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14 **IN THE UNITED STATES DISTRICT COURT**
15 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**
16 **SAN JOSE DIVISION**

18 INARI MEDICAL, INC.,
19 Plaintiff,
20
21 v.
22 IMPERATIVE CARE, INC.,
23 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: Courtroom 7, San Jose
Hon. Eumi K. Lee

[PUBLIC VERSION]

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1002	<i>MedTech Data Insights – Vital Signs</i> , Nephron Research, Medical Devices & Supplies (June 4, 2024)	Joseph R. Re
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1004	<i>Inari Medical, Inc.</i> , William Blair Equity Research Initiation Report (July 25, 2024)	Joseph R. Re
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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, <i>available at</i> https://www.penumbrainc.com/products/neuro-thrombectomy/ (last accessed Sept. 3, 2024)	Joseph R. Re
1015	Penumbra, Indigo System Lightning, <i>available at</i> https://www.penumbrainc.com/products/peripheral-thrombectomy-indigo-system/ (last accessed Sept. 3, 2024)	Joseph R. Re
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1044	Curriculum Vitae of Dr. Robert Dana Tomalty	Dr. Robert Dana Tomalty

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

5 I. INTRODUCTION

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

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

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

25 ***Second***, claim 1 requires a “clot treatment system” having a “first clot aspiration
26 assembly” with a “first catheter” and “first pressure source” and a “second clot aspiration
27 assembly” with a “second catheter” and a “second pressure source” where the second catheter
28 is advanceable through the first. Yet physicians rarely use Symphony with two catheter

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

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

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

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

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

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

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

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

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

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

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

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

11 **II. FACTUAL BACKGROUND**

12 **A. Imperative Care Founded To Treat Patients Suffering From Stroke**

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

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

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

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

4 **B. Imperative Care Joins the Growing VTE Thrombectomy Market**

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

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

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

1 doctors and hospitals.” Strange Decl., ¶ 13.

2 The Parties also agree that their competitors have traditionally adapted core
3 technologies from other treatment areas, such as neurovascular or coronary, to target peripheral
4 or pulmonary vasculatures for the treatment of VTE. Mot. at 7-9; *see also* Ex. 1013 at 31:13-
5 32:10. All share the same basic concept of vacuuming a clot from a blood vessel. The Parties
6 further agree that Penumbra is a clear example of this evolution. Mot. at 6 n.5. In late 2007,
7 Penumbra received FDA clearance for its aspiration-based mechanical thrombectomy device
8 for the treatment of acute ischemic stroke and intracranial large vessel occlusions. This device
9 was known as the Penumbra System[®]. Ex. 1014. Over several years, Penumbra adapted the
10 core technology of the Penumbra System[®] for use in peripheral arterial and venous applications
11 culminating in the 2014 launch of its Indigo[®] Aspiration System. Ex. 1015. In December
12 2019, the FDA cleared Indigo[®] for treating PE. Ex. 1016 (FDA 510(k) Summary, K192833).
13 Penumbra now has the second largest market share (~30%) in the VTE thrombectomy market
14 and is Inari’s primary competitor. Ex. 1003 at 1; Ex. 1002 at 4; Ex. 1013 at 20:14-23.

15 **C. The Year-Long Dispute Between the Parties**

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

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

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

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

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

13 **D. Imperative Care Files IPRs In The Patent Office**

14 In July 2024, Imperative Care filed a petition for *inter partes* review ("IPR") of Inari's
15 '011 patent. Ex. 28. An IPR permits anyone to petition the Patent Office to cancel patents in
16 view of earlier publications. 35 U.S.C. § 311. Like the '921 patent in this Motion, the '011
17 patent claims a valve having a filament that partially wraps around a tube. In its IPR petition,
18 Imperative Care showed that the Schaffer and Hartley patent publications render the claims of
19 the '011 patent invalid, just like Imperative Care has done below for the '921 patent. Ex. 28 at
20 16-70. Notably, the claims of the '011 and '921 patents overlap, so the findings in the IPR will
21 decide the key issues underlying invalidity on this Motion.

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

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

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

3 **III. LEGAL STANDARDS**

4 The Parties agree that to obtain a preliminary injunction, Inari must show that (1) it is
5 “likely to succeed on the merits,” (2) it is “likely to suffer irreparable harm in the absence of
6 preliminary relief,” (3) the “balance of equities tips in [Inari’s] favor,” and (4) “an injunction
7 is in the public interest.” Mot. at 18 (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S.
8 7, 20 (2008)). While the factors are not “applied mechanically,” the Parties agree that Inari
9 **must** establish the first two factors to be entitled to a preliminary injunction. *Id.* at 18, n.10;
10 *see Amazon.com Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001).

11 “A preliminary injunction should preserve the status quo which is the ‘last uncontested
12 status which preceded the controversy.’” *Archive Corp. v. Cipher Data Prods, Inc.*, 12 USPQ
13 2d 1464, 1468 (C.D. Cal. 1988) (quoting *Tanner Motor Livery, Ltd. v. Avis, Inc.*, 316 F.2d 804,
14 809 (9th Cir. 1963)). Here, the last uncontested status was after December 19, 2023, when the
15 first of the two patents asserted in this Motion issued. At that time, Symphony was FDA cleared
16 and on the market. Mot. at 15; Nalbone Dec., ¶ 12.

17 Inari argues that an injunction “effectively maintains the status quo” because Imperative
18 Care “is just bringing the Symphony system to market.” Mot. at 3. But Inari admits Symphony
19 has been marketed since March 2023. *Id.* at 15. Thus, rather than preserve the status quo
20 pending a trial on the merits, Inari seeks to upset the status quo by removing Symphony from
21 the market and depriving doctors of an important new technology in the fight against DVT.
22 *See ICU Med. Inc. v. Alaris Med. Sys., Inc.*, No. SA CV 04-689 AHS, 2004 WL 1874992, *25
23 (C.D. Cal. July 30, 2004) (finding a preliminary injunction “could not preserve the status quo
24 and would conversely create new market conditions” where accused product sold before the
25 patent issued). Under these circumstances, Inari “must clear a higher bar” to justify its
26 mandatory injunction. *UTTO Inc. v. Metrotech Corp.*, No. 22-CV-01904-WHO, 2022 WL
27 1814145, at *2 (N.D. Cal. June 2, 2022). “In general, mandatory injunctions ‘are not granted
28 unless extreme or very serious damage will result and are not issued in doubtful cases or where

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

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

7 **IV. ARGUMENT**

8 **A. Inari Is Not Likely to Succeed on the Merits**

9 If Imperative Care “raises a substantial question concerning either infringement or
 10 validity, i.e., asserts an infringement or invalidity defense that the patentee cannot prove lacks
 11 substantial merit, the preliminary injunction should not issue.” *Amazon.com*, 239 F.3d at 1350-
 12 51 (internal quotes omitted). “Vulnerability is the issue at the preliminary injunction stage,
 13 while validity is the issue at trial. The showing of a substantial question as to invalidity thus
 14 requires less proof than the clear and convincing showing necessary to establish invalidity
 15 itself.” *Id.* at 1359. Below, Imperative Care identifies substantial questions concerning
 16 infringement or validity, or both for the three asserted claims. Because Inari cannot prove these
 17 questions lack substantial merit, Inari cannot satisfy its burden on the first preliminary
 18 injunction factor.

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

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

27 **a. Symphony Is Not Sold for the Treatment of PE**

28 The preamble of Claim 1 of the ’910 patent recites, “A clot treatment system for treating

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

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

10 Inari also alleges that doctors have used Symphony “off-label” to treat PE. Mot. at 16,
11 20. Yet, Inari never explicitly argues that “off-label” use constitutes infringement. *See e.g.*,
12 Brown Dec. ¶¶131-132 (no argument off-label use is infringement). Nor could it. Inari’s CEO

13 [REDACTED]
14 [REDACTED] Ex. 1018 (Hykes Dep. Tr.) at 59:4-60:5. Rather, Inari’s CEO [REDACTED]
15 [REDACTED]
16 [REDACTED] *Id.* Consequently,
17 Inari has failed to show that any off-label use is likely to support a finding of infringement.

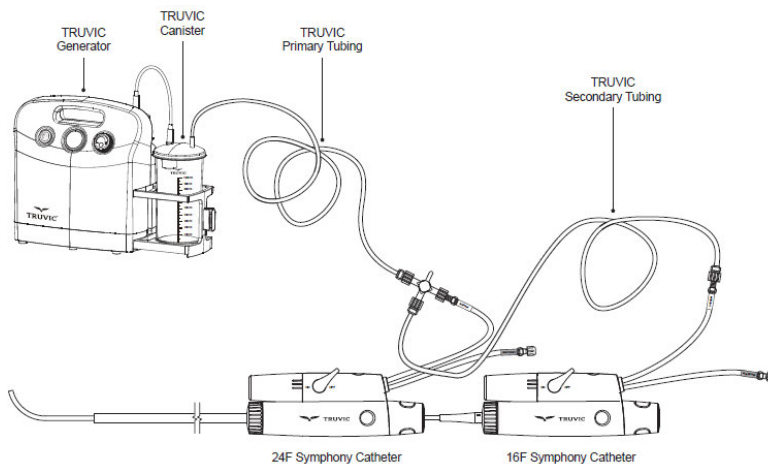
18 Further, Inari’s allegations of “off-label” use are threadbare and cannot support a
19 finding that Inari is likely to prove infringement. Inari did not identify any specific instances
20 of “off-label” use or any witnesses with first-hand knowledge of such uses. Instead, Inari relies
21 exclusively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

26 **b. Symphony Does Not Have a Second Pressure Source**

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

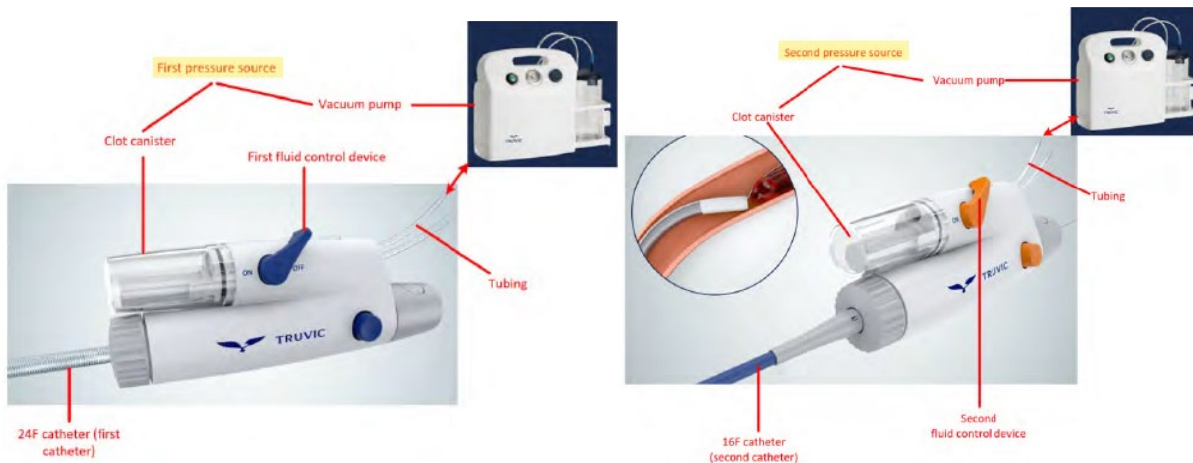
1 with “a second catheter” and a “*second pressure source.*” Symphony is not sold with or
 2 instructed for use with a “second pressure source” and, therefore, cannot infringe Claim 1.

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



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

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

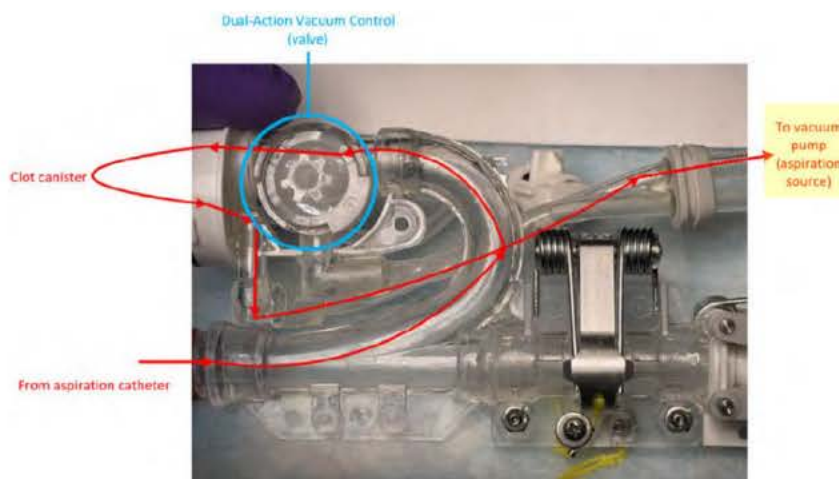


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 28 Mot. at 21, 23 (yellow highlight added); *see also* Brown Dec., ¶¶136, 158 (including same

1 figures). Instead, Inari argues that components located far away from the electric generator
 2 also form part of the first and second pressure sources, including the TruView™ Clot Container
 3 (labeled by Inari as “clot canister”). Inari’s expert, Mr. Brown, [REDACTED]

4 [REDACTED]
 5 [REDACTED] Ex. 1019 at 182:11-183:4.

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



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

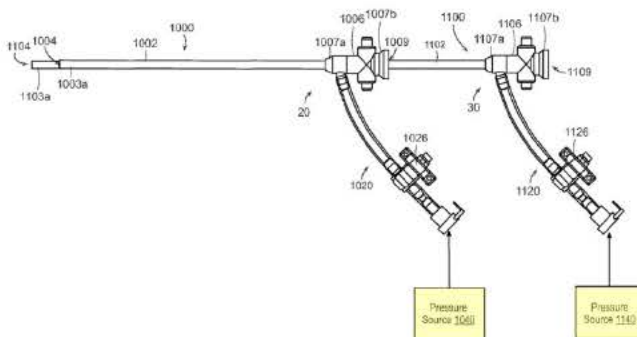


FIG. 11

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

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

2 **c. Most Symphony Procedures Do Not Use Two Catheters**

3 Claim 1 recites a “clot treatment system” having “a first catheter” and “a second
4 catheter.” Imperative Care sells its 16F and 24F catheters separately. Scott Dec., ¶ 20.
5 Moreover, almost all Symphony procedures to treat DVT (the only FDA-cleared use) use one
6 catheter (either the Symphony 16F or 24F), not a first and second catheter. *Id.* at ¶ 9.
7 Imperative Care’s records show that only ~1.5% of cases performed for DVT use the
8 Symphony 16F and 24F systems together – the balance (~98.5%) use only the Symphony 16F
9 or 24F catheter. *Id.* Thus, virtually all Symphony procedures cannot infringe claim 1 of the
10 ’910 patent, and this claim certainly cannot justify Inari’s broad request for an injunction
11 barring the sale of *all* Symphony systems, even when sold with only one catheter.

12 **2. Substantial Questions of Validity Cloud Inari’s Patents**

13 **a. Claim 1 of the ’910 Patent is Invalid**

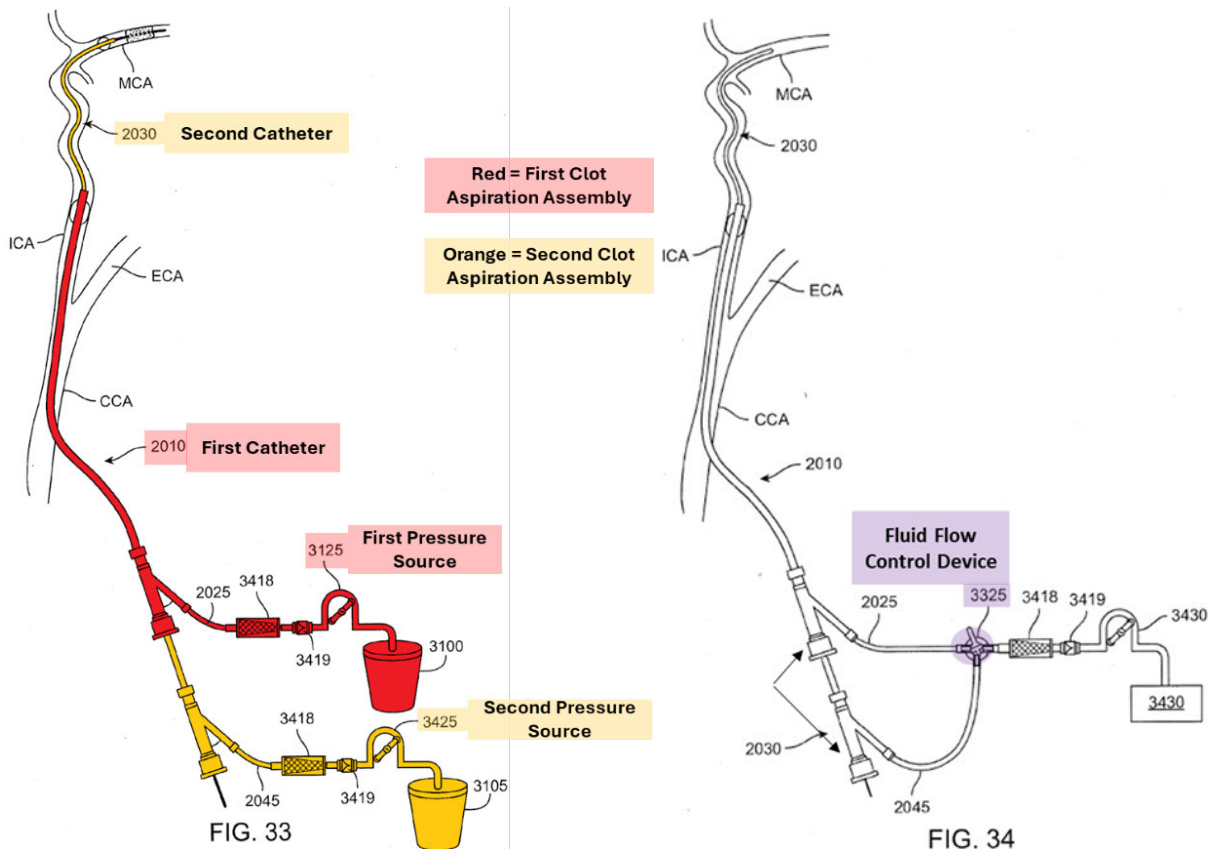
14 A patent claim is invalid “if the differences between the claimed invention and the prior
15 art are such that the claimed invention as a whole would have been obvious before the effective
16 filing date of the claimed invention to a person having ordinary skill in the art [hereinafter
17 “POSITA”]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

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

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

7 **i. Overview of Garrison**

8 Garrison describes aspiration systems for removing clots from patients. Ex. 29 at
 9 [0007]. Garrison provides many examples of these clot treatment systems, including systems
 10 having (1) a first clot aspiration assembly with a first catheter and first pressure source and (2)
 11 a second clot aspiration assembly with a second catheter and a second pressure source:



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

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

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

9 **ii. The Examiner Was Misinformed During Prosecution of the**
10 **’910 Patent**

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

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

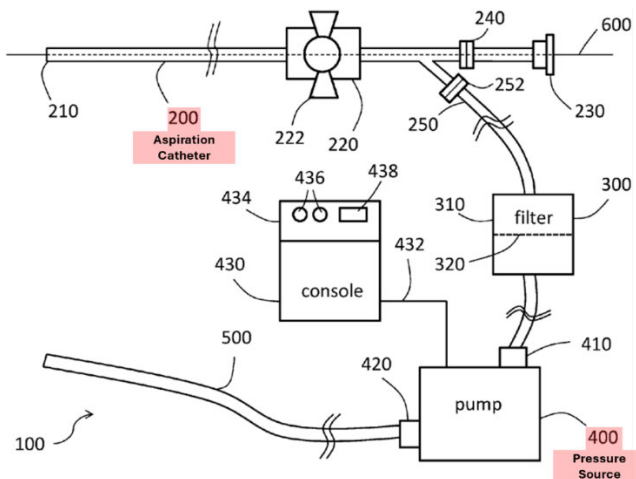
23 However, the Examiner was misinformed. Inari has admitted in this litigation that it
24 was common for POSITAs to adapt catheter systems used to aspirate clots in smaller blood
25 vessels (such as blood vessels in the brain) to aspirate clots in larger blood vessels, such as PE.
26 Thornton Dec.,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

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

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

11 Inari did not invent using aspiration catheters to treat PE or aspiration catheters
 12 measuring 16 French or greater. Laub describes an aspiration system for removing “unwanted
 13 material such as emboli, thrombi, tumors, or debris” from a patient’s vasculature. Ex. 1021 at
 14 ¶ [0002]. Laub explicitly discloses that “[s]ystems according to certain embodiments of the
 15 present invention may be used, for example, to remove clots from patients suffering from or at
 16 risk of *pulmonary embolisms*.” *Id.* at ¶ [0005] (emphasis added).

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



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

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

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

5 A POSITA would have found it obvious to adapt Garrison’s aspiration system to use
6 catheters of 16 French or greater to treat PE based on Laub. Thornton Dec., ¶¶ 109-138. The
7 Supreme Court has held that merely combining prior art elements according to known methods
8 to yield predictable results is obvious. *KSR*, 550 U.S. at 416. Claim 1 of the ‘910 patent does
9 exactly that. The claim merely combines Garrison’s prior art clot treatment system with Laub’s
10 16 French or greater catheters to treat PE. Thornton Dec., ¶¶ 110-121.

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

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

1 catheters could be used interchangeability across different parts of the vasculature while other
 2 aspiration catheters (e.g., Garrison) could not. Moreover, Inari's witnesses have [REDACTED]

3 [REDACTED]
 4 [REDACTED] See, e.g., Ex. 1013 at 31:13-32:10. Further,
 5 Inari's expert [REDACTED]

6 [REDACTED]
 7 [REDACTED] Ex. 1019 at 210:12-212:3.

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

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

20 **b. Claims 1 and 10 of the '921 Patent Are Invalid**

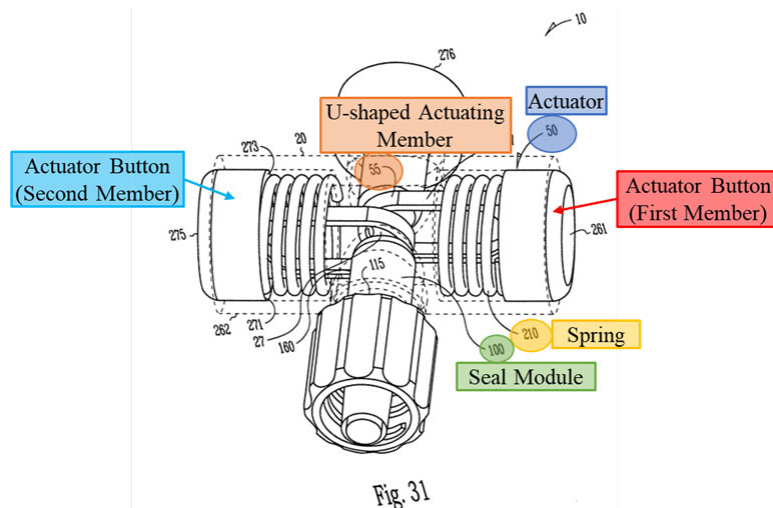
21 "A claim is anticipated under 35 U.S.C. § 102 if each and every limitation is found
 22 either expressly or inherently in a single prior art reference." *IPXL Holdings v. Amazon.com,*
 23 *Inc.*, 430 F.3d 1377, 1381 (Fed. Cir. 2005) (internal citations omitted). Claims 1 and 10 of the
 24 '921 patent are anticipated (and therefore invalid) by Schaffer or rendered obvious by the
 25 combination of Schaffer and the Hartley patent publication. Thornton Dec., ¶¶ 54-84.

26 During prosecution of the '921 patent, the Patent Examiner found that "Hartley"
 27 disclosed almost every limitation of claim 1. Ex. 1012 at 7-8; see also Ex. 1019 at 134:14-
 28 140:3 [REDACTED]. The only limitation the Examiner

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

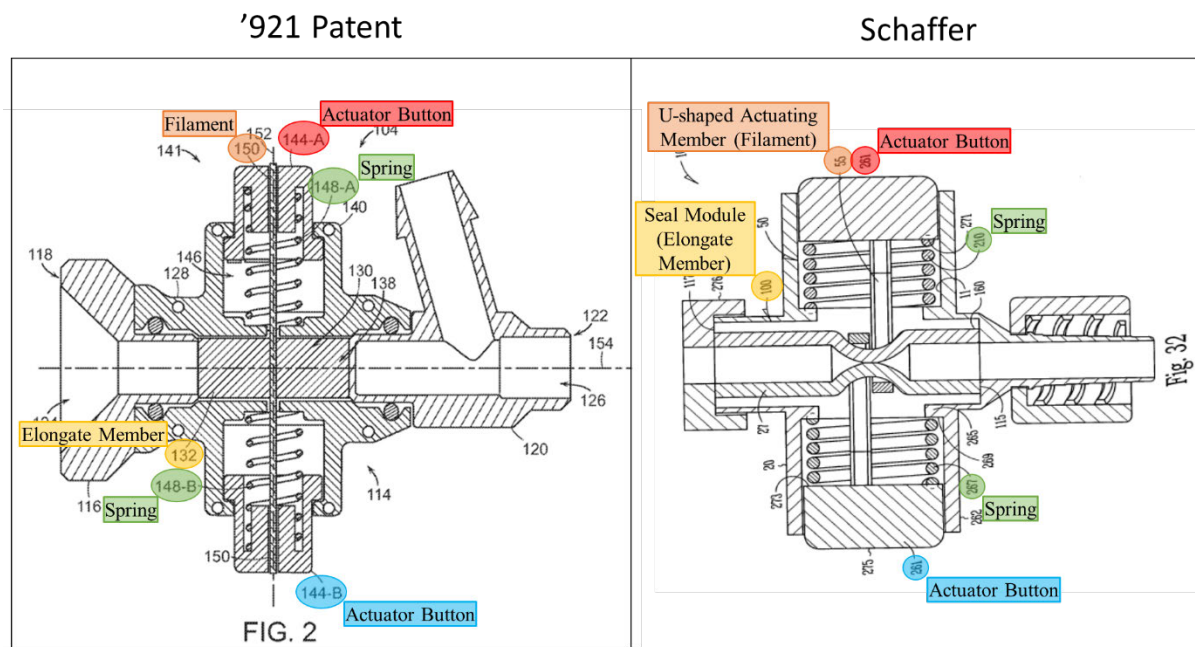
5 **i. Schaffer Anticipates Claims 1 and 10 of the ‘921 Patent**

6 Schaffer describes a hemostasis valve “that blocks the flow of gas or fluid completely
 7 and immediately with or without an instrument in place within the gas/fluid path.” Ex. 32 at
 8 ¶¶ [0002], [0008].¹ As shown in Figure 32 below, Schaffer’s hemostasis valve has a tubular
 9 seal module 100 extending through the center of the valve and an actuator comprising: (a) two
 10 actuator buttons 261 positioned on opposite sides of the seal module, (b) two biasing members
 11 in the form of compression springs 210/267 coupled to the actuator buttons, and (3) two U-
 12 shaped actuating members 55 that compress the seal module to close the valve:



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

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



12 Ex. 2 at Fig. 2; Ex. 1025 at Fig. 32. Importantly, Inari's expert concedes "Schaffer ... discloses

13 a biasing member," the only limitation the Examiner found missing from the prior art during

14 prosecution. Brown Dec., ¶ 227. Because Schaffer discloses all the components claimed in

15 the '921 patent, Schaffer anticipates Claims 1 and 10.

16 Inari barely addresses Schaffer in its Motion despite having notice that Schaffer

17 invalidates similar patent claims through Imperative Care's '011 IPR. See Mot. 28-29

18 (addressing Schaffer in one sentence). Inari's expert briefly argues that "Schaffer ... does not

19 disclose circumferential constriction of the valve using a filament, instead using rigid U-shaped

20 actuators, as opposed to a flexible filament required by the claims, which allows for

21 circumferential restrictions. Brown Dec., ¶ 228; see also Mot. at 28. Inari's expert is wrong

22 for several reasons. Thornton Dec., ¶¶ 67-79.

23 First, Inari's expert attempts to improperly read several limitations into the claims that

24 do not exist. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc)

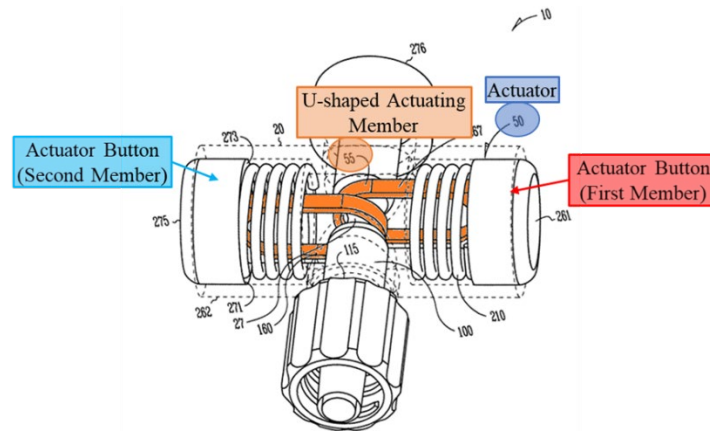
25 (recognizing that "reading limitations from the specification into the claim" is improper). The

26 claims do not require "circumferential constriction of the valve" but only "a filament extending

27 at least partially around" the valve. Similarly, the claims do not require a "flexible filament"

28 but only a "filament."

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



14 Fig. 31

15 Ex. 1025, Fig. 31.

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

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

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

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

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

9 Hartley discloses a “filament” even if the Court assumes Inari’s dictionary-based
10 construction. Hartley describes using a string, suture, band, or other suitable material to wrap
11 around a tube in a hemostasis valve. Ex. 31 at [0017], [0031]. [REDACTED]

12 [REDACTED]
13 Ex. 1012 at 7; Ex. 1019 at 134:14-138:11.

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

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

1 Inari’s expert also speculates that if “flexible filaments were substituted in Schaffer for
2 the rigid U-shaped member, the assembly process would become unnecessarily cumbersome
3 and expensive in terms of manufacturing time, and a [POSITA] would not be motivated to
4 modify Schaffer in a manner that would incur these costs.” Brown Dec., ¶ 228. Yet, whether
5 a POSITA would ultimately commercialize a device is immaterial to whether a POSITA would
6 have found the device obvious. *Geo. M. Martin Co. v. Alliance Mach. Sys. Int’l LLC*, 618 F.3d
7 1294, 1302-1303 (Fed. Cir. 2010) (rejecting manufacturing argument). Further, Inari’s expert
8 provides no support for the allegation that the manufacturing process would have become so
9 unwieldy that it would discourage the routine substitution of one known component (strings)
10 for another (U-shaped activating members).

11 **iii. Inari Fails to Support Any Secondary Indicia**

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

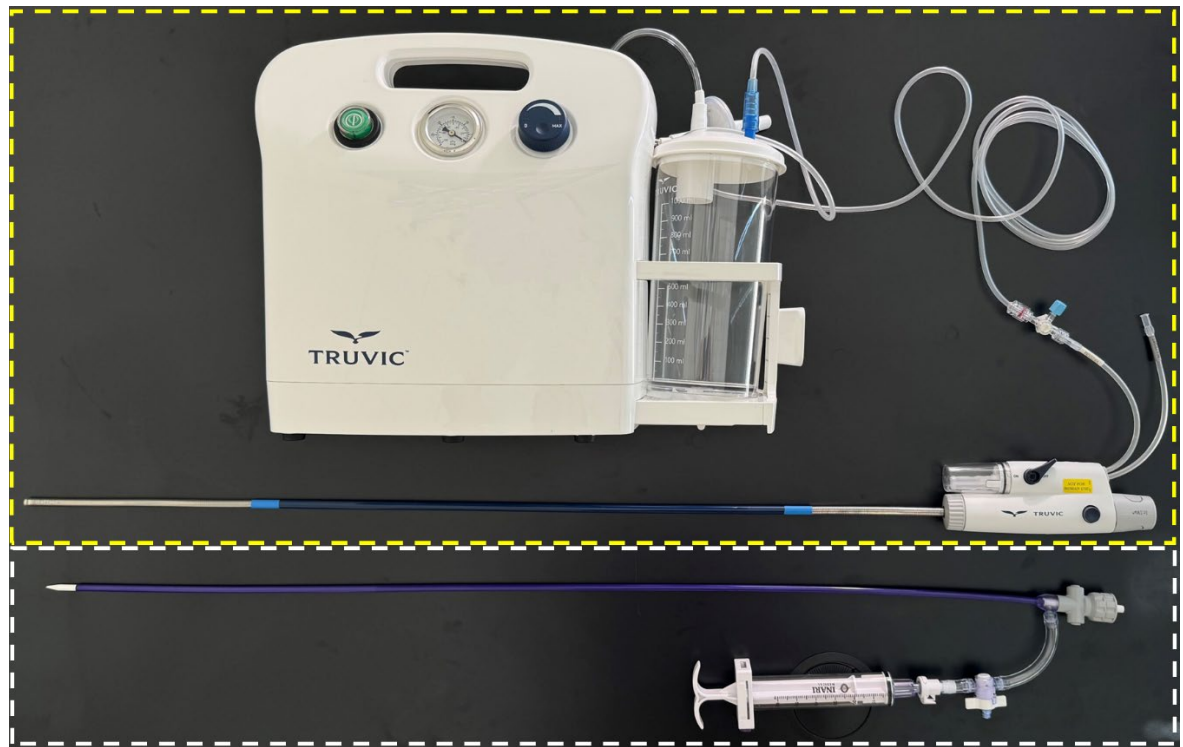
20 For these reasons, Schaffer combined with Hartley raises substantial questions of
21 unpatentability concerning Claims 1 and 10 of the ‘921 patent

22 **3. Symphony Is Not A “Copycat” of Any Inari Product**

23 Inari suggests that Symphony infringes the ’910 and ’921 patents because it is a
24 “copycat” device. Mot. at 19. However, the claims of the patent, not whether something is a
25 “copycat” device, control the infringement analysis. *Markman v. Westview Instruments, Inc.*,
26 517 U.S. 370, 373 (1996). As discussed above, Symphony does not infringe the ’910 patent
27
28

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

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



18 **a. Symphony Uses An Electric Generator, Not Syringes**

19 Symphony creates suction in a different way than Inari’s products. Symphony
 20 generates suction with an electric generator outside the sterile field connected by lengthy tubing
 21 to the Symphony catheters. The generator provides on-demand, continuous aspiration through
 22 the Symphony catheter system to capture the blood clot. Ex. 7 at 3. In contrast, Inari’s products
 23 rely on a simple syringe attached to the FlowTrier or ClotTrier catheters within the sterile
 24 field to generate negative pressure. Rather than provide on-demand, continuous aspiration, the
 25

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

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



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 9 **b. Symphony Has an Integrated Handle, Not Separate Components**

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



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 21 In contrast, [REDACTED]

22 [REDACTED] See Ex. 1026 (Merritt Dep. Tr.) at 34:16-36:16.
 23
 24 Consequently, Inari’s products do not include many of the features available with the
 25 Symphony such as the TruView™ Clot Container. See Scott Dec., ¶¶ 8-19 (describing features).

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

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

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

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

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

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

18 **B. Inari Cannot Establish Irreparable Harm**

19 Even if Inari had shown a likelihood of success on the merits (it did not), Inari must
20 also "make a clear showing that it is at risk of irreparable harm, which entails showing a
21 likelihood of substantial and immediate irreparable injury." *Apple Inc. v. Samsung Elecs. Co.*,
22 695 F.3d 1370, 1374 (Fed. Cir. 2012) ("*Apple II*"); *see also Minerva Surgical, Inc. v. Hologic,*
23 *Inc.*, No. 3:17-CV-02013-JD, 2018 WL 306689, at *1 (N.D. Cal. Jan. 5, 2018) ("Irreparable
24 harm will not be presumed even if the moving party demonstrates likely infringement and
25 validity."). Inari must also show that "a sufficiently strong causal nexus relates the alleged
26 harm to the alleged infringement." *Apple II* at 1374. The causal nexus requirement "ensures
27 that an injunction is not entered on account of 'irreparable harm caused by otherwise lawful
28 competition.'" *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 640 (Fed. Cir. 2015) ("*Apple*

1 IV”). It is especially important where, as here, the patentee relies on lost sales or market share
2 to show irreparable harm, because “[s]ales lost to an infringing product cannot irreparably harm
3 a patentee if consumers buy that product for reasons other than the patented feature.” *Apple I*,
4 678 F.3d at 1324. “A mere showing that [Inari] might lose some insubstantial market share as
5 a result of [Imperative Care’s] infringement is not enough.” *Id.* at 1324–25.

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

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

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

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

1 Further, Inari cites the declaration of Ben Merritt, an Inari engineer and named inventor,
2 as alleged support. Mot. at 31. But he merely lists purported “innovations” in Inari’s
3 FlowTrievers system (among “many others not discussed” in his declaration) that, according to
4 him, have *collectively* “contributed to Inari providing best-in-class treatment for both PE and
5 DVT patients.” Merritt Decl., ¶ 46. Mr. Merritt never identifies which, if any, of the numerous
6 innovations are the subject of this Motion. Nor could he [REDACTED]

7 [REDACTED] Ex. 1026 at 15:5-23.

8 Inari could not offer any evidence to suggest that customer demand for Symphony is
9 tied in any way to Inari’s asserted claims because those claims cover specific features. Claim
10 1 of the ’910 patent covers a particular clot treatment system for treating a PE, where the only
11 purportedly inventive feature is its recitation of a second large bore aspiration catheter, which
12 can be advanced through a larger, first aspiration catheter. See Ex. 4 at 4-8; see also Ex. 1019
13 at 90:7-101:17 [REDACTED]; Thornton Dec., ¶¶ 109-
14 138 (explaining how Garrison describes each element). No evidence suggests these features
15 drive demand for Symphony. Nor could it. First, the FDA has not cleared Symphony for use
16 in treating PE and thus Imperative Care does not market Symphony for that purpose. Second,
17 the vast majority of Symphony DVT cases do not use two aspiration catheters so clearly
18 physicians do not buy Symphony for this feature. Scott Dec., ¶ 9. In fact, even Inari’s
19 ClotTrievers does not use two catheters, and Inari admits that FlowTrievers uses two catheters
20 only “in about 12%” of DVT cases, further demonstrating that physicians do not buy these
21 products for two catheters. Mot. at 7. Moreover, Inari’s primary competitor, Penumbra,
22 maintains a 30% share of the VTE mechanical thrombectomy market even though its products
23 do not use two catheters. Ex. 1002 at 4.

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

1 [REDACTED] Ex. 1018 at 73:23-75:23. But that is a characteristic common with prior art valves,
 2 such as Shaffer. Moreover, the buttons are the only features of the valve any physician can see
 3 because, as Inari's engineer [REDACTED]

4 [REDACTED]
 5 [REDACTED] Ex. 1026 at 207:25-208:9. If the physicians do not even know what
 6 components are inside the valve, those components certainly cannot cause customer demand.

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

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

16 On the other hand, Inari admits Symphony sales [REDACTED] and thus do
 17 not even register in the market share data. Strange Decl., ¶ 10; see also Ex. 1013 at 57:4-58:18
 18 [REDACTED] Moreover, every Symphony sale
 19 occurred after mid-2023, well after Inari's market share began declining to Penumbra. Scott
 20 Dec., ¶ 7. As for future sales and market share, [REDACTED]

21 [REDACTED] Mot. at 31 (citing Strange
 22 Decl., ¶ 14). Even if that could be accurately predicted, and it could not, [REDACTED]

23 [REDACTED]
 24 [REDACTED] See Strange Dec., ¶ 10 [REDACTED]

25 [REDACTED] Inari argues this incredibly small (and speculative) future share loss to Imperative
 26 Care is sufficient for the Court to find irreparable harm. Mot. at 32. Inari's argument is contrary
 27 to law. As the Federal Circuit has held, "a mere showing that [Inari] might lose some
 28 insubstantial market share as a result of [Imperative Care's] infringement is not enough." *Apple*

1 I, 678 F.3d at 1324–25.

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

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

19 **3. Inari’s Delay in Filing this Motion Confirms No Irreparable Harm**

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

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

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

3 **C. The Balance of Hardships Favors Imperative Care**

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

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

17 By contrast, Inari will not suffer any hardship if Symphony remains on the market.
18 Indeed, Inari admits it "is the leader in the [VTE thrombectomy] market" and maintains a
19 dominant share of the sub-market for PE. Mot. at 6. The VTE thrombectomy market continues
20 to grow year-over-year and remains grossly underpenetrated. *Id.* Thus, both Inari and industry
21 analysts expect Inari's revenues to continue to grow. *See* Ex. 1001 at 5-6; Ex. 1002 at 4; Ex.
22 1013 at 66:5-67:9. Though Imperative Care hopes to capture a growing share of that growing
23 market in the years to come, thus far its total sales have been, in ██████████
24 Strange Dec., ¶ 10. Thus, Inari will not suffer hardship because of Symphony.

25 The balance of hardships weighs even more in Imperative Care's favor in view of Inari's
26 poor showing on the first two preliminary injunction factors. *See Avocent Huntsville, LLC v.*
27 *ZPE Sys., Inc.*, No. 3:17-CV-04319-WHO, 2018 WL 1411100, at *17 (N.D. Cal. Mar. 21,
28 2018) ("an appropriate balance of potential hardships must consider the patentee's showing on

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

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

12 **D. The Public Interest Weighs Against an Injunction**

13 Inari argues “the public is best served by enforcing patents that are likely valid and
14 infringed.” Mot. at 34. But that argument assumes Inari’s asserted claims are valid and
15 infringed. As shown above, substantial questions of noninfringement and invalidity exist here.
16 *See Minerva*, 2018 WL 306689 at *6 (“Vindication of valid patent rights is without a doubt in
17 the public’s interest, but that factor is less germane here in light of *Minerva*’s failure to
18 demonstrate a likelihood of success on the merits.”). Likewise, in view of Inari’s poor showing
19 on the irreparable harm factor, a broad injunction cannot serve the public interest. *See UTTO*,
20 2022 WL 1814145 at *6 (finding “when a claim does not appear to have merit and the harm
21 does not appear to be dire, it would be inequitable and against the public interest to impose the
22 extraordinary remedy of an injunction”).

23 Imperative Care does not dispute there is a public interest in enforcing valid patent
24 rights. However, that principle “is not without limit.” *Juicero, Inc. v. iTaste Co.*, No. 17-CV-
25 01921-BLF, 2017 WL 4676280, at *7 (N.D. Cal. Oct. 17, 2017); *see also Cordis Corp. v. Bos.*
26 *Sci. Corp.*, 99 F. App’x 928, 935 (Fed. Cir. 2004) (finding public’s interest in enforcing valid
27 patent rights “cannot control in every case without obliterating the public interest component
28 of the preliminary injunction inquiry”). Where, such as here, the requested injunction poses a

1 threat to public health, and limits a physician’s choice of life-saving treatment, courts refuse to
2 enter preliminary injunctions. *See, e.g., Cordis*, 99 F. App’x at 935 (affirming denial of
3 preliminary injunction against sale of competing medical device); *see also Minerva*, 2018 WL
4 306689 at *6 (finding “public interest unlikely to be served by an injunction” that would limit
5 available treatment options).

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

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

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

1 [REDACTED] Ex. 1026 at 105:1-106:22.

2 If the physician needs more suction to remove the clot, the doctor must disconnect the syringe,
3 empty the blood and clot from the syringe, reattach the syringe, and recharge the syringe by
4 withdrawing the plunger. This process is time consuming, cumbersome, and messy. [REDACTED]

5 [REDACTED] Ex. 1026 at
6 106:17-107:24. Symphony’s on-demand and continuous suction eliminates this cumbersome
7 procedure. Tomalty Dec., ¶¶ 10-13.

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

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

17 The Inari products do not have differential flow. Every syringe pull withdraws a
18 standard 60cc of blood and clot from the patient. [REDACTED]

19 [REDACTED]

20 [REDACTED] See Ex. 1026 at 106:17-107:24; Tomalty Dec.,
21 ¶¶ 14-16. It would be against the public interest to withdraw Symphony and these important
22 innovations from the market when some physicians prefer Symphony to either of Inari’s
23 products to treat DVT. Tomalty Dec., ¶¶ 18-22. Accordingly, an injunction would not serve
24 the public interest in this case.

25 **V. CONCLUSION**

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

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Respectfully Submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 9, 2024

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