d 1296 (Fed. Cir. 2013).....13

Atlanta Attachment Co. v. Leggett & Platt, Inc.,
2007 U.S. Dist. LEXIS 96972 (N.D. Ga. Feb. 23, 2007) 17

Baker Hughes Inc. v. Nalco Co.,
675 F. Supp. 2d 547 (S.D. Tex. 2009) 17

Biagro W. Sales, Inc. v. Grow More, Inc.,
423 F.3d 1296 (Fed. Cir. 2005).....9

Broadcom Corp. v. Emulex Corp.,
732 F.3d 1325 (Fed. Cir. 2013).....13

Bushnell, Inc. v. Brunton Co.,
673 F. Supp. 2d 1241 (D. Kan. 2009).....7

Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.,
134 F.3d 1085 (Fed. Cir. 1998).....8

Celsis in Vitro, Inc., v. CellzDirect, Inc.,
664 F.3d 922 (Fed. Cir. 2012).....13, 18

Douglas Dynamics, LLC v. Buyers Prods. Co.,
717 F.3d 1336 (Fed. Cir. 2013).....13, 15, 16

Edwards Lifesciences AG v. CoreValve, Inc.,
699 F.3d 1305 (Fed. Cir. 2012).....15

Enercon GmbH v. Int'l Trade Comm'n,
151 F.3d 1376 (Fed. Cir. 1998).....10

Hill v. Xyquad, Inc.,
939 F.2d 627 (8th Cir. 1991) 19

i4i Ltd. P'ship, v. Microsoft Corp.,
598 F.3d 831 (Fed. Cir. 2010).....18

LifeNet Health v. LifeCell Corp.,
837 F.3d 1316 (Fed. Cir. 2016).....10

Metalcraft of Mayville, Inc. v. Toro Co.,
848 F.3d 1358 (Fed. Cir. 2017).....7, 12, 13

Morris & Associates, Inc. v. Cooling & Applied Tech., Inc.,
2010 WL 4484640 (E.D.N.C. July 30, 2010) 14, 15

Mylan Inst. LLC v. Aurobindo Pharma Ltd.,
857 F.3d 858 (Fed. Cir. 2017).....13

Mylan Institutional LLC v. Aurobindo Pharm. Ltd.,
2016 U.S. Dist. LEXIS 180551 (E.D. Tex. Nov. 19, 2016) 7

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2015).....9

Polara Eng'g, Inc. v. Campbell Co.,
894 F.3d 1339 (Fed. Cir. 2018).....8

Polymer Techs., Inc. v. Bridwell,
103 F.3d 970 (Fed. Cir. 1996).....15

Presidio Components, Inc. v. Am. Tech. Ceramics Corp.,
702 F.3d 1351 (Fed. Cit. 2012).....13

Revision Military, Inc. v. Balboa Mfg., Co.,
700 F.3d 524 (Fed. Cir. 2012).....7, 17

Robert Bosch LLC v. Pylon Mfg. Corp.,
659 F.3d 1142 (Fed. Cir. 2011).....7, 13, 18

Smith Int'l, Inc. v. Hughes Tool Co.,
718 F.2d 1573 (Fed. Cir. 1983).....18

Teleflex, Inc. v. Ficosa N. Am. Corp.,
299 F.3d 1313 (Fed. Cir. 2002).....9

Tinnus Enters., LLC v. Telebrands Corp.,
846 F.3d 1190 (Fed. Cir. 2017).....7

Titan Tire, Corp. v. Case New Holland, Inc.,
566 F.3d 1372 (Fed. Cir. 2009).....8

Trading Techs. Int'l, Inc. v. eSpeed, Inc.,
2008 U.S. Dist. LEXIS 86953 (N.D. Ill. May 22, 2008). 15

Tuf-Tite, Inc. v. Fed. Package Networks, Inc.,
2014 U.S. Dist. LEXIS 163352 (N.D. Ill. Nov. 21, 2014).....18

Veeco Instruments Inc. v. SGL Carbon, LLC,
2017 U.S. Dist. LEXIS 181935 (E.D.N.Y. Nov. 2, 2017).....7

Statutes

35 U.S.C. § 154(a)(1).....6

35 U.S.C. § 271(a) 10

35 U.S.C. § 282.....8

35 U.S.C. § 283.....6

Plaintiff Biomedical Device Consultants & Laboratories of Colorado, LLC ("BDC"), hereby moves this Court to preliminarily enjoin ViVitro Labs, Inc. ("Defendant" or "ViVitro") from making, using, offering to sell, selling or importing any product that practices the inventions of U.S. Patent No. 9,237,935 entitled "Fatigue Testing System for Prosthetic Devices" ("the '935 patent" or "Patent-in-Suit"), including but not limited to ViVitro's ADC™ Heart Valve Durability Tester.[2]

I. INTRODUCTION

BDC has revolutionized the market for heart valve durability testers, and has protected its invention and investment through patents. Defendant ViVitro seeks to capitalize on BDC's work by offering an infringing product. BDC's best-selling system, the VDT-3600i, is used for testing the durability of prosthetic heart valves and is covered by a family of patents, including the '935 Patent. The technology behind the VDT-3600i made it the market standard, rendering prior products obsolete—including ViVitro's then-offered tester—and earning BDC the dominant market position and a reputation for innovation. Attempting to capitalize on this new technology pioneered by BDC, ViVitro is now offering an infringing test system known as the ViVitro ADC™ Heart Valve Durability Tester. ViVitro's infringement must be stopped by a preliminary injunction. If ViVitro is allowed to continue its infringing activities, BDC will suffer an irreparable and irretrievable loss of market position, loss of business opportunities, harm to business relationships, and damage to its reputation as an industry-leading innovator in equipment for the durability testing of heart valves.

[2] The '935 patent is attached as Exhibit A to the Complaint. Dkt. 1-1.

BDC filed this lawsuit only after trying unsuccessfully for months to stop Defendant's commercialization of the infringing ADC Heart Valve Durability Tester without court intervention. ViVitro has rejected these efforts, continues to market its soon-to-be-launched product at trade shows and, to the best of BDC's knowledge, plans to begin shipping the infringing products this fall. A preliminary injunction enjoining Defendant from continuing to infringe the '935 patent is warranted because, as explained below, (1) BDC is likely to succeed on the merits; (2) BDC is likely to suffer irreparable harm in the absence of preliminary relief, if ViVitro is permitted to launch the product; (3) the balance of equities tips in BDC's favor; and (4) an injunction would be in the public interest.

II. FACTUAL BACKGROUND

A. Field of Technology and BDC's Role

Prosthetic heart valves must be tested to ensure that they will function for the anticipated life of a patient by opening and closing under the flows and pressures that are present within the human vascular system. Declaration of Michael Girard ("Girard Decl."), ¶6. The International Organization for Standardization ("ISO"), and other international bodies, set the standards for testing the durability of heart valves. *Id*. Testing standards require that prosthetic valves be able to withstand a certain number of cycles of opening and closing of the valve leaflets, usually in the hundreds of millions (representing years of service in a human body), and that a specific pressure differential be generated across the valve when closed. *Id*., ¶7. In order to complete hundreds of millions of cycles in a commercially viable timeframe, durability testing is done on an "accelerated" basis. In other words, the speed of the cycles is faster than a normal human heartbeat (a normal beat rate is 70 beats per minute ("bpm")). Using current technology at accelerated

cycling of up to 800 bpm (though anything over 200 bpm is considered "accelerated"), testing takes approximately six months. *Id*., ¶8.

Providing fluid flow through the test valve and pressure across it requires a "drive mechanism" such as a pump that drives fluid into a test chamber. *Id*., ¶10. Before commercialization of the technology of the Patent-In-Suit, durability testing equipment (and methods of using that equipment) used drive mechanisms that had limited control over the closing rate and often produced "pressure spikes" when maintaining pressure above the testing threshold for the amount of time required by testing standards. These pressure spikes are undesirable because they wear out valves during testing faster than they would be worn out in the human body, causing false test failures. *Id*., ¶10.

To better manage the valve closing dynamics and differential pressure spikes, and thus better comply with the durability testing standards, BDC developed a novel test system that, among other things, placed an "excess volume area" on the outflow side of a sample test valve. Declaration of Craig Weinberg ("Weinberg Decl."), ¶5. BDC employees also developed a method of operating the test system using this excess volume area that helps control differential pressure spikes. This excess volume area improves the test environment by minimizing unnatural and undesirable pressure spikes and provides advantages of speed and longevity in the drive system. *Id*., ¶9. Specifically, the excess volume area can alleviate some of the system pressure during the drive phase. *Id*., ¶7. The excess volume area also reduces pressure recoil by releasing fluid downstream of the valve during the return phase (when pressure is released) that helps build pressure back up on that side of the valve. *Id*.

B. BDC's Heart Valve Durability Test Equipment

BDC revolutionized the market for heart valve durability testing equipment by providing an accelerated testing device utilizing a closed system that can reduce pressure spikes by providing an excess volume area on the outflow side of the valve. *Id*., ¶5. BDC has commercialized the '935 Patent with its VDT-3600i heart valve durability tester. *Id*., ¶8. The VDT-3600i has become a core component of BDC's overall business; the VDT-3600i is BDC's best-selling medical device test system. *Id*., ¶¶9-16, 20.

The specialized nature of heart valve durability systems means that there are a limited number of competitors in the marketplace. *Id*., ¶¶17-19. There are currently only three competitors: Defendant ViVitro (which until recently was promoting its obsolete technology), TA Instruments-Waters LLC, and Dynatek Labs. *Id*., ¶¶15, 25. However, the superior performance of the VDT-3600i has made it the industry standard for heart valve durability testing. BDC's VDT-3600i has an estimated 70-75% worldwide market share. *Id*., ¶16.

Market share in the heart valve durability testing equipment market is important due to incumbency effects. *Id*., ¶17. A single testing system can only test a few devices at a time. *Id*. To bring a new prosthetic valve device to market, however, medical device manufacturers need testing data from many, often dozens, of sample devices. *Id*. Therefore, testing system customers need multiple systems. Customers will generally purchase test systems from the same manufacturer as part of a larger testing program for commercial use. *Id*. Customers generally do not buy testing equipment from multiple sources in order to avoid introducing additional testing variables (*i.e.*, differences between testing machines from different suppliers) into the test data that would be submitted to the FDA, or international regulatory agencies. *Id*., ¶18. The lifespan of valve durability testing equipment is often ten to fifteen years, meaning that once a customer has decided

which testing equipment to use, it will likely be a long time before a competitor has the opportunity to usurp the place of an incumbent. *Id*.

C. Defendant's ADC Heart Valve Durability Tester Infringes the '935 Patent and Competes Against BDC's VDT-3600i

The ADC Heart Valve Durability Tester is marketed as a device for accelerated cyclic testing of a valved prosthetic device comprising (1) a pressure source that drives the test system at an accelerated rate above 200 beats per minute, (2) the claimed pressure chambers on each side of the valve, (3) a fluid conduit structurally and fluidly connecting the chambers, and (4) the claimed excess volume area for storing fluid when the fluid is under compression. *Id*., ¶¶9-17.



Defendant's test system competes directly with BDC's.

D. BDC Attempts to Stop the Irreparable Harm Through Negotiation, But is Unsuccessful

In summer of 2022, BDC learned that ViVitro was distributing marketing materials for a new tester, the ADC Heart Valve Durability Tester. Weinberg Decl., ¶15. In August 2022, BDC sent a letter to Defendant notifying it of its infringement of the '935 Patent (as well as other BDC patents). *Id*., ¶36. In its response, instead of focusing on why Defendant did not infringe BDC's patent, ViVitro claimed that one of BDC's annotations pointed to the wrong feature. *Id*., ¶37. BDC gathered additional information about the ADC Heart Valve Durability Tester, including

observing it in operation at a conference in Boston in September 2022. *Id*., ¶39. After waiting approximately six weeks—the time frame within which ViVitro's President claimed more information would issue—BDC sent another letter warning ViVitro of its infringement. *Id*., ¶41. After giving itself multiple unilateral extensions to respond to BDC's letter (with multiple requests to engage), nearly three months later, on January 31, 2023, Defendant provided its substantive response. *Id*., ¶42. Notably, Defendant did not attempt to argue that the ADC Heart Valve Durability Tester does not meet the limitations of the independent claim of the Patent-in-Suit. Instead, it simply stated that the Patent-in-Suit is invalid, but provided clearly different and unrelated prior art. *Id*. It provided no chart or any other indication as to why any particular prior art was invalidating. Defendant continued to market its ADC Heart Valve Durability Tester at the MD&M West conference in Anaheim, California, recently held February 7-9, 2023. *Id*., ¶43. Further, Defendant has shown that it plans to continue marketing to U.S. purchasers, both in the United States and abroad. In other words, Defendant is actively marketing and selling the ADC Heart Valve Durability Tester and expects to deliver testers in the fall of 2023. *Id*., ¶44.

III. ARGUMENT

The Patent Act provides a patentee with the "right to exclude others from making, using, offering for sale, or selling the [patented] invention." 35 U.S.C. § 154(a)(1). To protect this right, courts "may grant injunctions in accordance with the principals of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283.

To obtain a preliminary injunction, a patentee must show (1) that it is likely to succeed on the merits; (2) that it is likely to suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in its favor; and (4) that an injunction would be in the public

interest." *Metalcraft of Mayville, Inc. v. Toro Co*., 848 F.3d 1358, 1363 (Fed. Cir. 2017).[3] A patentee makes this showing where the factors above are "supported by sound evidence." *Veeco Instruments Inc. v. SGL Carbon, LLC*, 2017 U.S. Dist. LEXIS 181935, *77-78 (E.D.N.Y. Nov. 2, 2017) (citations omitted).[4] In addition, the Federal Circuit has made clear that district courts must consider "the fundamental nature of patents as property rights granting the owner the right to exclude." *Robert Bosch LLC v. Pylon Mfg. Corp*., 659 F.3d 1142, 1149 (Fed. Cir. 2011) (emphasis added). For the reasons set forth below, the Court should enter a preliminary injunction to preserve BDC's exclusive patent rights and market position.

A. BDC is Likely to Succeed on the Merits

To demonstrate a likelihood of success on the merits, BDC must show "that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Tinnus Enters., LLC v. Telebrands Corp*., 846 F.3d 1190, 1202 (Fed. Cir. 2017). BDC is not required to prove that it is certain to win. It is enough to show that "success is more likely than not." *Revision Military, Inc. v. Balboa Mfg., Co*., 700 F.3d 524, 526 (Fed. Cir. 2012). As

[3] Federal Circuit law governs the substantive aspects of a decision to grant a preliminary injunction in a patent case. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 n.12 (Fed. Cir. 1988). Regional Circuit law governs "purely" procedural questions involving the grant of a preliminary injunction. *Id.*

[4] Sound evidence may include well-founded declarations of the patentee related to market conditions. *See, e.g., Metalcraft*, 848 F.3d at 1368 (irreparable harm based on senior marketing manager's declaration that "some customers 'prefer to purchase an entire line of products from the same manufacturer for consistency'"); *Bushnell, Inc. v. Brunton Co.,* 673 F. Supp. 2d 1241, 1262 (D. Kan. 2009) (irreparable harm found where Executive testified that "the market will not allow Bushnell to raise prices to recoup its losses"); *Mylan Institutional LLC v. Aurobindo Pharm. Ltd.*, 2016 U.S. Dist. LEXIS 180551, *70 (E.D. Tex. Nov. 19, 2016) (irreparable harm based on testimony from CFO that plaintiff projected that "half or more" of plaintiff's "revenue from isosulfan blue sales" would be lost if defendant were allowed to infringe).

demonstrated below, BDC meets this requirement.

1. The '935 patent is Presumptively Valid

Under 35 U.S.C. § 282, the '935 patent is "presumed valid . . . at every stage of the litigation." *Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc*., 134 F.3d 1085, 1088 (Fed. Cir. 1998). As the Federal Circuit has made clear:

> [A] patent enjoys the same presumption of validity during preliminary injunction proceedings as at other stages of litigation. Thus, if a patentee moves for a preliminary injunction and the alleged infringer does not challenge validity, the very existence of the patent with its concomitant presumption of validity satisfies the patentee's burden of showing a likelihood of success on the validity issue.

Titan Tire, Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1377 (Fed. Cir. 2009) (internal citation omitted).

"At trial, the party challenging validity must prove that the claims are invalid by clear and convincing evidence." *Polara Eng'g, Inc. v. Campbell Co*., 894 F.3d 1339, 1348 (Fed. Cir. 2018). To oppose a preliminary injunction with an invalidity defense, however, the accused infringer must establish a "substantial question" of invalidity, bearing in mind the clear and convincing burden that will apply at trial. *Titan Tire*, 566 F.3d at 1379-80. Accordingly, although a "substantial question" need not rise to the level of clear and convincing evidence, it must be enough for the Court to conclude that Defendant is "more likely than not" to satisfy its clear and convincing evidence burden by the time trial comes. *Id*. To date, Defendant has presented no such evidence. Defendant has provided no chart or any other indication as to why any particular prior art was invalidating, and the prior art it previously provided to Plaintiff is clearly different and unrelated to the '935 invention. *Id*.

2. Defendant's ADC Heart Valve Durability Tester Infringes at Least Claims 1, 2-4, 8-9, 12 and 13 of the '935 patent

"An infringement analysis proceeds first to claim construction to determine the scope and meaning of the asserted claims, and second to a comparison of the properly construed claims with the allegedly infringing product to determine whether the product embodies every limitation of the claims." *Biagro W. Sales, Inc. v. Grow More, Inc*., 423 F.3d 1296, 1301 (Fed. Cir. 2005).

Claim Construction

Claim construction begins with the words of the claims, which "are generally given their ordinary and customary meaning." *Phillips v. AWH Corp*., 415 F.3d 1303, 1312-14 (Fed. Cir. 2015). Indeed, there is "a 'heavy presumption' that a claim term carries its ordinary and customary meaning." *Teleflex, Inc. v. Ficosa N. Am. Corp*., 299 F.3d 1313, 1325 (Fed. Cir. 2002). "[T]he ordinary and customary meaning of a claim is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1313. No construction is necessary when "the ordinary meaning of claim language as understood by a person of skill in the art [is] readily apparent even to lay judges." *Philips,* 415 F.3d at 1314.

Most of the language used in the relevant claims—claims 1-4, 8-9 and 12-13—can be readily understood by a person of ordinary skill in the art, and the plain and ordinary meaning should suffice without further construction by the Court. The ordinary meaning is "readily apparent," and thus claim construction in this matter "involves little more than the application of the widely accepted meaning of commonly understood words." *Id*. at 1314. Based on the '935 patent, a person of ordinary skill would understand that the term "compliance chamber," as used in claims 9 and 12, means "a cavity or volume that functions to absorb some of the pressure in the system." *See* Girard Decl. ¶20; '935 Patent at 9:8-16. As such, additional claim construction is not necessary to decide this motion and Defendant's infringement of the asserted claims is clear.

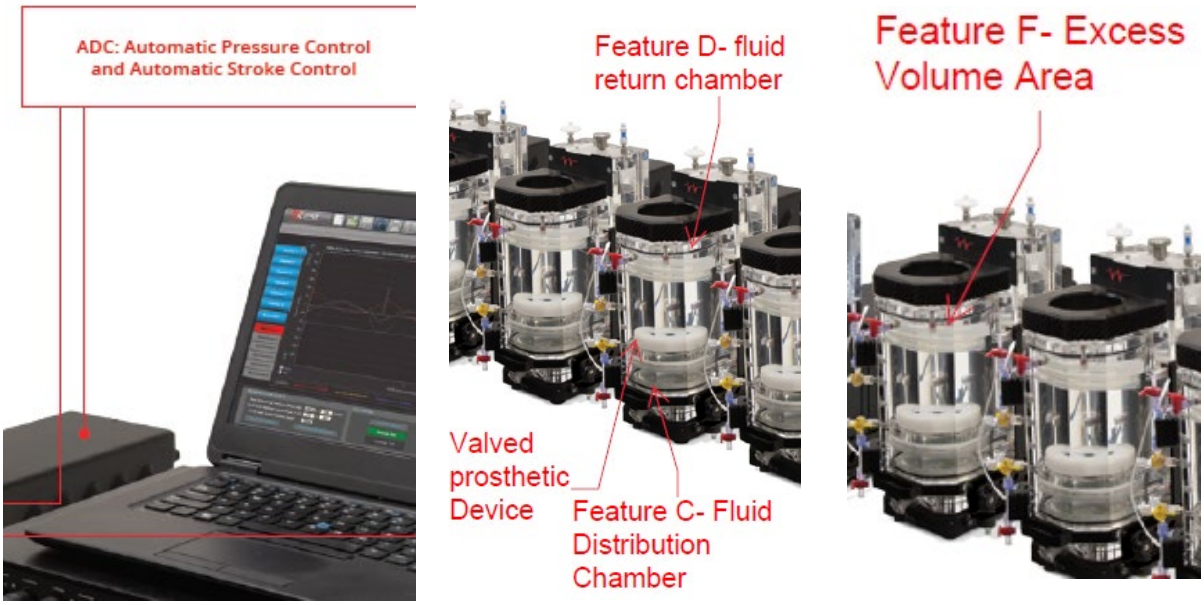
Infringement Analysis

Direct infringement consists of making, using, offering to sell, or selling a patented invention in the United States, or importing a patented invention into the United States, without consent of the patent owner. 35 U.S.C. § 271(a); *LifeNet Health v. LifeCell Corp.*, 837 F.3d 1316, 1325 (Fed. Cir. 2016). A patentee bears the burden of proving infringement at trial of the asserted patent claims by a "preponderance of the evidence." *See, e.g.*, *Enercon GmbH v. Int'l Trade Comm'n,* 151 F.3d 1376, 1384 (Fed. Cir. 1998).

As set forth in detail in the infringement charts of expert Mike Girard, the ADC Heart Valve Durability Tester includes all limitations of independent claim 1 and dependent claims 2-4, 8-9 and 12-13 of the Patent-in-Suit. The ADC Heart Valve Durability Tester is a "device for accelerated cyclic testing of a valved prosthetic device" that contains a "pressure source," as annotated by ViVitro as the "ADC: Automatic Pressure Control and Automatic Stroke Control. Girard Decl., page 9. It contains a pressurizable test chamber with a fluid distribution chamber positioned underneath the prosthetic valve being tested, and a fluid return chamber located above the valve. *Id.* at pages 10-11. It also contains an "excess volume area," shown by a red arrow below, which is the volume adjacent to the annular compliance ring. *Id.* at page 12. These features can be seen in the annotated figures below, and are further explained in the Girard Declaration.

Thus, the ADC Heart Valve Durability Tester meets all limitations of independent claim 1.

The ADC Heart Valve Durability Tester also meets the additional limitations of dependent claim 2, because it has a "dedicated linear electromagnetic motor" and a "[f]luid sensor for bellows

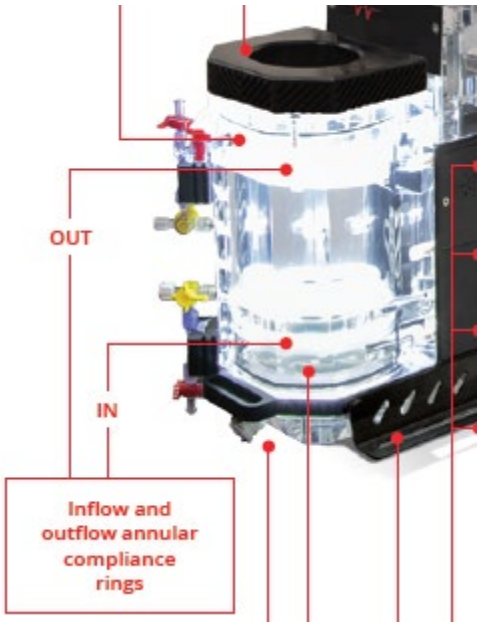


leak detection," which a person of ordinary skill would understand discloses "fluid displacement using a bellows system to convert the linear drive motor movements into fluid pressures." Girard Decl., pages 12-13. The ADC Heart Valve Durability Tester brochure expressly describes use of a linear motor, as required by claim 4, and two ports with sensors, as required for claim 13. *See id.* pages 14, 16-17. A person of ordinary skill in the art would understand that the motor is configured to operate cyclically or acyclically, as described in claim 3, through disclosure of a linear motor with the option to be driven by the "external waveform in." *Id.* page 14.

The ADC Heart Valve Durability Tester further meets the limitations of dependent claims 8-9 and 12. According to the sales brochure, it has "[l]arge, customizable [test] chamber[s]" and "[i]nflow and outflow chamber annular compliance rings optimize differential pressure

waveforms." Girard Decl., Ex. B at 2.

These annular compliance rings hold a compressible gas adjacent to a membrane that separates the gas from the fluid, and the compliance ring on the "outflow" side defines an interface



with the compliance chamber within the fluid return chamber. *See* Girard Decl., at 15. Under pressure, the gas compresses, which allows the test fluid to occupy a portion of the volume of that compliance chamber. The compressed gas acts as a spring force against the fluid that moves into the excess volume formerly occupied by the compressible gas. *Id.* Through this functionality, the ADC Heart Valve Durability Tester meets the additional limitations of claim 8 (compressible gas providing a spring force), claim 9 (a compliance chamber defining a cavity within the fluid return chamber), and claim 12 (compliance chamber provides a volume that compresses under pressure).

B. BDC Will Suffer Irreparable Harm If Defendant's Infringement Is Not Stopped

To show irreparable harm, BDC must show that absent an injunction, it will suffer irreparable harm and that a causal nexus between the harm and infringement exists. *See Metalcraft*, 848 F.3d at 1368. "Where the injury cannot be quantified, no amount of money

damages is calculable, and therefore the harm cannot be adequately compensated and is irreparable." *Id*. In the context of patent infringement, lost market share, lost research and development opportunities, injury to reputation and goodwill, and price erosion are all valid grounds for finding irreparable harm. *Celsis in Vitro, Inc., v. CellzDirect, Inc*., 664 F.3d 922, 930 (Fed. Cir. 2012) (emphasis added); *Mylan Inst. LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 872 (Fed. Cir. 2017); *Aria Diagnostics v. Sequenom, Inc.*, 726 F.3d 1296, 1304 (Fed. Cir. 2013); *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1153-55 (Fed. Cir. 2011).

ViVitro's threatened launch of the ADC Heart Valve Durability Tester presents irreparable harm, unless this launch is stopped before it begins. BDC has been, and is, the clear market leader for a testing system with a fluid test chamber for accelerated cyclic pressure testing. By all indications, Defendant's ADC Heart Valve Durability Tester was designed and intended to compete directly with BDC's fluid test chamber. Indeed, ViVitro has copied not just BDC's durability tester but also its service options, showing that ViVitro recognizes BDC as a key competitor it seeks to displace. Weinberg Decl. ¶30. This is "one factor suggesting strongly the potential for irreparable harm." *Apple Inc. v. Samsung Elecs. Co*., 809 F.3d 633, 653-54 (Fed. Cir. 2015) (citation omitted); *see also Douglas Dynamics, LLC v. Buyers Prods. Co*., 717 F.3d 1336, 1345 (Fed. Cir. 2013) (harm suffered "where two companies are in competition against one another" is "often irreparable"); *Presidio Components*, 702 F.3d at 1363 (same).

1. Loss of Market Share

Lost market share constitutes irreparable harm, particularly where that lost share is difficult to reverse or quantify due to "incumbency effects," (i.e., markets where customers prefer to remain with an incumbent supplier). *Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1336 (Fed. Cir.

2013). That is precisely the case here. As described above, a company typically purchases multiple systems from a single supplier and uses them for many years. If ViVitro were permitted to start distributing its infringing product, it could have a decades-long effect on BDC. Weinberg Decl., ¶18.

The market for medical device testing systems has substantial incumbency effects: if BDC loses market share now the lost customers will be lost for the foreseeable future. In the medical device test systems market, a customer's first purchase is for the purpose of running a pilot testing program. If the pilot test is successful, the customer will then purchase more of the *same* test systems from the same manufacturer as part of a larger testing program for commercial use. *Id.* Once these purchases have been made, it could be up to fifteen years before the customer is in the market to purchase a test system again. Therefore, if Defendant is not enjoined now, customers running pilot programs may permanently switch to Defendant and BDC will irreparably lose its position in the market place for the foreseeable future. *See Morris & Associates, Inc. v. Cooling & Applied Tech., Inc*., 2010 WL 4484640, at *9 (E.D.N.C. July 30, 2010) (finding irreparable harm when system was designed to last "a significant lifetime"). It will also be impossible to calculate the losses associated with that long-term stream of revenue, both due to the long-term and compounding nature of the harm, and because a variety of external factors make it extremely difficult or impossible to predict which follow-on sales would have occurred for a particular lost customer..

To make matters worse, the market for heart valve durability testing systems is small. The customers are few but rewards are large. BDC's systems' pricing starts between $75,000 and $85,000, but BDC sells under 40 systems a year. These systems annually result in 70-75% share

of the worldwide market. Accordingly, the market is sensitive to disruption. Even a handful of sales of Defendant's infringing system will harm BDC's relationships with customers, harm its reputation as an innovator with a unique product, reduce its research and development activities, and permanently erode its prices (these harms are discussed further below). In such a market, BDC cannot simply be put back into position at the end of trial. *See Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975-76 (Fed. Cir. 1996) ("years after infringement has begun, it may be impossible to restore a patentee's [] exclusive position by an award of damages and permanent injunction."). Indeed, the entire value of BDC's patents is to protect its exclusive position in the market. *See, e.g.*, *Edwards Lifesciences AG v. CoreValve, Inc.*, 699 F.3d 1305, 1314 ("A patentee's right to exclude is a fundamental tenet of patent law."). Without that exclusivity, BDC will be irreparably harmed.

2. Reputational Harm

Damage to a patent owner's reputation constitutes irreparable harm. *See Douglas Dynamics*, 717 F.3d at 1344 (irreparable injury encompasses "erosion in reputation and brand distinction"). A plaintiff seeking a preliminary injunction must demonstrate that irreparable harm is likely in the absence of an injunction; notably, it is not necessary to prove that irreparable harm is certain. *See e.g., Morris & Associates*, 2010 WL 4484640, at *10. The Federal Circuit has stated that a company's "reputation as an innovator will certainly be damaged if customers found the same 'innovations' appearing in competitors' [products]." *Douglas Dynamics*, 717 F.3d at 1344-45. Thus, courts have found irreparable injury where "infringing products in the marketplace would damage" a patentee's "reputation as an innovator and diminish the appearance of viability to its customers." *Trade Techs*., 2008 U.S. Dist. LEXIS 86953, at *9.

As explained above, BDC has invested significantly, not only to develop its patented technology, but to promote it in a way that enhances its reputation. These efforts have resulted in widespread industry acclaim from customers, which have stated that:

- "[BDC's] testing is more likely to meet dynamic regulatory requirements"
- "BDC is a true partner with our R&D team"
- "The novel design and implant location of [a customer's] device meant that standard reliability testing equipment was not applicable. Custom equipment designed from scratch would be required. Working with BDC, we were able to quickly build a test fixture . . . ."
- "[BDC is] an excellent thought partner in problem solving."

http://www.bdclabs.com/about-us/client-testimonials/. Contributing to BDC's reputation for innovation is the fact that the VDT-3600i was a differentiated product for heart valve testing—it was the only type of machine on the market. In fact, the VDT-3600i became the "industry standard" for prosthetic heart valve durability testing.

However, BDC's VDT-3600i is no longer a differentiated product given the presence of Defendant's infringing system in the market. Once lost, BDC's reputation cannot be regained and cannot be compensated through money damages. The foregoing demonstrates precisely the type of harm that warrants injunctive relief. *See Douglas Dynamics*, 717 F.3d at 1345 ("erosion in reputation and brand distinction" from being "being forced to compete against products that incorporate and infringe its own patented inventions" constitutes irreparable harm).

3. BDC Will Lose Incalculable Sales of Related Products/Services as a Result of Defendant's Infringing Product

A heart valve tester is not a stand-alone device; it must be integrated with a novel test system and other functionally related products. Customers who choose to buy Defendant's product are likely to end up purchasing fully-integrated machine and line solutions from Defendant.

Defendant's sales will not only adversely affect sales of BDC's system, but also BDC's related products and services, such as catheter testing, stent and graft testing, and heart valve testing. Court have found that damages related to sales of functionally related products, also known as convoyed sales, are "both irreparable and difficult to quantify." *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 2007 U.S. Dist. LEXIS 96972, at *20 (N.D. Ga. Feb. 23, 2007) (granting injunction and finding legal remedies to be inadequate where plaintiff lost convoyed product sales due to an infringing product in direct competition); *Baker Hughes Inc. v. Nalco Co.*, 675 F. Supp. 2d 547, 554 (S.D. Tex. 2009) (granting preliminary injunction, finding that damage to patentee's business reputation could immeasurably harm its ability to sell functionally related products).

C. The Balance of Equities Favors Entry of a Preliminary Injunction.

In balancing the parties' harms, "a district court 'must balance the harm that will occur to the moving party from the denial of the preliminary injunction with the harm that the non-moving party will incur if the injunction is granted.'" *Anderson v. TOL, Inc.*, 927 F. Supp. 2d 475, 488 (M.D. Tenn. 2013) (quoting *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988)). The factor heavily favors a preliminary injunction.

First, as demonstrated, the likelihood of success on BDC's infringement case is very high. This is an "equitable factor" that favors BDC "in the ultimate balance of the equities." *Id*. (quoting *Revision Military, Inc. v. Balboa Mfg. Co.*, 700 F.3d 524, 526 (Fed. Cir. 2012)). Second, BDC has shown it has much to lose if preliminary injunctive relief is not granted due to the head-to-head competition with its own technology embodied in Defendant's Heart Valve Durability Tester. Third, any harm Defendant may claim from entry of an injunction would be minimal—since to BDC's knowledge it has not yet delivered any products—and in any event is self-inflicted by the

calculated risk it undertook in entering the marketplace with a copycat concept with full knowledge of the '935 patent and BDC's strong belief that commercializing the ViVitro ADC™ Heart Valve Durability Tester would constitute infringement. This "natural consequence of infringing activity … does not weigh against issuance of an injunction." *Anderson*, 927 F. Supp. 2d at 488; *see also Celsis*, 664 F.3d at 931 (injunction warranted where potential harm to infringing party was "the result of its own calculated risk in selling a product with knowledge of [the plaintiff's] patent"); *i4i Ltd. P'ship, v. Microsoft Corp.*, 598 F.3d 831, 863 (Fed. Cir. 2010) ("[N]either commercial success, nor sunk development costs, shield an infringer from injunctive relief . . . . [The infringer] is not entitled to continue infringing simply because it successfully exploited its infringement."). Moreover, the ViVitro ADC™ Heart Valve Durability Tester will first be delivered in fall of 2023, so any harm to Defendant would be minimal. *See Tuf-Tite, Inc. v. Fed. Package Networks, Inc.*, 2014 U.S. Dist. LEXIS 163352, at *26 (N.D. Ill. Nov. 21, 2014) (balance of harms favor patentee where infringer "has only recently entered the market" with infringing product).

D. The Public Interest Favors Entry of a Preliminary Injunction

The Federal Circuit has indicated that courts should be more likely to grant an injunction "in traditional cases, such as this, where the patentee and adjudged infringer both practice the patented technology." *Robert Bosch*, 659 F.3d at 1150. Further, the Patent Act "reflects a strong public policy interest in 'promot[ing] the progress of the useful arts.'" *Anderson*, 927 F.Supp.2d at 489 (quoting *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1577 (Fed. Cir. 1983)). Thus, although "the public often benefits from healthy competition . . . the public generally does not benefit when that competition comes at the expense of a patentee's investment-backed property right." *Apple*, 809 F.3d at 647. This factor favors entry of a preliminary injunction.

E. Bond

Bond in this case should be minimal. District courts have broad discretion in determining the amount of a bond to secure a preliminary injunction. *Hill v. Xyquad, Inc.*, 939 F.2d 627, 632 (8th Cir. 1991). BDC's infringement case is strong. Moreover, ViVitro is only just beginning to make inroads into the domestic market in selling its ViVitro ADC™ Heart Valve Durability Tester. Therefore, the potential lost profits to ViVitro of a preliminary injunction at this early stage are still likely small. In light of these circumstances, bond should be no more than $10,000.

IV. CONCLUSION

For the foregoing reasons, BDC respectfully requests that this Court grant this motion and enter a preliminary injunction against Defendant that prohibits Defendant from any further direct or indirect infringement of the '935 patent and specifically from making, using, offering to sell, selling, or importing the ViVitro ADC™ Heart Valve Durability Tester and any other product that infringes the '935 patent, and for such other relief this Court deems just and proper.

Respectfully submitted this 12th day of April, 2023.

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