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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

INARI MEDICAL, INC., Plaintiff, v. IMPERATIVE CARE, INC., Defendants.	Civil Action No. 5:24-cv-03117-EKL **DEFENDANT IMPERATIVE CARE'S OPPOSITION TO PLAINTIFF INARI MEDICAL'S MOTION FOR A PRELIMINARY INJUNCTION** Hearing Date: TBD Time: TBD Location: Courtroom7, San Jose Hon. Eumi K. Lee **[PUBLIC VERSION]**

TABLE OF CONTENTS

Page No.

I. INTRODUCTION 1

II. FACTUAL BACKGROUND 5

A. Imperative Care Founded To Treat Patients Suffering From Stroke 5

B. Imperative Care Joins the Growing VTE Thrombectomy Market 6

C. The Year-Long Dispute Between the Parties 7

D. Imperative Care Files IPRs In The Patent Office 8

III. LEGAL STANDARDS 9

IV. ARGUMENT 10

A. Inari Is Not Likely to Succeed on the Merits 10

1. Sales of Symphony Cannot Infringe Claim 1 of the ’910 Patent 10

a. Symphony Is Not Sold for the Treatment of PE 10

b. Symphony Does Not Have a Second Pressure Source 11

c. Most Symphony Procedures Do Not Use Two Catheters 14

2. Substantial Questions of Validity Cloud Inari’s Patents 14

a. Claim 1 of the ’910 Patent is Invalid 14

i. Overview of Garrison 15

ii. The Examiner Was Misinformed During Prosecution of the ’910 Patent 16

iii. Laub Discloses Catheters 16F and Greater For PE 17

iv. A POSITA Would Have Found It Obvious to Adapt Garrison to Treat PE Based on Laub 18

b. Claims 1 and 10 of the ‘921 Patent Are Invalid 19

i. Schaffer Anticipates Claims 1 and 10 of the ‘921 Patent 20

ii. Schaffer Combined with Hartley Renders Claims 1 and 10 of the ’921 Patent Obvious 23

TABLE OF CONTENTS
(*cont'd*)

Page No.

iii. Inari Fails to Support Any Secondary Indicia 24

3. Symphony Is Not A "Copycat" of Any Inari Product 24

a. Symphony Uses An Electric Generator, Not Syringes 25

b. Symphony Has an Integrated Handle, Not Separate Components 26

c. Symphony Relies on Aspiration, Not Scraping the Blood Vessels 27

d. Inari's CEO Admits The "Copycat" Allegation Is Speculative 27

B. Inari Cannot Establish Irreparable Harm 27

1. Inari Fails to Show a Causal Nexus Between Infringement and Harm 28

2. Inari Cannot Blame Imperative Care for Its Declining Market Share 30

3. Inari's Delay in Filing this Motion Confirms No Irreparable Harm 31

C. The Balance of Hardships Favors Imperative Care 32

D. The Public Interest Weighs Against an Injunction 33

V. CONCLUSION 35

TABLE OF AUTHORITIES

Page No(s).

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239 F.3d 1343 (Fed. Cir. 2001) 9, 10

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612 F.2d 1112 (9th Cir.1980) 10

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695 F.3d 1370 (Fed. Cir. 2012) 3, 27, 28

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809 F.3d 633 (Fed. Cir. 2015) 27

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678 F.3d 1314 (Fed. Cir. 2012) 3, 28, 31

Archive Corp. v. Cipher Data Prods, Inc.,
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No. 3:17-CV-04319-WHO, 2018 WL 1411100 (N.D. Cal. Mar. 21, 2018) 32

Cohesive Techs., Inc. v. Waters Corp.,
543 F.3d 1351 (Fed. Cir. 2008) 24

Conceptus, Inc. v. Hologic, Inc.,
No. 09-cv-02280 WHA, 2012 WL 44064 (N.D. Cal. Jan. 9, 2012).....31

Cordis Corp. v. Bos. Sci. Corp.,
99 F. App'x 928 (Fed. Cir. 2004).....33, 34

Douglas Dynamics, LLC v. Buyers Prods. Co.,
717 F.3d 1336 (Fed. Cir. 2013) 31

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944 F.3d 1366 (Fed. Cir. 2019) 24

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No. SA CV 04-689 AHS, 2004 WL 1874992 (C.D. Cal. July 30, 2004).....9

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207 F. Supp.3d 1081 (N.D. Cal 2016).....31

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No. 17-CV-01921-BLF, 2017 WL 4676280 (N.D. Cal. Oct. 17, 2017).....33

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550 U.S. 398 (2007).....14, 18, 23

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517 U.S. 370 (1996).....24

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No. 3:17-CV-02013-JD, 2018 WL 306689 (N.D. Cal. Jan. 5, 2018).....27, 28, 33, 34

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No. 22-CV-01904-WHO, 2022 WL 1814145 (N.D. Cal. June 2, 2022).....9, 33

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782 F.2d 995 (Fed. Cir. 1986) 33

Winter v. Nat. Res. Def. Council, Inc.,
555 U.S. 7 (2008).....9, 10, 32

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35 U.S.C. § 102.....19

35 U.S.C. § 103.....14

35 U.S.C. § 271.....1, 11

35 U.S.C. § 311.....8

INDEX OF EXHIBITS

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1002	*MedTech Data Insights – Vital Signs*, Nephron Research, Medical Devices & Supplies (June 4, 2024)	Joseph R. Re
1003	*Flash Update, Inari Medical, Biomedical Devices and Services*, Canaccord Genuity Capital Markets, US Equity Research (May 12, 2024)	Phil Nalbone
1004	*Inari Medical, Inc.*, William Blair Equity Research Initiation Report (July 25, 2024)	Joseph R. Re
1006	*US Device Guide – Mechanical Thrombectomy/Thrombolysis (Peripheral/Venous)*, Endovascular Today	Joseph R. Re
1012	Excerpts of USPTO File History for U.S. Pat. App. No. 17/226,318 (issued as U.S. Pat. No. 11,844,921)	Troy Thronton
1013	Transcript of the Aug. 16, 2024 Deposition of Kevin Strange (condensed)	Joseph R. Re
1014	Penumbra, Neuro Thrombectomy System, *available at* https://www.penumbrainc.com/products/neuro-thrombectomy/ (last accessed Sept. 3, 2024)	Joseph R. Re
1015	Penumbra, Indigo System Lightning, *available at* https://www.penumbrainc.com/products/peripheral-thrombectomy-indigo-system/ (last accessed Sept. 3, 2024)	Joseph R. Re
1016	FDA Clearance Letter and 510(k) Summary for 510(k) Application No. K192833 (Dec. 20, 2019)	Joseph R. Re
1017	Petition for *Inter Partes Review* of U.S. Patent No. 11,744,691 (filed Aug. 12, 2024)	Joseph R. Re
1018	Transcript of Aug. 21, 2024 Deposition of Andrew John Hykes (condensed)	Joseph R. Re
1019	Transcript of Aug. 27, 2024 Deposition of Brian Brown (condensed)	Joseph R. Re
1020	Excerpts of USPTO File History for U.S. Pat. App. No. 18/329,450 (issued as U.S. Pat. No. 11,969,333)	Joseph R. Re

INDEX OF EXHIBITS
(*cont'd*)

1021	U.S. Patent Publication No. 2017/0043066 A1 ("Laub")	Troy Thronton
1022	Excerpts of USPTO File History for U.S. Pat. App. No. 18/342,553 (issued as U.S. Pat. No. 11,974,910)	Troy Thronton
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1026	Transcript of Aug. 22, 2024 Deposition of Benjamin Merritt (condensed)	Joseph R. Re
1027	Symphony Thrombectomy System brochure (Imperative Care, 2024)	Lance Scott
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INDEX OF EXHIBITS
(*cont'd*)

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1035	Resume of Troy Thornton	Troy Thronton
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1038	U.S. Patent No. 5,938,645 ("Gordon")	Troy Thronton
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1042	*Inari Medical, Inc. (NARI)*, *Key Takeaways from the 2024 Wells Fargo Healthcare Conference*, Wells Fargo Equity Research (Sept. 6, 2024)	Phil Nalbone
1043	*Inari Medical Inc. – North America, 2024 MS Healthcare Conference Takeaways*, Morgan Stanley Research (Sept. 4, 2024)	Phil Nalbone
1044	Curriculum Vitae of Dr. Robert Dana Tomalty	Dr. Robert Dana Tomalty

Defendant Imperative Care, Inc. ("Imperative Care") hereby opposes Plaintiff Inari Medical, Inc.'s ("Inari") Motion for a Preliminary Injunction ("Motion"). This Opposition is concurrently filed with the Declarations of Dr. Tomalty, Dr. Turk, Lance Scott, Phil Nalbone, Troy Thorton, and Joseph Re, and the exhibits attached to some of those declarations.

I. INTRODUCTION

None of the four preliminary injunction factors favor Inari. On each factor, Inari's arguments are unsupported speculation, completely irrelevant, or plainly contrary to the facts. Inari's poor showing cannot satisfy its heightened burden to upset the status quo and prevent physicians from continuing to use Symphony to remove blood clots from patients.

1. *Inari is not likely to succeed on the merits.* Inari's brief distorts the ***three*** asserted claims even though the claim language controls all issues. Inari's patent claims are ***not*** to the general ideas of aspirating blood clots or using aspiration to treat pulmonary embolisms ("PE") or deep vein thrombosis ("DVT"). Nor do they claim the method of rapid aspiration, which Inari calls "Whoosh." Rather, the claims are to specific features of certain well-known catheter devices for removing blood clots.

Claim 1 of the 910 Patent. Inari has asserted only ***one*** patent claim directed to a multi-component catheter system for removing blood clots (claim 1 of the '910 patent), but that claim is narrow. ***First***, it requires that the system treat "clot material comprising a pulmonary embolism." But Inari concedes Imperative Care's Symphony does not have FDA clearance for such uses. And Inari concedes Imperative Care's on-going PE clinical trial for FDA clearance is exempted from any patent infringement. *See* Dkt. 24-7 (Inari's Proposed Order excluding FDA trials from this Motion); Mot. at 16, n.9; 35 U.S.C. § 271(e)(1). While Inari alleges that physicians have used Symphony "off-label" for PE, it never alleges Imperative Care is in any way responsible for, or even encourages, those uses. Mot. at 16.

Second, claim 1 requires a "clot treatment system" having a "first clot aspiration assembly" with a "first catheter" and "first pressure source" and a "second clot aspiration assembly" with a "second catheter" and a "second pressure source" where the second catheter is advanceable through the first. Yet physicians rarely use Symphony with two catheter

assemblies, and ***never*** use Symphony's second catheter with its own, separate pressure source. Thus, Symphony could not possibly infringe claim 1 of the '910 patent.

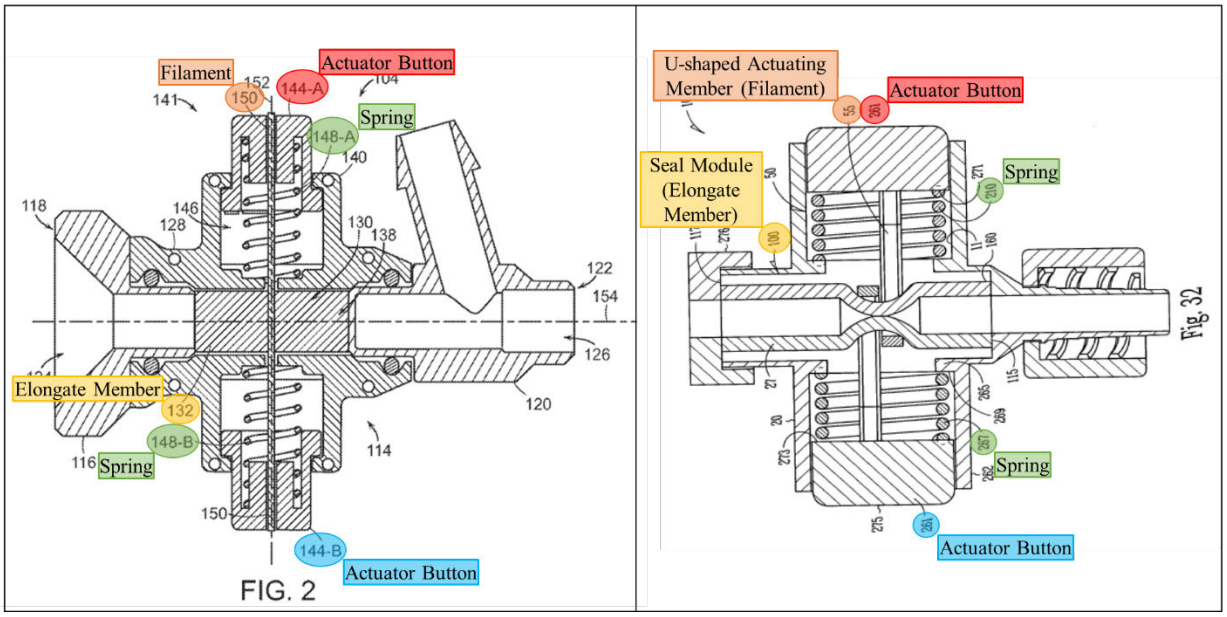
Inari repeatedly accuses Imperative Care of making a "copycat" of Inari's products, but never shows the competing products side by side. Any comparison shows that Symphony is a very different device with clear advantages over Inari's products. Inari's older devices require physicians to manually operate syringes to create a vacuum for each catheter. In contrast, Symphony uses a single electric generator as the source of negative pressure for both catheters. Regardless, the claim language controls infringement, not baseless copying allegations. Symphony never uses two pressure sources, even in the rare case when it uses a second catheter inside the first. Inari's misguided infringement allegations identify Symphony's only pressure source ***twice***, pretending it is two different sources, as the claim requires.

Moreover, aspiration systems with two catheter assemblies and two separate pressure sources were well known before Inari. One example is shown in an earlier patent publication, referred to as "Garrison," which disclosed such a two-pressure-source system for aspirating blood clots from the brain. Indeed, Imperative Care brought Garrison to Inari's attention in response to Inari's September 2023 cease and desist letter, yet Inari proceeded with this Motion.

Claims 1 and 10 of the '921 patent. Claims 1 and 10 of the '921 patent are the other two claims asserted in the Motion. These claims are not to an aspiration system, but only to a specific valve having "an active tensioning mechanism" with a movable "actuator" coupled to a "filament" extending around an "elongate member defining a lumen" to open and close the lumen. Claim 1 also requires a "biasing member configured to bias" the actuator to close the lumen. Claim 10 further requires a "second actuator" acting like the first actuator and a "second biasing member configured to bias the second actuator" to the closed position.

Such valves existed well before Inari and the '921 patent. Shown below is a comparison between the figures in the '921 patent and an earlier U.S. patent known as "Schaffer." As illustrated, both valves have virtually identical components, springs, actuator buttons, and a filament wrapped around the lumen. The '921 patent claims reciting these same components are clearly invalid in view of Shaffer.

’921 Patent | Schaffer



Because the three asserted claims are either not infringed, or invalid, or both, Inari cannot show a likelihood of success on the merits.

2. *Lack of Irreparable Harm.* Inari also fails to show the alleged infringement caused it any irreparable harm. ***First***, Inari argues that it has been losing money and market share over the past few years. But Inari cannot accurately blame its financial troubles and market-share declines on Imperative Care’s sale of Symphony. Inari and its primary competitor, Penumbra, hold over 90% of the vascular thrombectomy market. Inari admits it has been losing market share to Penumbra for several years, as Penumbra has introduced improved aspiration systems. The Symphony sales, which Inari admits have been “negligible,” all occurred after mid-2023 and do not even register in the market share data. That Inari “might lose some insubstantial market share” to Imperative Care’s Symphony “is not enough” to support a finding of irreparable harm. *Apple, Inc. v. Samsung Elecs. Co.*, Ltd., 678 F.3d 1314, 1324–25 (Fed. Cir. 2012) *(“Apple I”)*.

Second, Inari fails to show how any infringement of the three patent claims at issue in this Motion caused it irreparable harm. As part of the irreparable harm showing, Inari must demonstrate a causal nexus between the infringement and harm, because “[s]ales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons

other than the patented feature." *Id.* at 1324. Inari made no attempt to make such a showing, nor could it.

Regarding the '910 patent, Symphony has never been sold for treating PE, physicians rarely use telescoping catheters for treating DVT, and physicians never use a second pressure source, all of which are required claim elements. Regarding the '921 patent, no evidence suggests customers buy Symphony because of its hemostasis valve, let alone for the claimed features of the valve, most of which are hidden within the opaque housing of the Symphony handle. Indeed, Inari contends its FlowTriever and ClotTriever products practice the asserted claims but admits that customers are driven to buy those products because of numerous features unrelated to the claimed elements. Thus, Inari has not shown the required nexus between the alleged infringement and any irreparable harm. Inari's lack of irreparable harm is also reflected in how slowly it filed this Motion. Inari has known about Symphony since March 2023, yet waited until July 24, 2024, to file this Motion.

Inari's failure to show a likelihood of success and irreparable harm defeats this Motion, as Inari recognizes the first two factors ***must*** be established to obtain preliminary relief. Mot. at 18, n.10. Regardless, the remaining two factors also favor Imperative Care.

3. *Balance of Hardships.* Imperative Care would suffer an immediate hardship if it could no longer sell Symphony. It would lose all its investment in Symphony and its purchase of Truvic would have been for naught. An injunction would also kill Imperative Care's incentive to continue its research to improve the product, especially if the injunction lasted for a significant period. In contrast, Inari is a much larger, publicly held company. It has a large market share along with Penumbra and its sales have been growing for years and are projected to keep growing as the market grows. Inari admits the market is large, growing, and severely underpenetrated, with 94% of the patient population not being served at all with any mechanical thrombectomy device. Inari's alleged hardship is pure speculation that sales of Symphony might somehow eventually slow Inari's rate of growth. On balance, Inari's hardship without an injunction pales in comparison to Imperative Care's if it were enjoined.

4. *Public Interest.* The fourth factor also favors Imperative Care, as Inari submitted no

evidence that an injunction would be in the public interest. It irrelevantly argues that its devices are superior to traditional treatments but ignores how it compares to Symphony and what the public would lose without Symphony. In a market so underpenetrated, all makers of mechanical thrombectomy devices should be trying to improve their devices so that more physicians use them to serve more patients, the apparent goal of Inari. Unlike Inari, Imperative Care has submitted a physician declaration explaining Symphony's benefits over the older Inari devices and why it would be against the public interest to take the product off the market.

Inari's poor showing on all four preliminary injunction factors cannot justify a pre-trial order preventing physicians from using Symphony to remove blood clots from patients. Thus, this Court should deny Inari's Motion.

II. FACTUAL BACKGROUND

A. Imperative Care Founded To Treat Patients Suffering From Stroke

Imperative Care has developed technologies for physicians and with physicians since its founding. The company was co-founded in 2015 by Dr. Nick Hopkins, the neurosurgeon who pioneered a minimally invasive way to treat stroke patients, and Fred Khosravi, a renowned Silicon Valley medical device engineer and successful founder of numerous medical device companies. Nalbone Dec., ¶ 5. Imperative Care provides engineering solutions based on clinical needs. Upon inception, the founders assembled a strong leadership bench and a deep team of founding clinical advisors. One of the founding clinical advisors is Aquilla "Quill" Turk, D.O., a neuroendovascular surgeon at Greenville Health System. Dr. Quill has provided a declaration in support of this opposition. *Id.* at ¶ 6. Together, the Imperative Care team focused on developing the next generation of stroke care across the entire patient journey.

Imperative Care has demonstrated an unwavering commitment to developing medical innovations that drive the best results for stroke and vascular patients. Thrombectomy is one of the most powerful treatments in medicine. These procedures can transform a person's prognosis in minutes – restoring blood flow that can make the difference between life and death.

Imperative Care's goal is to make thrombectomy available to more patients – first in stroke, and now for vascular disease. In 2019, it introduced the Zoom Stroke Solution family

of products, which brought intracranial access to the market and the fullest lineup of aspiration devices and accessories for the treatment of ischemic stroke. These products have now been used to treat more than 50,000 patients. *Id.* at ¶ 7.

B. <u>Imperative Care Joins the Growing VTE Thrombectomy Market</u>

Thrombectomy is not limited to neurovascular applications. Imperative Care agrees with Inari that the market for venous thromboembolism ("VTE") is enormous and grossly underserved. Although several companies have introduced mechanical thrombectomy devices in recent years, such devices are used in only 10% of cases in the intermediate- and high-risk patient populations suffering from VTE. Ex. 1004 at 14-15. Indeed, as Inari admits, its devices are used in only 6% of cases that could benefit from its products. Mot. at 6.

Numerous medical device companies, both large (e.g., Boston Scientific, Penumbra) and small (e.g., AngioDynamics, Innova Vascular), are working to address this huge clinical need. *See* Ex. 1006 (identifying VTE companies). In 2021, Imperative Care joined the effort by acquiring Truvic. Nalbone Dec., ¶ 8-9. Truvic was developing Symphony to improve upon the existing standard of care. Part of Truvic's development work included researching competitive products and innovating solutions to avoid the problems associated with those products. Some of that research is reflected in Imperative Care's FOIA requests, which Inari concedes "are not uncommon in the medical device industry …." Mot. at 14. Truvic did not file the requests to copy Inari's products, as Inari suggests, but rather to improve upon those products, which Imperative Care has successfully done. Nalbone Decl., ¶ 10.

Today, Imperative Care's purchase of Truvic has led to two FDA-cleared thrombectomy products, Prodigy, for peripheral arterial and venous applications, and Symphony. *Id.* at ¶ 9. Additionally, in 2023, Imperative Care initiated a prospective, multicenter, single-arm trial to assess safety and efficacy of Symphony in the treatment of acute pulmonary embolism. *Id.* at ¶ 12. That clinical trial is ongoing. Imperative Care expects to leverage its successes in the neurovascular market as it develops these additional treatment options for patients with VTE. As Inari's own CFO has admitted, Imperative Care is "well-managed, and has experience in neurovascular applications, which gives it added credibility to

doctors and hospitals." Strange Decl., ¶ 13.

The Parties also agree that their competitors have traditionally adapted core technologies from other treatment areas, such as neurovascular or coronary, to target peripheral or pulmonary vasculatures for the treatment of VTE. Mot. at 7-9; *see also* Ex. 1013 at 31:13-32:10. All share the same basic concept of vacuuming a clot from a blood vessel. The Parties further agree that Penumbra is a clear example of this evolution. Mot. at 6 n.5. In late 2007, Penumbra received FDA clearance for its aspiration-based mechanical thrombectomy device for the treatment of acute ischemic stroke and intracranial large vessel occlusions. This device was known as the Penumbra System®. Ex. 1014. Over several years, Penumbra adapted the core technology of the Penumbra System® for use in peripheral arterial and venous applications culminating in the 2014 launch of its Indigo® Aspiration System. Ex. 1015. In December 2019, the FDA cleared Indigo® for treating PE. Ex. 1016 (FDA 510(k) Summary, K192833). Penumbra now has the second largest market share (~30%) in the VTE thrombectomy market and is Inari's primary competitor. Ex. 1003 at 1; Ex. 1002 at 4; Ex. 1013 at 20:14-23.

C. <u>The Year-Long Dispute Between the Parties</u>

Inari tracked Imperative Care's progress in the market. In February 2023, Inari knew that the FDA cleared Symphony for treating DVT. Hykes Dec., ¶ 23; Ex. 10. Imperative Care, still under the Truvic name, immediately began marketing Symphony and, in March 2023, distributed detailed brochures at a trade show. Ex. 7. Inari admits it received that Symphony brochure at that trade show. *Id.* at ¶ 21. Imperative Care began selling Symphony in August 2023 and Inari concedes it was aware of the Symphony sales. Nalbone Dec., ¶ 12; Mot. at 15.

Inari wrote to Imperative Care in September 2023, asserting the sale of Symphony infringed several Inari patents. Ex. 22. But that letter did not include the two patents Inari asserts on this Motion, which had not yet issued. *Id.* In January 2024, after Inari specified certain claims, Imperative Care responded with a detailed 38-page analysis of why Inari's assertions were misguided. Ex. 25. The letter explained the prior art references, especially Garrison, and showed why those references render the identified claims invalid. *Id.* Inari did not respond for three months. Ex. 26. Instead, Inari returned to the Patent Office to pursue

new patents, including the '910 patent, apparently convinced Imperative Care raised significant invalidity arguments. To obtain those new patents, Inari had its Chief Medical Officer ("CMO") argue to the Patent Examiner that Garrison was limited to neurovascular applications and that Inari's new patent claims would be patentable over Garrison if they were limited to larger catheters ("16 French or greater") for treating "a pulmonary embolism." *Id.* The Examiner, in no position to disagree, allowed the claims on that basis.

One of those new claims became claim 1 of the '910 patent. After obtaining allowance of that patent, Inari finally wrote back to Imperative Care, relying on that allowance to argue that Garrison was no longer probative of invalidity. Ex. 26 at 2. But as shown in this opposition, the Examiner was misled and made a serious mistake by allowing the '910 patent.

In May 2024, Inari sued Imperative Care on eight patents. It has since added a ninth. On July 24, 2024, it filed the present motion.

D. <u>Imperative Care Files IPRs In The Patent Office</u>

In July 2024, Imperative Care filed a petition for *inter partes* review ("IPR") of Inari's '011 patent. Ex. 28. An IPR permits anyone to petition the Patent Office to cancel patents in view of earlier publications. 35 U.S.C. § 311. Like the '921 patent in this Motion, the '011 patent claims a valve having a filament that partially wraps around a tube. In its IPR petition, Imperative Care showed that the Schaffer and Hartley patent publications render the claims of the '011 patent invalid, just like Imperative Care has done below for the '921 patent. Ex. 28 at 16-70. Notably, the claims of the '011 and '921 patents overlap, so the findings in the IPR will decide the key issues underlying invalidity on this Motion.

In August 2024, Imperative Care filed a second petition for IPR of Inari's '691 patent. Ex. 1017. The '691 patent claims an aspiration system with accelerated response, which Inari calls "Whoosh." The patent also includes claims specific to PE. In its IPR petition, Imperative Care showed that Garrison renders the '691 patent claims invalid, just as Imperative Care shows below for the '910 patent. Once again, the claims of the '691 and '910 patents overlap, so the findings in the IPR will decide the key issues underlying invalidity on this Motion.

The Patent Board will decide whether to institute the '011 IPR by January 8, 2025, and

the '691 IPR by February 12, 2025. Imperative Care intends to file similar IPRs on the other asserted patents, including the two on this Motion.

III. LEGAL STANDARDS

The Parties agree that to obtain a preliminary injunction, Inari must show 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 [Inari's] favor," and (4) "an injunction is in the public interest." Mot. at 18 (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). While the factors are not "applied mechanically," the Parties agree that Inari ***must*** establish the first two factors to be entitled to a preliminary injunction. *Id.* at 18, n.10; *see Amazon.com Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001).

"A preliminary injunction should preserve the status quo which is the 'last uncontested status which preceded the controversy.'" *Archive Corp. v. Cipher Data Prods, Inc.*, 12 USPQ 2d 1464, 1468 (C.D. Cal. 1988) (quoting *Tanner Motor Livery, Ltd. v. Avis, Inc.*, 316 F.2d 804, 809 (9th Cir. 1963)). Here, the last uncontested status was after December 19, 2023, when the first of the two patents asserted in this Motion issued. At that time, Symphony was FDA cleared and on the market. Mot. at 15; Nalbone Dec., ¶ 12.

Inari argues that an injunction "effectively maintains the status quo" because Imperative Care "is just bringing the Symphony system to market." Mot. at 3. But Inari admits Symphony has been marketed since March 2023. *Id.* at 15. Thus, rather than preserve the status quo pending a trial on the merits, Inari seeks to upset the status quo by removing Symphony from the market and depriving doctors of an important new technology in the fight against DVT. *See ICU Med. Inc. v. Alaris Med. Sys., Inc.*, No. SA CV 04-689 AHS, 2004 WL 1874992, *25 (C.D. Cal. July 30, 2004) (finding a preliminary injunction "could not preserve the status quo and would conversely create new market conditions" where accused product sold before the patent issued). Under these circumstances, Inari "must clear a higher bar" to justify its mandatory injunction. *UTTO Inc. v. Metrotech Corp.*, No. 22-CV-01904-WHO, 2022 WL 1814145, at *2 (N.D. Cal. June 2, 2022). "In general, mandatory injunctions 'are not granted unless extreme or very serious damage will result and are not issued in doubtful cases or where

the injury complained of is capable of compensation in damages.'" *Marlyn Nutraceuticals, Inc. v. Mucos Pharma GmbH & Co.*, 571 F.3d 873, 879 (9th Cir. 2009) (quoting *Anderson v. United States*, 612 F.2d 1112, 1114 (9th Cir.1980)).

As explained below, Inari has failed to show any of the factors favor an injunction, much less make a "clear showing" that it is entitled to the "extraordinary remedy" of a preliminary injunction. *Winter*, 555 U.S. at 22. Accordingly, the Court should deny the motion.

IV. ARGUMENT

A. Inari Is Not Likely to Succeed on the Merits

If Imperative Care "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 (internal quotes omitted). "Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself." *Id.* at 1359. Below, Imperative Care identifies substantial questions concerning infringement or validity, or both for the three asserted claims. Because Inari cannot prove these questions lack substantial merit, Inari cannot satisfy its burden on the first preliminary injunction factor.

1. Sales of Symphony Cannot Infringe Claim 1 of the '910 Patent

"To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly." *Southwall Techs., Inc. v. Cardinal IG Co.,* 54 F.3d 1570, 1575 (Fed. Cir. 1995). Imperative Care's manufacture, use, or sale of Symphony cannot infringe Claim 1 of the '910 patent because Symphony lacks at least three limitations: (1) Symphony is not sold or cleared for the treatment of PE and Inari admits the use of Symphony in the ongoing FDA trials are not infringements; (2) Symphony does not have a "second pressure source;" and (3) almost all Symphony procedures do not use a "second clot aspiration assembly."

a. Symphony Is Not Sold for the Treatment of PE

The preamble of Claim 1 of the '910 patent recites, "A clot treatment system for treating

clot material comprising a pulmonary embolism ...." Claim 1 also recites that "the second catheter is positioned proximate to the pulmonary embolism" and generates suction "to aspirate blood and at least a portion of the pulmonary embolism into the second catheter." Inari's expert assumes that treating a PE is a requirement of Claim 1. Brown Dec., ¶ 131.

However, the Parties agree that the FDA has not cleared Symphony for the treatment of PE, which means that Imperative Care cannot and does not manufacture or sell the Symphony for that use. Mot. at 16. While Imperative Care is currently conducting an FDA trial to evaluate Symphony in treating PE, Inari concedes that Symphony's use in this trial is exempted from infringement under 35 U.S.C. § 271(e)(1). *Id.* at 16, n.9.

Inari also alleges that doctors have used Symphony "off-label" to treat PE. Mot. at 16, 20. Yet, Inari never explicitly argues that "off-label" use constitutes infringement. *See e.g.,* Brown Dec. ¶¶131-132 (no argument off-label use is infringement). Nor could it. Inari's CEO [redacted] Ex. 1018 (Hykes Dep. Tr.) at 59:4-60:5. Rather, Inari's CEO [redacted] *Id.* Consequently, Inari has failed to show that any off-label use is likely to support a finding of infringement.

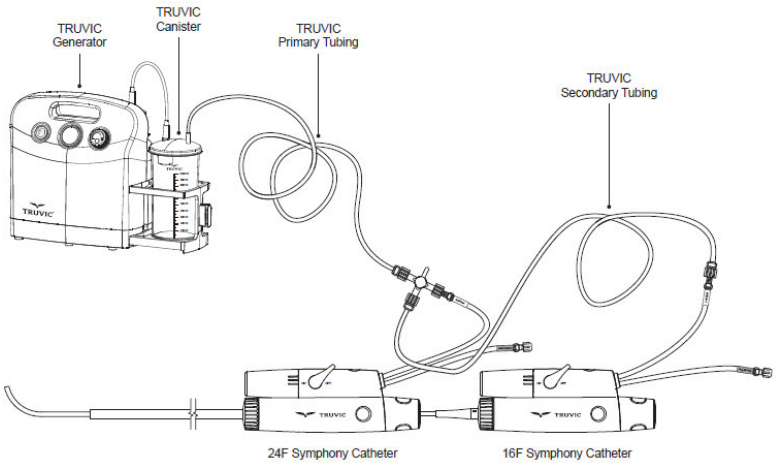
Further, Inari's allegations of "off-label" use are threadbare and cannot support a finding that Inari is likely to prove infringement. Inari did not identify any specific instances of "off-label" use or any witnesses with first-hand knowledge of such uses. Instead, Inari relies exclusively on its CEO to "support" the allegation. Mot. at 16 (citing Hykes Dec., ¶ 30). However, Inari's CEO [redacted] Ex. 1018 at 56:23-57:14, 60:7-64:15. Regardless, Imperative Care investigated Inari's claims and, like Inari, has been unable confirm any specific "off-label" uses of Symphony. Scott Dec., ¶¶ 30-34.

b. <u>Symphony Does Not Have a Second Pressure Source</u>

Claim 1 recites a "clot treatment system" having (1) a "first clot aspiration assembly" with "a first catheter" and a "first pressure source" and (2) a "second clot aspiration assembly"

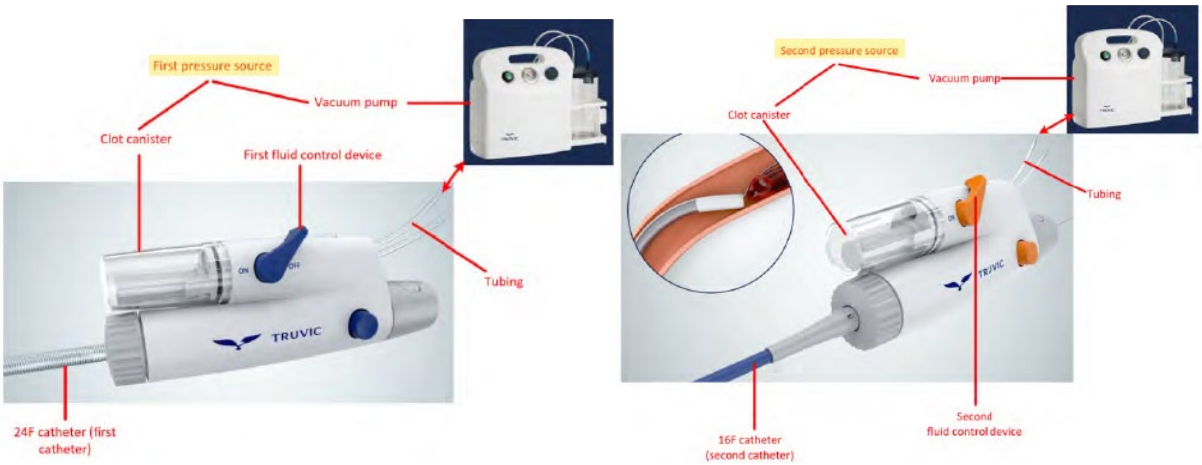
with "a second catheter" and a "***second pressure source***." Symphony is not sold with or instructed for use with a "second pressure source" and, therefore, cannot infringe Claim 1.

Symphony's lone pressure source is its electric generator. Scott Dec., ¶ 15. In most DVT procedures, the generator is connected to a single catheter. In the rare instance when a physician simultaneously uses two Symphony catheters, the Symphony IFU instructs the physician to connect both catheters to the <u>same</u> electric generator using the primary and secondary tubing and four-way stopcock supplied by Imperative Care as shown below:



Id.; Ex. 8 at 9. Inari has presented no evidence, nor does any exist, to show that Imperative Care instructs physicians to use a second pressure source with Symphony. Consequently, Inari is unlikely to succeed in proving that the use of Symphony infringes Claim 1 of the '910 patent.

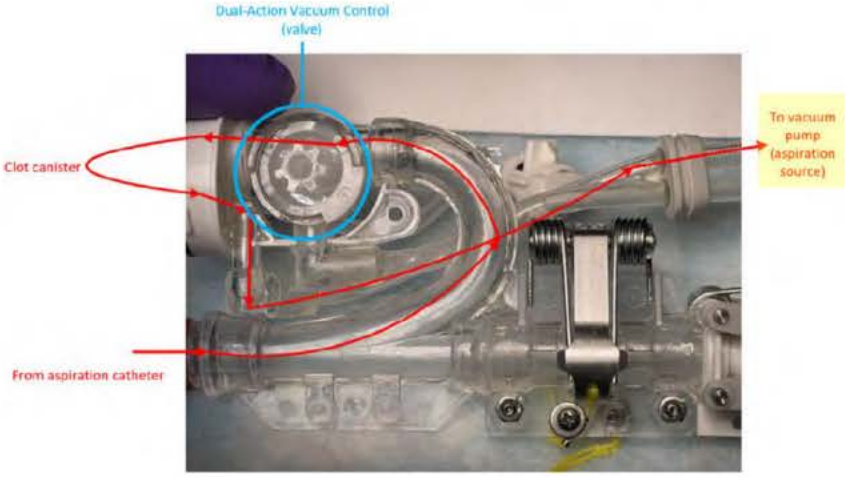
In its Motion, Inari identifies the same electric generator ("vacuum pump") as allegedly forming part of the "first pressure source" and the "second pressure source":



Mot. at 21, 23 (yellow highlight added); *see also* Brown Dec., ¶¶136, 158 (including same

figures). Instead, Inari argues that components located far away from the electric generator also form part of the first and second pressure sources, including the TruView™ Clot Container (labeled by Inari as "clot canister"). Inari's expert, Mr. Brown, [redacted] Ex. 1019 at 182:11-183:4.

Inari's argument that the "first pressure source" and "second pressure source" include components that do not generate pressure is frivolous. Inari's expert admits in the below figure from his declaration that the electric generator (i.e., vacuum pump) is the "aspiration source":



Brown Dec., ¶¶ 143, 163 (yellow highlight added). Likewise, the '910 patent consistently describes the first and second pressure sources as two separate pressure sources, not a combination of one pressure source with distant catheter components:

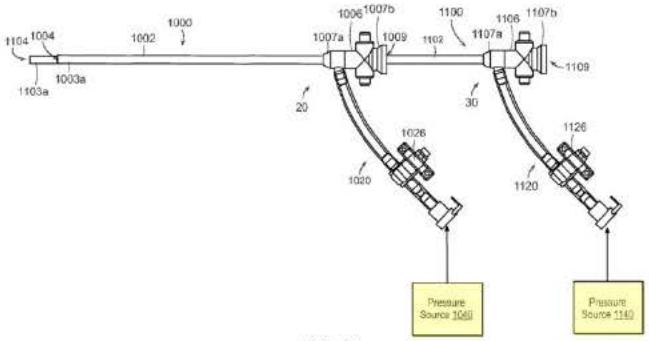


FIG. 11

Ex. 1 at Fig. 11 (yellow highlight added). The '910 patent explains that two pressure sources allow the physician to apply different negative pressures to each catheter, something Symphony's single electric generator cannot do. *Id.* at 27:18-33; Scott Dec., ¶ 15. Indeed, Inari's FlowTriever includes two syringes exactly as described in the '910 patent. For these

reasons, Inari is not likely to succeed in proving that Symphony has a second pressure source.

c. Most Symphony Procedures Do Not Use Two Catheters

Claim 1 recites a "clot treatment system" having "a first catheter" and "a second catheter." Imperative Care sells its 16F and 24F catheters separately. Scott Dec., ¶ 20. Moreover, almost all Symphony procedures to treat DVT (the only FDA-cleared use) use one catheter (either the Symphony 16F or 24F), not a first and second catheter. *Id.* at ¶ 9. Imperative Care's records show that only ~1.5% of cases performed for DVT use the Symphony 16F and 24F systems together – the balance (~98.5%) use only the Symphony 16F or 24F catheter. *Id*. Thus, virtually all Symphony procedures cannot infringe claim 1 of the '910 patent, and this claim certainly cannot justify Inari's broad request for an injunction barring the sale of ***all*** Symphony systems, even when sold with only one catheter.

2. Substantial Questions of Validity Cloud Inari's Patents

a. Claim 1 of the '910 Patent is Invalid

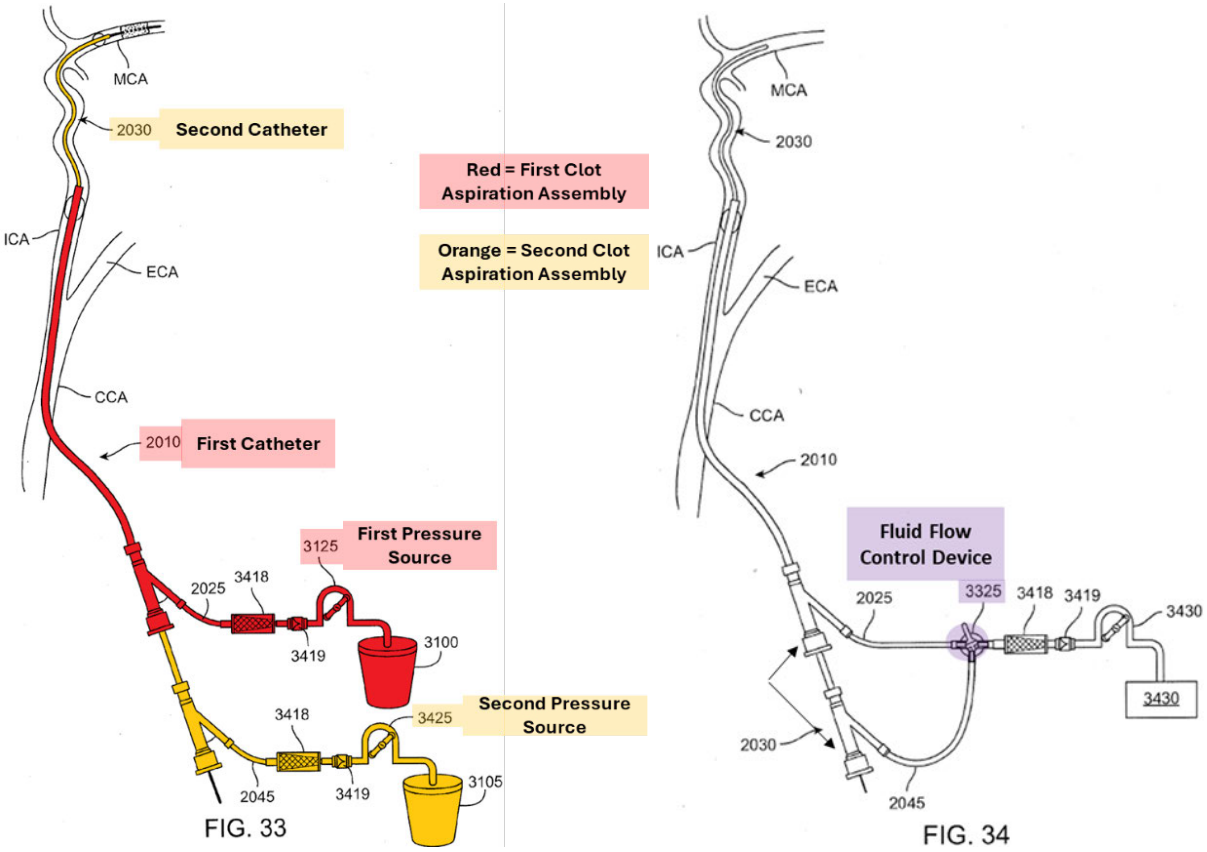
A patent claim is invalid "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art [hereinafter "POSITA"] to which the claimed invention pertains." 35 U.S.C. § 103; *KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 406 (2007). Claim 1 of the '910 patent is rendered obvious (and therefore invalid) by the combination of the "Garrison" and "Laub" patent publications.

During prosecution of the '910 patent, the Patent Examiner found that "Garrison" disclosed almost every limitation of claim 1. Ex. 4 at 4-8; *see also* Ex. 1019 at 90:7-101:17 [redacted] Thornton Dec., ¶¶ 109-138. The only limitations the Examiner did not find in Garrison were a description of using Garrison's system to treat a ***pulmonary embolism*** and a description of a second catheter having a size of ***16 French or greater***. Ex. 5 at 8. The Examiner reached this conclusion based on the arguments of Inari's CMO (and an interested inventor of the '910 patent), who convinced the Examiner that "it would not have been obvious to one of ordinary skill in the art to have applied the teachings of Garrison … to treat pulmonary embolism." Ex. 1020 (file history excerpts) at 22.

Yet these arguments are incorrect. Inari has admitted in this litigation that medical device companies routinely "repurpose" devices designed for other parts of the vasculature to treat PE, directly contradicting the arguments made to the Examiner. Brown Dec., ¶ 61; *see also* Turk Dec., ¶¶ 24-35. Moreover, Laub, which was never submitted to the Examiner for consideration, describes using aspiration catheters having a size of 16 French or greater to treat PE, the very limitations that were allegedly missing from the prior art. Ex. 1021 at ¶¶ [0005], [0028].

i. <u>Overview of Garrison</u>

Garrison describes aspiration systems for removing clots from patients. Ex. 29 at [0007]. Garrison provides many examples of these clot treatment systems, including systems having (1) a first clot aspiration assembly with a first catheter and first pressure source and (2) a second clot aspiration assembly with a second catheter and a second pressure source:



Id. at Figs. 33-34. In related examples, Garrison also discloses using a valve 3325 (i.e., fluid control device) to control when the pressure source is connected to the catheter(s). *Id.* at [0132]. A POSITA would have found it obvious to use a fluid flow control device 3325 with each of

the clot aspiration assemblies shown in Figure 33. *See* Thornton Dec., ¶ 134 (providing basis).

Garrison also describes the purpose of the fluid flow control device (valve 3325). Garrison explains that the physician can close the fluid flow control device to generate vacuum pressure in the portions of the system between the pressure source and the valve prior to treating the patient. Ex. 29 at [0134]. Garrison then explains that the physician can open the valve to release the built-up pressure. *Id.* Garrison explains this method "would enable the maximum level of aspiration in a rapid fashion with one user …." *Id*. This method falls squarely within what Inari recites in claim 1 of the '910 patent. *See e.g.*, Thornton Dec., ¶¶ 125-126.

ii. <u>The Examiner Was Misinformed During Prosecution of the '910 Patent</u>

Garrison posed a significant invalidity problem for Inari because it discloses almost every limitation of claim 1 of the '910 patent. However, Garrison primarily describes using its aspiration systems to remove blood clots in the brain and does not specifically mention PE. *See e.g.*, Ex. 29 at ¶ [0002] (describing "treatment of cerebral occlusions"). Garrison also describes catheters ranging in diameter from 5F-10F. *See id.* at ¶¶ [0063], [0124].

Thus, to obtain the '910 patent, Inari amended the patent claims to specifically recite treating a "pulmonary embolism" and to require a second catheter having "a size of 16 French or greater." Ex. 1022 at 10-13. Inari also had its CMO argue to the Examiner that a POSITA would not have found it obvious to use Garrison's system to treat pulmonary embolisms or to increase the size of Garrison's catheters. *Id.* at 15-16; *see also* Ex. 1020 at 22. The Examiner had no choice but to accept the CMO's representations because there was no third-party participant to submit contrary evidence.

However, the Examiner was misinformed. Inari has admitted in this litigation that it was common for POSITAs to adapt catheter systems used to aspirate clots in smaller blood vessels (such as blood vessels in the brain) to aspirate clots in larger blood vessels, such as PE. Thornton Dec., ¶¶ 116-121. Catheter designers understand how to appropriately size a catheter for the intended treatment site. For example, Inari's expert admits that some of Inari's competitors chose to "repurpose existing thrombectomy systems designed to treat clots in

smaller arteries, including neurovascular or coronary aspiration-based thrombectomy systems, to treat PE or DVT." Brown Dec., ¶ 61. Inari specifically identifies its largest competitor, Penumbra, as one company that "adapted its existing thrombectomy designs for the removal of emboli/thrombi from smaller neurovascular, peripheral arteries, and coronary arteries to create a thrombectomy device for VTE." *Id.*; *see also* Mot. at 6, n.5 ("Penumbra's devices were adapted from a preexisting product for treatment of clots in small arteries."). These real-world examples confirm the obviousness of Inari's claims and prove that Inari knew POSITAs would have found it obvious to increase the size of Garrison's system for use in other parts of the vasculature. Inari's arguments in this case directly contradict its arguments to the Examiner.

iii. <u>Laub Discloses Catheters 16F and Greater For PE</u>

Inari did not invent using aspiration catheters to treat PE or aspiration catheters measuring 16 French or greater. Laub describes an aspiration system for removing "unwanted material such as emboli, thrombi, tumors, or debris" from a patient's vasculature. Ex. 1021 at ¶ [0002]. Laub explicitly discloses that "[s]ystems according to certain embodiments of the present invention may be used, for example, to remove clots from patients suffering from or at risk of ***pulmonary embolisms***." *Id.* at ¶ [0005] (emphasis added).

Like Garrison, Laub's clot treatment system includes an aspiration catheter connected to a pump (i.e., pressure source):

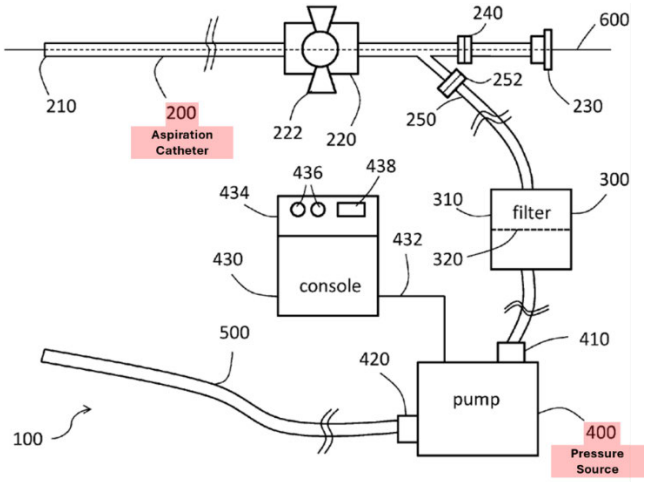


FIG. 1A

Id. at ¶ [0024], Fig. 1A. Laub's catheters have a diameter ranging from 5 French to 20 French and Laub specifically states, "[i]n some embodiments, aspiration catheter 200 has a French ***size***

of at least 16 Fr." *Id.* at ¶ [0028] (emphasis added). Consequently, Laub discloses the limitations the Examiner thought were missing from the prior art. Thornton Dec., ¶¶ 106-108.

iv. <u>A POSITA Would Have Found It Obvious to Adapt Garrison to Treat PE Based on Laub</u>

A POSITA would have found it obvious to adapt Garrison's aspiration system to use catheters of 16 French or greater to treat PE based on Laub. Thornton Dec., ¶¶ 109-138. The Supreme Court has held that merely combining prior art elements according to known methods to yield predictable results is obvious. *KSR,* 550 U.S. at 416. Claim 1 of the '910 patent does exactly that. The claim merely combines Garrison's prior art clot treatment system with Laub's 16 French or greater catheters to treat PE. Thornton Dec., ¶¶ 110-121.

Moreover, the Parties agree that POSITAs regularly adapted catheter-based medical devices initially developed for one portion of the vasculature to treat another. Thornton Dec., ¶ 116; Turk Dec., ¶¶ 24-35. Such adaptations were particularly common for treating blood clots because the various types of clots (e.g., pulmonary embolism, deep vein thrombosis ("DVT"), cerebral embolism) were related. Turk Dec., ¶¶ 36-39. Laub explains that blood clots tend to form in the larger arteries and move in the direction of blood flow. In some cases, "a thrombus can migrate to the vessels of the brain and cause stroke and possibly death," while in other cases "clots can migrate to the lungs and block the lungs main artery, resulting in a potentially fatal pulmonary embolism." Ex. 1021 at ¶ [0004]; *see also* Ex. 1023 at 2:13-19 (describing relationship between PE, DVT, and cerebral clots). Thus, POSITAs working on treating clots in one part of the body naturally relied upon innovations for treating clots in other parts of the body. Thornton Dec., ¶¶ 116-121; Turk Dec., ¶¶ 24-35.

In fact, the '910 Patent presumes that POSITAs possessed the knowledge and skill to adapt aspiration systems designed for one part of the vasculature for use in another. For example, while the '910 patent describes many devices and systems for treating PE, it recognizes that the described devices could be used in other parts of the vasculature including for example, "***intravascular procedures for treating cerebral embolism*** …." Ex. 1 at 4:51-58 (emphasis added).) The '910 patent does not identify any special reasons why its aspiration

catheters could be used interchangeability across different parts of the vasculature while other aspiration catheters (e.g., Garrison) could not. Moreover, Inari's witnesses have [redacted] *See, e.g.*, Ex. 1013 at 31:13-32:10. Further, Inari's expert [redacted] Ex. 1019 at 210:12-212:3.

Like the '910 patent, Garrison also suggests adapting its aspiration systems with components for use in other parts of the vasculature. *See e.g.,* Ex. 29 at ¶¶ [0070], [0144] (incorporating by reference patents addressing other parts of the vasculature). Further, the '910 patent and Garrison are not alone in presuming that a POSITA would have found it obvious to adapt aspiration catheters designed for one part of the vasculature for another. Other prior art patents disclose aspiration systems intended for use across all portions of the vasculature. For example, Brady describes catheters capable of removing clots "from the cerebral arteries" and the "pulmonary arteries." Ex. 1024 at [0001]; *see also* Ex. 1023 at 1:17-24, 1:62-2:32 (describing catheters for treating the chambers of the heart and medium to large blood vessels).

For at least these reasons, a POSITA would have found it obvious to adapt Garrison's aspiration system to use catheters having a size of 16 French or greater to treat PE based on Laub and the knowledge of a POSITA. Thornton Dec., ¶¶ 110-121.

b. <u>Claims 1 and 10 of the '921 Patent Are Invalid</u>

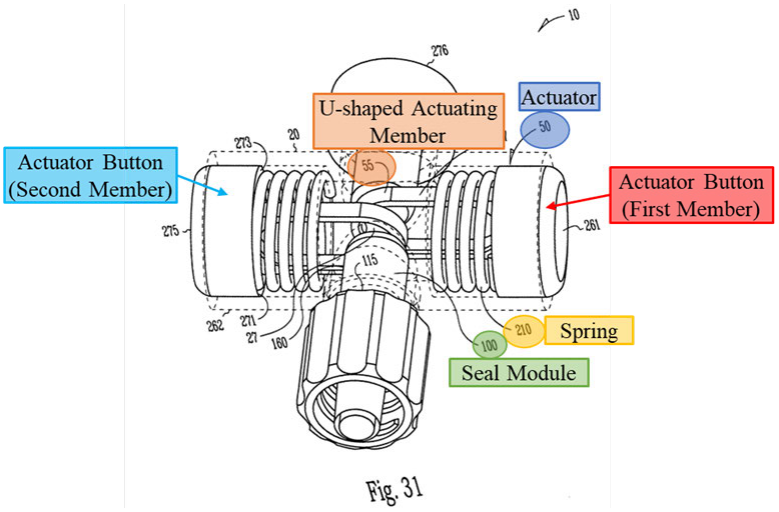
"A claim is anticipated under 35 U.S.C. § 102 if each and every limitation is found either expressly or inherently in a single prior art reference." *IPXL Holdings v. Amazon.com, Inc.,* 430 F.3d 1377, 1381 (Fed. Cir. 2005) (internal citations omitted). Claims 1 and 10 of the '921 patent are anticipated (and therefore invalid) by Schaffer or rendered obvious by the combination of Schaffer and the Hartley patent publication. Thornton Dec., ¶¶ 54-84.

During prosecution of the '921 patent, the Patent Examiner found that "Hartley" disclosed almost every limitation of claim 1. Ex. 1012 at 7-8; *see also* Ex. 1019 at 134:14-140:3 [redacted]. The only limitation the Examiner

did not find in Hartley was "a biasing member configured to bias the actuator to the first position." Ex. 1012 at 7. However, the Examiner did not have Schaffer during prosecution. Schaffer discloses a valve having the exact biasing elements missing from Hartley plus the other claim elements and, therefore, anticipates Claims 1 and 10 of the '921 patent.

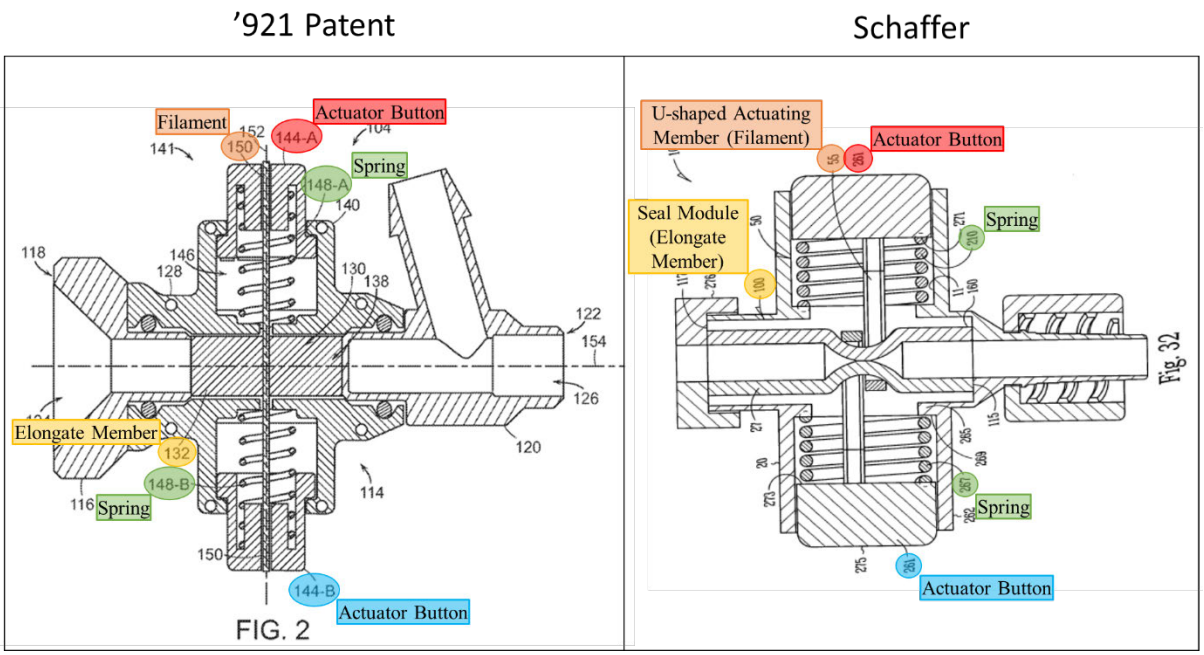
i. <u>Schaffer Anticipates Claims 1 and 10 of the '921 Patent</u>

Schaffer describes a hemostasis valve "that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path." Ex. 32 at ¶¶ [0002], [0008].[1] As shown in Figure 32 below, Schaffer's hemostasis valve has a tubular seal module 100 extending through the center of the valve and an actuator comprising: (a) two actuator buttons 261 positioned on opposite sides of the seal module, (b) two biasing members in the form of compression springs 210/267 coupled to the actuator buttons, and (3) two U-shaped actuating members 55 that compress the seal module to close the valve:



Ex. 1025, Fig. 31. As illustrated in the side-by-side comparison below, Schaffer's hemostasis valve has the same components in the same arrangement as the valve claimed in the '921 patent:

[1] Figures 30-34 in Schaffer are unclear. However, Schaffer submitted clearer figures during prosecution that were inadvertently omitted from the published application. *See* Ex. 1025. Imperative Care uses the clearer images in this brief.



Ex. 2 at Fig. 2; Ex. 1025 at Fig. 32. Importantly, Inari's expert concedes "Schaffer ... discloses a biasing member," the only limitation the Examiner found missing from the prior art during prosecution. Brown Dec., ¶ 227. Because Schaffer discloses all the components claimed in the '921 patent, Schaffer anticipates Claims 1 and 10.

Inari barely addresses Schaffer in its Motion despite having notice that Schaffer invalidates similar patent claims through Imperative Care's '011 IPR. *See* Mot. 28-29 (addressing Schaffer in one sentence). Inari's expert briefly argues that "Schaffer ... does not disclose circumferential constriction of the valve using a filament, instead using rigid U-shaped actuators, as opposed to a flexible filament required by the claims, which allows for circumferential restrictions. Brown Dec., ¶ 228; *see also* Mot. at 28. Inari's expert is wrong for several reasons. Thornton Dec., ¶¶ 67-79.

First, Inari's expert attempts to improperly read several limitations into the claims that do not exist. *See Phillips v. AWH Corp.,* 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc) (recognizing that "reading limitations from the specification into the claim" is improper). The claims do not require "circumferential constriction of the valve" but only "a filament extending at least partially around" the valve. Similarly, the claims do not require a "flexible filament" but only a "filament."

Second, Inari's expert inaccurately describes Schaffer as including "rigid U-shaped actuators." Yet Schaffer never uses the term "rigid" to describe the actuating members 55 – "rigid" is a term that Inari made up. Instead, Schaffer explains that the U-shaped actuating members 55 "in one option includes aluminum" and "[i]n another option ... include plastic." Ex. 32 at [0081]. As shown below, the U-shaped actuating members 55 are thin and, therefore, would be flexible (assuming that is a requirement of a "filament"). Thornton Dec., ¶ 68.

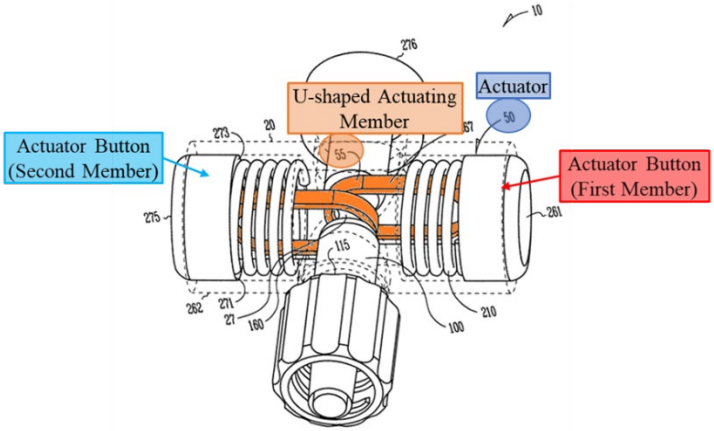


Fig. 31

Ex. 1025, Fig. 31.

Third, Inari ignores that the '921 patent broadly defines "filament" to encompass components like Schaffer's U-shaped actuating members 55. The '921 patent states that "the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape." Ex. 2 at 9:15-17. The patent also explains that the filament can be made from various materials including "a polymer, a synthetic, and/or a metal." *Id.* at 9:7-10. Schaffer's U-shaped actuating members 55 are at least a polymer or metal "ribbon, flat wire … or tape" and, therefore, satisfy the "filament" requirement in Claims 1 and 10 of the '921 patent. *See* Thornton Dec., ¶¶ 48-53, 67-69; Ex. 28 at 13-14 (explaining construction).

Inari accuses Imperative Care of trying to apply "an indefensibly overbroad meaning" to "filament" by "removing the requirement of flexibility …." Mot. at 20. But Imperative Care's definition comes directly from the '921 patent and the '921 patent claims do not have a "requirement of flexibility." Inari's argument that the Court should simply adopt a dictionary definition of "filament" that is inconsistent with the patent has been repeatedly rejected by the

Federal Circuit. *Id.* at 19-20 (citing Exs. 39-40); *see Phillips,* 415 F.3d at 1321 (explaining the problem with using dictionary definitions).

With that said, the Court does not need to resolve the meaning of "filament" to find substantial questions of invalidity for claims 1 and 10 of the '921 patent. Even if Schaffer does not include a "filament," Hartley does, and a POSITA would have found it obvious to substitute Hartley's filament for Schaffer's U-shaped actuating mechanisms. Thornton Dec., ¶¶ 70-79.

ii. <u>Schaffer Combined with Hartley Renders Claims 1 and 10 of the '921 Patent Obvious</u>

Hartley discloses a "filament" even if the Court assumes Inari's dictionary-based construction. Hartley describes using a string, suture, band, or other suitable material to wrap around a tube in a hemostasis valve. Ex. 31 at [0017], [0031]. [redacted] Ex. 1012 at 7; Ex. 1019 at 134:14-138:11.

POSITAs would have found it obvious to substitute Hartley's strings (or sutures/bands) for Schaffer's U-shaped actuating members. Thornton Dec., ¶¶ 73-79. The addition of Hartley's strings to Schaffer's valve would have merely entailed substitution of one known element (Hartley's strings) for another (Schaffer's U-shaped actuating members) to yield the predictable results of constricting the central lumen of Schaffer's valve to form a seal. *Id.* The Supreme Court has previously held that combinations of known elements in this fashion are obvious. *KSR,* 550 U.S. at 416.

Inari's expert argues that "[i]t would not be obvious to substitute flexible filaments for the U-shaped rigid members disclosed by Schaffer because the flexible filament would not engage and disengage the containment structure in the manner taught by Schaffer to open and close the resilient member, and would instead engage with a circumferential motion ...." Brown Dec., ¶ 228. That is not true. The strings, sutures, or bands would extend partially around the elongate member and form a U-shaped member just like Schaffer's existing actuating members. Thornton Dec., ¶¶ 73-79. These are all simple constructs to collapse a flexible tube. Inari's expert fails to identify any reasons the strings/sutures/bands would work differently.

Inari's expert also speculates that if "flexible filaments were substituted in Schaffer for the rigid U-shaped member, the assembly process would become unnecessarily cumbersome and expensive in terms of manufacturing time, and a [POSITA] would not be motivated to modify Schaffer in a manner that would incur these costs." Brown Dec., ¶ 228. Yet, whether a POSITA would ultimately commercialize a device is immaterial to whether a POSITA would have found the device obvious. *Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC,* 618 F.3d 1294, 1302-1303 (Fed. Cir. 2010) (rejecting manufacturing argument). Further, Inari's expert provides no support for the allegation that the manufacturing process would have become so unwieldy that it would discourage the routine substitution of one known component (strings) for another (U-shaped activating members).

iii. <u>Inari Fails to Support Any Secondary Indicia</u>

Inari argues "secondary indicia of nonobviousness strongly support" nonobviousness. Mot. at 29-30. However, secondary considerations have no bearing on anticipation and, therefore, are irrelevant to the Schaffer anticipation ground above. *Cohesive Techs., Inc. v. Waters Corp.,* 543 F.3d 1351, 1364 (Fed. Cir. 2008). Further, Inari must establish a nexus between any alleged secondary indicia and the claimed invention. *Fox Factory, Inc. v. SRAM, LLC,* 944 F.3d 1366, 1373 (Fed. Cir. 2019). Here, Inari just vaguely argues there was a long-felt need for better VTE treatments. Mot. at 30. Inari makes no effort to tie any secondary indicia to the claims asserted in this Motion and, therefore, has failed to meet its burden.

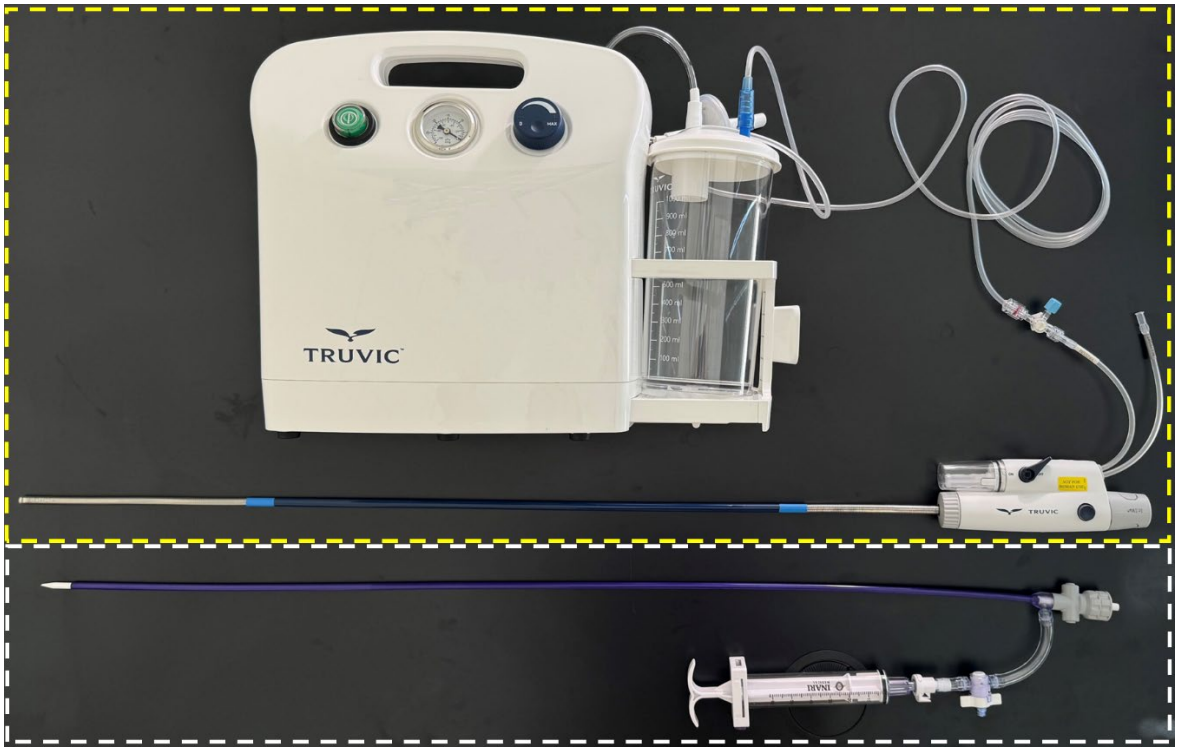
For these reasons, Schaffer combined with Hartley raises substantial questions of unpatentability concerning Claims 1 and 10 of the '921 patent

3. <u>Symphony Is Not A "Copycat" of Any Inari Product</u>

Inari suggests that Symphony infringes the '910 and '921 patents because it is a "copycat" device. Mot. at 19. However, the claims of the patent, not whether something is a "copycat" device, control the infringement analysis. *Markman v. Westview Instruments, Inc.,* 517 U.S. 370, 373 (1996). As discussed above, Symphony does not infringe the '910 patent

because it is missing at least three claim limitations.[2] *Supra* § IV.A.1.

Moreover, a simple side-by-side comparison of Symphony (yellow boxing) with Inari's FlowTriever Triever 20 (white boxing) reveals that Symphony is not a "copycat" device and includes many significant differences. In fact, Imperative Care relied on Penumbra's INDIGO Aspiration System as the predicate device for FDA approval, not Inari's products. Ex. 10 at 1.

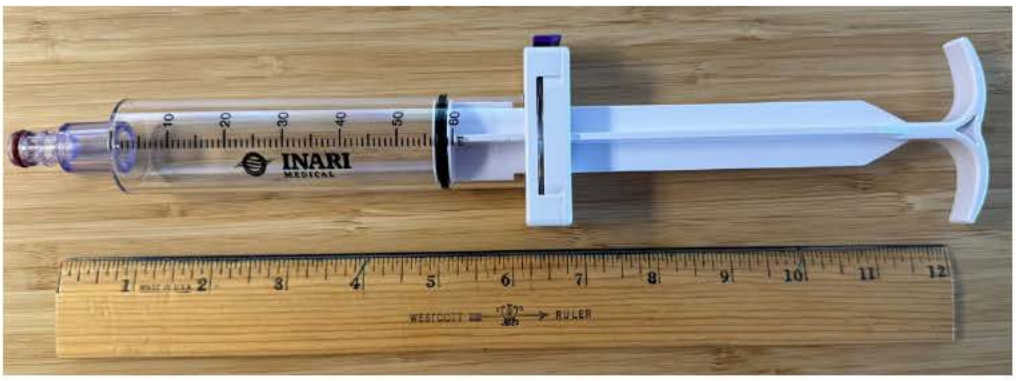


a. <u>Symphony Uses An Electric Generator, Not Syringes</u>

Symphony creates suction in a different way than Inari's products. Symphony generates suction with an electric generator outside the sterile field connected by lengthy tubing to the Symphony catheters. The generator provides on-demand, continuous aspiration through the Symphony catheter system to capture the blood clot. Ex. 7 at 3. In contrast, Inari's products rely on a simple syringe attached to the FlowTriever or ClotTriever catheters within the sterile field to generate negative pressure. Rather than provide on-demand, continuous aspiration, the

[2] Imperative Care also cannot infringe the '921 patent because the Shaffer valve is more like the claimed valve than Imperative Care's valve. Any infringement theory would distort the claims or show their invalidity. This is explained in the Thorton Declaration. *See* Thornton Dec., ¶¶ 85-91.

physician must physically pull back the syringe each time he/she wants to provide negative pressure to the catheter.



b. <u>Symphony Has an Integrated Handle, Not Separate Components</u>

Symphony includes an integrated handle, referred to as the BigShot™ Controller, that includes the system's dual-action vacuum lever, hemostasis valve, accessory lock, PowerVent, and TruView™ Clot Container. Ex. 7 at 7. The TruView™ Clot Container further includes a filter that separates blood from clot material and allows the physician to rapidly assess progress.

In contrast, [redacted] *See* Ex. 1026 (Merritt Dep. Tr.) at 34:16-36:16. Consequently, Inari's products do not include many of the features available with the Symphony such as the TruView™ Clot Container. *See* Scott Dec., ¶¶ 8-19 (describing features).

Additionally, the hemostasis valve within Symphony's integrated handle is significantly different from Inari's valve. While Inari's valve uses two compression springs and two loops of filament to close the valve similar to the Schaffer patent (*see* Ex. 20 at 4

(depicting springs and loops)), Symphony's valve uses four levers attached to four torsion springs and a suture that extends from one side of the valve to the other (Scott Dec., ¶ 17).

c. Symphony Relies on Aspiration, Not Scraping the Blood Vessels

Symphony removes DVTs from the patient differently than Inari's ClotTriever (Inari's DVT product). Mot. at 2. Symphony relies on aspiration (i.e., suction) to remove DVTs. Scott Dec., ¶ 19. In contrast, ClotTriever relies on a "nitinol mesh bag" that is dragged through the blood vessel to scrape the clot off the vessel wall. Merritt Dec., ¶ 14; Ex. 1026 at 83:1-10; Brown Dec., ¶ 77 (showing bag). Inari's engineer [redacted] Ex. 1026 at 83:23-85:6.

d. Inari's CEO Admits The "Copycat" Allegation Is Speculative

Symphony is in no way a "copycat" of any Inari product. The above examples are just some of the many differences between the devices. Moreover, despite making the serious copying allegations in his declaration, Inari's CEO [redacted] Ex. 1018 at 149:8-153:1; *see also* Ex. 1013 at 117:7-22. Rather, [redacted] Ex. 1018 at 149:8-153:1. Further, [redacted] *Id.* at 149:8-150:19.

B. Inari Cannot Establish Irreparable Harm

Even if Inari had shown a likelihood of success on the merits (it did not), Inari must also "make a clear showing that it is at risk of irreparable harm, which entails showing a likelihood of substantial and immediate irreparable injury." *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012) ("*Apple II*"); *see also Minerva Surgical, Inc. v. Hologic, Inc.*, No. 3:17-CV-02013-JD, 2018 WL 306689, at *1 (N.D. Cal. Jan. 5, 2018) ("Irreparable harm will not be presumed even if the moving party demonstrates likely infringement and validity."). Inari must also show that "a sufficiently strong causal nexus relates the alleged harm to the alleged infringement." *Apple II* at 1374. The causal nexus requirement "ensures that an injunction is not entered on account of 'irreparable harm caused by otherwise lawful competition.'" *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 640 (Fed. Cir. 2015) ("*Apple*

IV"). It is especially important where, as here, the patentee relies on lost sales or market share to show irreparable harm, because "[s]ales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature." *Apple I,* 678 F.3d at 1324. "A mere showing that [Inari] might lose some insubstantial market share as a result of [Imperative Care's] infringement is not enough." *Id.* at 1324–25.

1. <u>Inari Fails to Show a Causal Nexus Between Infringement and Harm</u>

Inari argues that it will lose sales and cede market share to Imperative Care if Symphony remains on the market. *See* Mot. at 30-33. However, Inari fails to satisfy its burden to show a sufficiently strong causal nexus to the alleged infringement.

Inari ignores that the demand for Symphony is unrelated to Inari's asserted patent claims and thus to any possible infringement. Inari submitted no declarations from its physician customers, much less any evidence that physicians choose Symphony because of its allegedly infringing features. *See Minerva,* 2018 WL 306689 at *4 (no causal-nexus where patentee did not submit "any declarations from physicians or customers, any relevant sales figures, or any expert analysis of sales or the market"). In contrast, Imperative Care's physician customers have confirmed they do not base their purchasing decision on Symphony's hemostasis valve, or even its telescoping capability. Tomalty Dec., ¶ 9. Rather, they choose Symphony over Inari's products because they prefer Symphony's other unique features. *Id*. Thus, the demand for Symphony is unrelated to its allegedly infringing features. *See Genband US LLC v. Metaswitch Networks Corp*., 861 F.3d 1378, 1384 (Fed. Cir. 2017) ("If all but an insignificant number of purchases from the infringer would have been made even without the infringing feature, the causal connection to the asserted lost-sale-based injury is missing.").

Inari devoted only a single sentence to its causal-nexus argument, arguing that the similarities between the Parties' products "exist for features that drive the demand for [Imperative Care's] products, such as its unique and more effective hemostasis valve and the combination of system-level components claimed in its patents." Mot. at 31 (citing Merritt Decl., ¶ 46). This conclusory sentence and citation cannot possibly satisfy Inari's burden to show the "sufficiently strong causal nexus." *Apple II* at 1374.

Further, Inari cites the declaration of Ben Merritt, an Inari engineer and named inventor, as alleged support. Mot. at 31. But he merely lists purported "innovations" in Inari's FlowTriever system (among "many others not discussed" in his declaration) that, according to him, have ***collectively*** "contributed to Inari providing best-in-class treatment for both PE and DVT patients." Merritt Decl., ¶ 46. Mr. Merritt never identifies which, if any, of the numerous innovations are the subject of this Motion. Nor could he. [redacted] Ex. 1026 at 15:5-23.

Inari could not offer any evidence to suggest that customer demand for Symphony is tied in any way to Inari's asserted claims because those claims cover specific features. Claim 1 of the '910 patent covers a particular clot treatment system for treating a PE, where the only purportedly inventive feature is its recitation of a second large bore aspiration catheter, which can be advanced through a larger, first aspiration catheter. *See* Ex. 4 at 4-8; *see also* Ex. 1019 at 90:7-101:17 [redacted]; Thornton Dec., ¶¶ 109-138 (explaining how Garrison describes each element). No evidence suggests these features drive demand for Symphony. Nor could it. First, the FDA has not cleared Symphony for use in treating PE and thus Imperative Care does not market Symphony for that purpose. Second, the vast majority of Symphony DVT cases do not use two aspiration catheters so clearly physicians do not buy Symphony for this feature. Scott Dec., ¶ 9. In fact, even Inari's ClotTriever does not use two catheters, and Inari admits that FlowTriever uses two catheters only "in about 12%" of DVT cases, further demonstrating that physicians do not buy these products for two catheters. Mot. at 7. Moreover, Inari's primary competitor, Penumbra, maintains a 30% share of the VTE mechanical thrombectomy market even though its products do not use two catheters. Ex. 1002 at 4.

Regarding claims 1 and 10 of the '921 patent, they are directed to specific characteristics of hemostasis valves. Yet, Inari offers no evidence to show that physicians purchase either Inari's products ***or*** Symphony because they include the specific valve described in the claim having actuators, an elongate member, and a filament. At his deposition, Inari's CEO [redacted]

[redacted] Ex. 1018 at 73:23-75:23. But that is a characteristic common with prior art valves, such as Shaffer. Moreover, the buttons are the only features of the valve any physician can see because, as Inari's engineer [redacted] Ex. 1026 at 207:25-208:9. If the physicians do not even know what components are inside the valve, those components certainly cannot cause customer demand.

2. <u>Inari Cannot Blame Imperative Care for Its Declining Market Share</u>

Inari argues that it has been losing sales to Symphony, has been losing market share over the past few years, and has yet to turn a profit despite being founded more than a decade ago. Mot. at 30-31. But Inari cannot genuinely blame its financial troubles and market-share declines on Imperative Care's sale of Symphony. Inari and its primary competitor, Penumbra, hold over 90% of the VTE thrombectomy market. *See* Ex. 1002 at 4. Inari's executives have admitted that [redacted] *See, e.g.*, Ex. 1013 at 21:15-22:4; Ex. 1018 at 35:25-36:11. And, those share declines correlate to Penumbra's introduction of new and improved aspiration systems. Ex. 1002 at 4, Fig. 8.

On the other hand, Inari admits Symphony sales [redacted] and thus do not even register in the market share data. Strange Decl., ¶ 10; *see also* Ex. 1013 at 57:4-58:18 [redacted] Moreover, every Symphony sale occurred after mid-2023, well after Inari's market share began declining to Penumbra. Scott Dec., ¶ 7. As for future sales and market share, [redacted] Mot. at 31 (citing Strange Decl., ¶ 14). Even if that could be accurately predicted, and it could not, [redacted] *See* Strange Dec., ¶ 10 [redacted]. Inari argues this incredibly small (and speculative) future share loss to Imperative Care is sufficient for the Court to find irreparable harm. Mot. at 32. Inari's argument is contrary to law. As the Federal Circuit has held, "a mere showing that [Inari] might lose some insubstantial market share as a result of [Imperative Care's] infringement is not enough." *Apple*

I, 678 F.3d at1324–25.

Inari relies on *Illumina, Inc. v. Qiagen, N.V.*, 207 F. Supp.3d 1081, 1093 (N.D. Cal 2016), to argue that it would be irreparably harmed if Imperative Care were allowed "to capture and define the market with pirated technology." Mot. at 32. But that argument relies on two incorrect assumptions. First, Imperative Care did not "pirate" (i.e. copy) Inari's technology. *Supra* § IV.A.3. Second, Symphony cannot "define the market," whatever that means. Symphony has joined numerous products that have long been in the VTE thrombectomy market. *See* Ex. 1006. Moreover, in *Illumina*, the court was concerned that the defendants' product performed poorly compared to plaintiff's product. *Illumina*, 207 F.Supp.3d at 1093. That is not the case here; no evidence suggests Symphony is less effective than Inari's products.

Inari relies on *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344-45 (Fed. Cir. 2013), to argue that Symphony may cause reputational harms in the future. But Inari offers no such evidence. Moreover, *Douglas Dynamics* reviewed the denial of a permanent injunction after liability was established. Similarly, Inari wrongly relies on *Conceptus, Inc. v. Hologic, Inc.*, No. 09-cv-02280 WHA, 2012 WL 44064, at *2 (N.D. Cal. Jan. 9, 2012), where the court denied a permanent injunction. Moreover, it found irreparable harm because the parties were the only two suppliers of the products at issue, a scenario far different from the crowded mechanical thrombectomy market.

3. <u>Inari's Delay in Filing this Motion Confirms No Irreparable Harm</u>

Inari's delay in filing this Motion further underscores its lack of irreparable harm. *See Apple I* at 1325 (finding "delay in bringing an infringement action and seeking a preliminary injunction are factors that could suggest that the patentee is not irreparably harmed by the infringement"). As explained above, Inari tracked Imperative Care's progress in the market from the very beginning, starting in February 2023 when Imperative Care obtained FDA clearance for Symphony. Hykes Dec., ¶ 23; Ex. 10. Inari obtained the Symphony brochure at a March 2023 trade show and concedes it was aware of Symphony sales in 2023. Ex. 7; Hykes Dec., ¶ 21; Mot. at 15.

Yet, Inari waited more than a year before filing its lawsuit and waited another two

months before filing this Motion. Inari's delay suggests that it has not, and will not be, irreparably harmed by the alleged infringement.

C. <u>The Balance of Hardships Favors Imperative Care</u>

The third preliminary injunction factor requires Inari to show that the "balance of equities tips in [Inari's] favor." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). That balance undeniably favors Imperative Care.

The Federal Circuit has recognized, "[t]he hardship on a preliminarily enjoined manufacturer who must withdraw its product from the market before trial can be devastating." *Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990). Inari admits that Imperative Care "will be harmed by the injunction" because the injunction "might force [Imperative Care] out of the VTE thrombectomy business, at least in the short term." Mot. at 33. Inari is right on this point. Imperative Care paid [redacted] to acquire Truvic Medical and has spent substantial resources since then to develop Symphony, obtain FDA clearance, and establish a foothold in the VTE thrombectomy market. Nalbone Dec., ¶ 8. Imperative Care would lose this substantial investment if it were forced to remove Symphony from the market, as explained in detail in the Nalbone declaration. *Id.* at ¶¶ 19-24.

By contrast, Inari will not suffer any hardship if Symphony remains on the market. Indeed, Inari admits it "is the leader in the [VTE thrombectomy] market" and maintains a dominant share of the sub-market for PE. Mot. at 6. The VTE thrombectomy market continues to grow year-over-year and remains grossly underpenetrated. *Id.* Thus, both Inari and industry analysts expect Inari's revenues to continue to grow. *See* Ex. 1001 at 5-6; Ex. 1002 at 4; Ex. 1013 at 66:5-67:9. Though Imperative Care hopes to capture a growing share of that growing market in the years to come, thus far its total sales have been, in [redacted] Strange Dec., ¶ 10. Thus, Inari will not suffer hardship because of Symphony.

The balance of hardships weighs even more in Imperative Care's favor in view of Inari's poor showing on the first two preliminary injunction factors. *See Avocent Huntsville, LLC v. ZPE Sys., Inc.*, No. 3:17-CV-04319-WHO, 2018 WL 1411100, at *17 (N.D. Cal. Mar. 21, 2018) ("an appropriate balance of potential hardships must consider the patentee's showing on

likelihood of success and irreparable harm."). For this reason, Inari's reliance on *Windsurfing Int'l Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986), is misplaced. There, the Federal Circuit vacated the district court's denial of a ***permanent*** injunction against an adjudged infringer. *Id.* Here, where nothing has been adjudicated, Inari has the burden to show it is likely to succeed on the merits.

Inari also argues that Imperative Care's "interest in entering a market pending a patent lawsuit does not outweigh [Inari's] interest in its patents." Mot. at 34. But Inari ignores that Imperative Care launched Symphony months before Inari even obtained the claims it now asserts. Scott Dec., ¶ 7. For this reason, Inari's reliance on the cases cited in the first paragraph of page 34 is misplaced. Mot. at 34. Under the circumstances of this case, the balance of hardships clearly favors Imperative Care.

D. <u>The Public Interest Weighs Against an Injunction</u>

Inari argues "the public is best served by enforcing patents that are likely valid and infringed." Mot. at 34. But that argument assumes Inari's asserted claims are valid and infringed. As shown above, substantial questions of noninfringement and invalidity exist here. *See Minerva*, 2018 WL 306689 at *6 ("Vindication of valid patent rights is without a doubt in the public's interest, but that factor is less germane here in light of Minerva's failure to demonstrate a likelihood of success on the merits."). Likewise, in view of Inari's poor showing on the irreparable harm factor, a broad injunction cannot serve the public interest. *See UTTO*, 2022 WL 1814145 at *6 (finding "when a claim does not appear to have merit and the harm does not appear to be dire, it would be inequitable and against the public interest to impose the extraordinary remedy of an injunction").

Imperative Care does not dispute there is a public interest in enforcing valid patent rights. However, that principle "is not without limit." *Juicero, Inc. v. iTaste Co.*, No. 17-CV-01921-BLF, 2017 WL 4676280, at *7 (N.D. Cal. Oct. 17, 2017); *see also Cordis Corp. v. Bos. Sci. Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004) (finding public's interest in enforcing valid patent rights "cannot control in every case without obliterating the public interest component of the preliminary injunction inquiry"). Where, such as here, the requested injunction poses a

threat to public health, and limits a physician's choice of life-saving treatment, courts refuse to enter preliminary injunctions. *See, e.g.*, *Cordis*, 99 F. App'x at 935 (affirming denial of preliminary injunction against sale of competing medical device); *see also Minerva*, 2018 WL 306689 at *6 (finding "public interest unlikely to be served by an injunction" that would limit available treatment options).

One Federal Circuit case is particularly instructive: *Cordis Corp. v. Bos. Sci. Corp.*, 99 F. App'x 928 (Fed. Cir. 2004). There, Cordis sought to preliminarily enjoin Boston Scientific from selling a drug-eluting stent that competed with Cordis' stent. *Id.* at 931. The Federal Circuit affirmed the denial of a preliminary injunction, observing "a strong public interest supports a broad choice of drug-eluting stents, even though no published study proves the superiority of either [party's stent]." *Id.* at 935. The Federal Circuit also highlighted that "the record contain[ed] evidence that some doctors prefer" the allegedly infringing stent over the Cordis stent. *Id.* at 935.

Similar circumstances exist in this case. The public interest demands a broad choice of treatment options for VTE. Tomalty Dec., ¶ 18-22. And, though Symphony will compete with Inari's products in the treatment of DVT, Inari cannot show Symphony is inferior to Inari's products. Indeed, Inari [redacted] Ex. 1018 at 270:18-21. Removing Symphony from the market would deprive patients of a potential treatment option for VTE. *See Minerva*, 2018 WL 306689 at *6 ("Of greater concern is the evidence in the record indicating that enjoining ADVANCED would limit women's treatment options in ablation procedures.").

Further, Symphony includes innovations not available in the Inari products. Tomalty Dec., ¶¶ 10-22. As one example, Symphony's electric generator allows the physician to apply a high-powered, on-demand, continuous aspiration to capture blood clots. Ex. 7 at 3. This on-demand, continuous vacuum allows the physician to quickly maximize clot removal. *Id.* In contrast, Inari's FlowTriever or ClotTriever systems do not provide on-demand or continuous aspiration. Each time the doctor wants to perform aspiration, the doctor must prime a syringe by pulling back on the syringe's plunger. [redacted]

[redacted] Ex. 1026 at 105:1-106:22. If the physician needs more suction to remove the clot, the doctor must disconnect the syringe, empty the blood and clot from the syringe, reattach the syringe, and recharge the syringe by withdrawing the plunger. This process is time consuming, cumbersome, and messy. [redacted] Ex. 1026 at 106:17-107:24. Symphony's on-demand and continuous suction eliminates this cumbersome procedure. Tomalty Dec., ¶¶ 10-13.

As another example, Symphony includes the TruView Clot Container, which allows physicians to quickly assess how much clot has been captured. In contrast, the FlowTriever and ClotTriever systems do not include a similar clot container. Rather, the blood and clot just flow into the syringe. The physician must then empty out the syringe in the operating room to examine it. Tomalty Dec., ¶ 17.

Symphony also includes an integrated blood management feature to reduce the total amount of blood withdrawn from the patient during a procedure called "differential flow." As explained in Dr. Tomalty's declaration, differential flow results in the withdrawal of minimal blood during a standard procedure – typically less than 200cc. Tomalty Dec., ¶¶ 14-16.

The Inari products do not have differential flow. Every syringe pull withdraws a standard 60cc of blood and clot from the patient. [redacted] *See* Ex. 1026 at 106:17-107:24; Tomalty Dec., ¶¶ 14-16. It would be against the public interest to withdraw Symphony and these important innovations from the market when some physicians prefer Symphony to either of Inari's products to treat DVT. Tomalty Dec., ¶¶ 18-22. Accordingly, an injunction would not serve the public interest in this case.

V. CONCLUSION

For all the above reasons, Imperative Care respectfully requests that this Court deny Inari's Motion for a Preliminary Injunction.

Respectfully Submitted,

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