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INARI MEDICAL, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

INARI MEDICAL, INC.,

Plaintiff,

v.

IMPERATIVE CARE, INC. ,

Defendant.

Case No. 4:24-cv-03117-YGR

INARI'S NOTICE OF MOTION AND MOTION FOR A PRELIMINARY INJUNCTION; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT

Hearing Date: Tuesday, October 15, 2024
Time: 2 p.m.
Location: Courtroom 1, Oakland
Judge: Yvonne Gonzalez Rogers

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NOTICE OF MOTION

Plaintiff Inari Medical, Inc. ("Inari") moves for a preliminary injunction and notices the hearing for this motion for October 15, 2024, at 2 p.m. in Courtroom 1, 4th Floor, 1301 Clay Street, Oakland, CA 94612. By this motion, Inari seeks to prohibit Imperative Care, Inc. ("Truvic") from making, using, selling, offering to sell, importing, marketing, or distributing its Symphony system in the United States. A preliminary injunction is warranted because Inari is likely to prevail on its claim that the Symphony system infringes Claim 1 of United States Patent No. 11,974,910 ("the '910 Patent") and Claims 1 and 10 of United States Patent No. 11,844,921 ("the '921 Patent"), Inari will suffer irreparable harm without an injunction, the balance of hardships favors Inari, and the public interest favors an injunction.

This motion is based on this Notice, the attached memorandum, the declarations of Drew Hykes (Inari's CEO), Benjamin Merritt (Inari's Senior Director of Engineering and an inventor on both the '910 and '921 Patents), Kevin Strange (Inari's Senior VP of Finance, Strategy & Business Development), Brian Brown (independent expert on medical thrombectomy devices), and Ramsey Al-Salam (counsel), and any other evidence or argument that the Court permits.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

The Court should issue an injunction precluding Truvic from marketing or selling its Symphony system. First, and most importantly, Inari is highly likely to prevail on its claim that the Symphony system infringes the three representative claims of the '910 and '921 Patents featured in this motion.[1] In pre-suit correspondence, Inari gave Truvic notice that the Symphony system infringes multiple Inari patents. In response, Truvic did not meaningfully contest that the claims of Inari's patents "read on" its system. Instead, Truvic argued that the Patent Office erred in issuing the patents because of certain "prior art" references. Truvic is wrong. Indeed, the Patent Office has since allowed additional related patents over exactly that same prior art.

[1] Inari asserts claims from nine patents. For efficiency, it has chosen representative claims from two for this motion. All featured claims are system/device claims that Truvic directly infringes. Inari could just have easily included claims directed at DVT, methods, the mechanical disks used in its FlowTriever systems, or other inventions; its asserted patents feature all of these.

Brian Brown, an independent expert, explains in his declaration why and how the Symphony system infringes, and why Truvic cannot raise a substantial question as to the claims' validity.

Second, Inari is also likely to suffer irreparable harm absent an injunction. Inari is a pioneering company focused on developing new systems and devices that remove blood clots from large blood vessels, particularly for deep-vein thrombosis ("DVT") and pulmonary embolisms ("PE"), conditions that kill a hundred thousand of people each year in the United States alone. As Inari CEO Drew Hykes explains, Inari was the first to develop thrombectomy devices especially designed to treat PE and DVT. Hykes Dec. ¶¶8-10. Starting more than a decade ago, before anyone else was doing so, its engineers began developing, iterating, and perfecting innovative catheter-based systems designed specifically for thrombectomy in veins and pulmonary arteries. *Id.* Inari's systems use, among other innovations, pre-charged accelerated aspiration (e.g., stored vacuum suction, including what Inari calls "WHOOSH"), telescoping catheters, and custom-built "hemostasis valves" to efficiently remove clots—and to do so in a way that minimizes blood loss and complications of other systems. Merritt Dec. ¶46. Inari was the first to have a mechanical thrombectomy device cleared for the treatment of PE, and Inari's most recent version of that device has been shown to result in ***a 90% higher survival rate*** than traditional thrombolytics therapy for those suffering from the worst and most life-threatening form of PE. Hykes Dec. ¶11. This is the first major breakthrough in the treatment of PE in decades, with mortality rates otherwise hovering close to what they were in the 1970s. *Id.* ¶5. Nevertheless, Inari's marketing and sales teams has had to spend years evangelizing Inari's products and convincing skeptical doctors, one-by-one, that Inari's products are safer and more effective than traditional approaches still recommended by many medical societies, especially for PE. *Id.* ¶16. To date, Inari has [redacted] its patented FlowTriever (primarily for PE) and ClotTriever (for DVT) products. *Id.*

Inari's work has transformed the market for treatment of PE and DVT, saving countless lives in the process. But, despite this success in saving lives, Inari is [redacted]. *Id.* ¶29. Inari knew, however, that it would [redacted]

[redacted]. *Id.* ¶18. And the Patent Office has agreed that Inari's innovations are worthy of patents—granting Inari more than 50 United States patents to date (Ex. 3 (list of Inari patents)), including the two featured here. *Id.*[2]

Inari's innovations have been noticed, and new companies are nipping at Inari's heels with devices that look startingly similar to Inari's. The most egregious of these is currently Truvic. Truvic's "Symphony" system has simply—without permission—copied many of Inari's patented innovations. Truvic's business model exacerbates the harm: it prices Symphony just under Inari's systems, ***and*** Truvic has recruited Inari's sales representatives and is using them to approach Inari's customers—the very customers Inari spent years convincing to try Inari's products. Truvic's actions threaten to erode the growing market that Inari created, currently leads, and single-handedly built. Inari will suffer irreparable harm if Truvic is allowed to proceed. *Id.* ¶¶19-27, 29-30.

Finally, the other injunction factors—balance of hardships and public interest—also favor Inari. Inari seeks an injunction for only a single Truvic product: the Symphony system. Truvic is just bringing the Symphony system to market, meaning that an injunction effectively maintains the status quo. As to public interest, Inari's developments are saving lives, and Inari would never have invested in them but for the patent system's protections. Further, Inari can meet full market demand for these products—saving patients money over traditional treatments in the process. But Inari cannot maintain its momentum in the face of infringing products.

This motion tests whether Inari's investments into its products and the patents that cover them has been warranted. A preliminary injunction does not disrupt the status quo because Truvic's sales are just beginning and it has not yet even been cleared to market its accused Symphony system for PE, something that is not expected to happen until early 2025. Inari asks the Court to stop the harm that Inari will suffer if Truvic is allowed to proceed—harm that will not be compensable with money damages. Inari respectfully moves for a preliminary injunction.

[2] For convenience, all exhibits are located in the appendix of exhibits submitted with this motion. Evidence of exhibits' authenticity is in the declarations submitted with this motion.

II. FACTUAL BACKGROUND

A. Inari Created The Market For PE Mechanical Thrombectomy

Venous thromboembolism ("VTE") is a disease where blood clots (i.e., embolisms, emboli, or thrombi) block veins or arteries. Brown Dec. ¶¶34-35. Deep vein thrombosis ("DVT") is a form of VTE where a thrombosis forms in a person's extremities or pelvic area. *Id.* Part of a DVT can break off and form a pulmonary embolism ("PE") as it travels to, and blocks, large arteries in the lungs. *Id.* PE is a leading cause of preventable hospital death worldwide. *Id.* ¶32. Almost a million Americans are affected by VTE annually, with a mortality rate of about 15% for those with intermediate risk PE—a statistic that has improved only minimally since the 1970s. Hykes Dec. ¶5.

People prone to VTE are typically treated with blood thinners that may prevent formation of new clots, but do not effectively break down existing ones. Brown Dec. ¶41. To break down existing clots, doctors have traditionally turned to "thrombolytic" medicines (or "lytics"). *Id.* ¶39. But lytics, although moderately successful in treating clots in small arteries, have limited effectiveness for clots in larger veins and pulmonary arteries and are associated with risks (like spontaneous brain bleeds), require multi-day ICU stays, and are pricy. *Id.* ¶40. Devices have long existed to remove smaller arterial clots, such as in the brain, but such devices have limited effectiveness and can cause unacceptable side effects when used for VTE. Merritt Dec. ¶¶27-29. This is because the size and structure of veins and larger pulmonary arteries, referred to as their "morphology," and the clots that form in them, present unique challenges for clot removal. *Id.* ¶8. In contrast to arteries, for example, veins are larger, have slower blood flow, and have less blood pressure. *Id.* ¶¶27.

This is the problem that Inari, formed in 2011, set out to solve. Hykes Dec. ¶4. Inari hired a team of engineers, obtained significant investor funding, and built a world-class sales force. *Id.* ¶7. It obtained FDA clearance for FlowTriever for treatment of peripheral vasculature (including DVT) a few years later. Then, in 2018, an improved version of FlowTriever became the first FDA-cleared mechanical thrombectomy system for treating PE. *Id.* ¶11. Recently, Inari conducted a clinical study (the FLAME study) that showed an astounding 90% survival

improvement in high-risk PE patients using FlowTriever over traditional lytics treatments. *Id.* Meanwhile, Inari received FDA clearance for the first version of ClotTriever in 2017 and conducted a study in 2018 that demonstrated its safety and effectiveness for DVT. *Id.* ¶12.

To this day, guidelines of the American College of Chest Physicians, American Heart Association, European Society of Cardiology, and Society of Interventional Radiology nevertheless continue to recommend traditional VTE treatments (i.e., anti-coagulants for most patients and systemic lytics for more severe cases of PE). Exs. 34-38; *see also* Hykes Dec. ¶6; Brown Dec. ¶39. To develop such specialized new products, obtain their FDA clearance after clinical trials, and then to convince doctors,[3] one-by-one, that Inari's products are safer and more effective than traditional therapies has required tremendous time and effort. Hykes Dec. ¶¶16-17. Once doctors give Inari's devices a chance, they are typically quickly converted, but it is a challenge to convince them to try something other than anti-coagulants and/or lytics in the first instance. *Id.* This challenge is particularly acute because many sellers of lytics-based interventional devices are large, well-established biotechnology companies (e.g., Boston Scientific) that have longer, more established relationships with hospitals than Inari. *Id.* ¶16.

As a result, Inari's mission of developing more effective products and converting doctors to them, has required years of sustained efforts and been costly. Inari estimates that it has spent [redacted] for FlowTriever and ClotTriever. *Id.* ¶¶7, 16. Inari's sales force has grown from [redacted], all focused on developing a market for Inari's superior devices and winning over doctors hesitant to deviate from traditional treatments. *Id.* ¶29.

Inari manufactures and assembles its products at its facility in Irvine, California. *Id.* ¶3. It also inspects, tests, packages, and ships finished goods from there, entirely in the USA. Inari is equipped to meet any and all demand for mechanical thrombectomy devices for VTE. *Id.* ¶32.

Inari's successes have led to awards and recognition, including a 1st place Innovation

[3] This includes interventional cardiologists, interventional radiologists, vascular surgeons, pulmonologists, hospitalists, hematologists, and ER doctors, because there is no single type of doctor that patients visit when they have a dangerous blood clot. The variety of types of doctors involved means that those who do not specialize in clots may be particularly reluctant to stray from conventional lytics. Hykes Dec. ¶16.

Award at Transcatheter Therapeutics' conference and Premier's Supplier Horizon Award. *Id.* ¶14. More importantly, its devices have been used in [redacted] patient procedures, saving thousands of lives in the process, and leading to patient testimonials that are nothing short of captivating. *Id.* ¶15 (including citing https://www.inarimedical.com/patient-success-stories).

B. The Market For Treatment Of PE And DVT

The overall market for ***all*** treatments for DVT and PE each year (pharmaceutical, mechanical, and surgical) is many billions of dollars.[4] Strange Dec. ¶9. After years of effort, Inari estimates that only 6% of the patients who could benefit from FlowTriever or ClotTriever are currently treated with those devices. *Id.* ¶7. By convincing doctors who use traditional anti-coagulants or lytics that Inari's products result in safer and more effective treatments, Inari has built its revenues from virtually nothing in 2016 to more than $500M today. Hykes Dec. ¶29. If Inari could serve all of the patients who could benefit from its products, its revenues would be [redacted]. Strange Dec., ¶9. Today, however, [redacted]. Hykes Dec. ¶29.

Inari is the leader in the market for non-lytic mechanical thrombectomy devices, particularly for PE. Inari's FlowTriever system [redacted] of that United States market for PE—and the primary competing device (from Penumbra) is different than (and has shortcomings compared to) Inari's.[5] Strange Dec. ¶10. For DVT, Inari's ClotTriever and FlowTriever collectively [redacted]

[4] The market in which Inari competes is unique for many reasons that distinguish it from other "widgets" that one might buy, but which heighten the need for an injunction here. For instance, the ultimate customers (i.e., patients having health crises) do not always have the time or wherewithal to shop around. Strange Dec. ¶8. They typically follow the recommendation of doctors, who may be reluctant to deviate from medical association guidelines, even though those guidelines sometimes lag years behind—which explains why the number of doctors using traditional treatments today still far outnumbers those that Inari has won over. *Id.* Also, the number of patients suffering from life-threatening VTE—although high—is fairly static each year; it does not grow like markets involving fad purchases do. This makes the hospitals and customers who are Inari's customers particularly important to keep.

[5] Penumbra's devices were adapted from a preexisting product for treatment of clots in small arteries. Although similar to Inari's in many respects, Penumbra's use (in at least some products) inferior off-the-shelf hemostasis valves (and/or luer connectors) and/or catheters that are mostly smaller than Inari's (*e.g.*, 7F, 8F, 12F, or, more recently, 16F, rather than 16F, 20F, and/or 24F, which is particularly impactful when telescoping. Brown Dec. ¶¶61, 98; Merritt Dec. ¶60.

[redacted], with a few other companies sharing the rest.[6] *Id.*

Inari currently sells its ClotTriever system (used for treatment of DVT only) for [redacted] and its FlowTriever system (used primarily for treatment of PE, but sometimes for DVT) for [redacted]. *Id.* ¶11. [redacted]. *Id.* About [redacted] of Inari PE patient cases and about [redacted] of its DVT cases are performed with FlowTriever using telescoping catheters (discussed further below). *Id.*

[redacted]

C. History Of Thrombectomy Devices

Many dozens of thrombectomy devices have gained FDA clearance, including many before Inari. *Id.* ¶11. These older devices were designed for removing clots from arteries, such as narrow arteries in the brain, however. As the name suggests, small arteries are tiny—often just 3-6 mm in diameter or smaller, and the smallest ones can be less than a fraction of a millimeter in diameter. Brown Dec. ¶36. This creates a particular biological environment that is different than the large veins in the limbs or larger pulmonary arteries in the chest, which can be, e.g., an order of magnitude larger (10x) in diameter than the small arteries that older devices were designed to treat. *Id.* A round vessel that is twice the diameter has approximately four times the cross-sectional area. *Id.* ¶199.

"Re-purposing" of devices designed to remove clots from smaller arteries for the types of VTE clots found in much larger veins and pulmonary arteries is sub-optimal for multiple reasons. Merritt Dec. ¶¶27-29; Brown Dec. ¶¶50-54. For instance, because of their location and how they are formed, VTE clots tend to be larger, older, more highly organized, and more fibrous than arterial clots. *Id.* ¶35. This, in turn, requires different catheters and extraction pressures

[6] Some of these other devices companies' devices for removing DVT clots are based on different principles than Inari's, such as water jets (AngioJet). Brown Dec. ¶206. Competing DVT-specific mechanical thrombectomy devices include AngioDynamics's (very complicated), Penumbra's (*see* n.5, *infra*), and Truvic's. *Id.*

and techniques than are needed for clots in small arteries, and requires consideration of greater blood loss risks. *Id.* ¶50.

Simply sizing up the smaller catheters used in devices for the arteries to ones with larger diameters does not resolve these challenges. DVT and PE clots are sometimes found deep in the body (e.g., in deep leg veins and pulmonary arteries) and in places that are harder to reach in relation to the catheter injection site (e.g., a knee or groin) than clots found in smaller arteries—meaning that a catheter must sometimes travel a tortuous and curving path with many turns through blood vessels of varying sizes, including ***through the heart***, to reach a clot that may then nearly fully block that much larger blood vessel at the location where it has lodged. *Id.* ¶54; Merritt Dec. ¶¶14, 15, 44. In PE, pulmonary arteries also occasionally branch like a tree, and clots occasionally form at those split points, resulting in clots with complex geometries. Brown Dec. ¶53. All of these realties create engineering challenges because the catheters that remove these clots must be rigid enough that they can be pushed through the body, flexible enough so that they can navigate the many twists and turns taken by blood vessels in the body, large enough to aspirate the entire clot, small enough to not get stuck in transit, and (at least for PE) effective at removing clots with unexpected shapes and geometries. Merritt Dec. ¶28. Partly for these reasons, catheters for thrombectomy devices for small arteries are typically sized to come close to filling those arteries (with a vessel-to-catheter ratio of essentially 1:1), still allowing blood flow for the patient around the catheter. *Id.* That approach will not work for larger veins and arteries. *Id.* Indeed, a catheter by itself cannot address all of the challenges; it must be finely tuned with an entire clot-removal system designed to balance all of these considerations.

Likewise, the suction forces needed to remove fibrous (older) clots in the deep veins and pulmonary articles (and techniques for applying these pressures) cannot simply be taken from arterial aspiration-based mechanical thrombectomy devices, given the different blood vessel sizes, different clot consistencies, and greater distances between pressure sources and clots. Brown Dec. ¶¶50-54. The clot size and structure in PE and DVT, and the complex clot geometry and chronicity in PE, necessarily requires more suction—or one or more bursts of pressure (as in WHOOSH)—over a larger area to effectively aspirate clots. *Id.*; Merritt Dec. ¶28.

Another difficulty with modifying a system for smaller arteries for VTE is that larger catheters risk far more blood loss. Brown Dec. ¶65. For example, a 24F[7] catheter has three times the circumference of a traditional 8F catheter, meaning it has nine times the area and can aspirate blood an order of magnitude faster. *Id.* The targeted vessels for PE and DVT are also critical to circulate blood to key locations all over the body, meaning that losing a large amount of blood during VTE thrombectomy creates different (and often) greater subsidiary risks than for other procedures. *Id.* ¶202. All of this requires new innovations (e.g., improved hemostasis valves) specifically designed to mitigate blood loss, but while still being easy for doctors to operate.

The engineering required to solve these problems demands more than reusing preexisting arterial thrombectomy devices. *Id.* ¶¶50-54. Such a crude solution will not work. *Id.* Likely for that reason, there have been only limited developments—besides Inari—in the treatment of DVT and PE over the past ***five decades***. *Id.* ¶¶38, 205. Most notably, mortality rates remain about the same now as they were in the 1970s. *Id.*; *see also* Hykes Dec. ¶5; Merritt Dec. ¶7.

Consistent with these realities, the Primary Patent Office Examiner who evaluated Inari's '910 Patent Application considered many prior art references relating to devices for removal of clots in the small arteries as part of her work. Ex. 4; Brown Dec. ¶¶101-104. This included U.S. Published Application Nos. US20150173782 ("Garrison I") and US20180064453 ("Garrison II"). Exs. 4, 29, 30. Similarly, the Primary Examiner for Inari's '921 Patent considered the field of art and determined that Inari disclosed and claimed a non-obvious innovation to hemostasis valves, including over U.S. Application No. US20030116731 ("Hartley") and U.S. Patent No. 9,980,813 ("Eller"). Exs. 6, 31, 33; Brown Dec. ¶¶116, 221. The Examiner also considered other references, such as U.S. Application No. US20030225379 ("Schaffer," Ex. 32) in the context of family members of the '921 Patent, never finding these references to be showstoppers in any way. With all of these (and a long list of other prior art references) in mind, she confirmed that Inari's inventions are novel, nonobvious, and entitled to patent protection.

D. Inari's Patent Portfolio

Inari's currently has more than fifty United States patents from ten families, with

[7] Catheter sizes are measured in "French" or "F." One French is roughly 3 millimeters.

significant ongoing prosecution and more patents regularly issuing. Hykes Dec. ¶18. The two patents featured in this motion both issued in the six months before Inari filed this case. Inari itself practices the patent claims featured in this motion (Brown Dec. ¶¶231-248) and, as detailed below, attributes much of its growing success to the innovations claimed in these patents. Inari also identifies these patents on its "virtual marking" page as ones that cover its ClotTriever ('921 Patent) and FlowTriever ('921/'910 Patents). *See* https://www.inarimedical.com/inari-patents.

1. Claim 1 Of The '910 Patent

On May 7, 2024, the Patent Office issued Inari's '910 Patent, entitled "System for Treating Embolism and Associated Devices and Methods." Ex. 1. The '910 Patent does not expire until August 8, 2039—fifteen years from now. *See* 35 U.S.C. § 154 (calculation of patent term); MPEP § 2701. Benjamin Merritt, Jacqueline Macias, Brian Strauss, Thomas Tu, John Coleman Thress, and Paul Lubock are inventors on this patent. *Id.*; *see also* Merritt Dec. ¶16.

Consistent with its title, the '910 Patent discloses and claims improved clot-removing systems and methods for PE that solve problems with prior art devices. Ex. 1 ('910 Patent) at Abstract, Fig. 9A-Fig 16E, 1:32-37, 4:17-55, 26:4-15, 35:52-36:34. Specifically, the '910 Patent discloses advancing aspiration catheters to a location proximate (close) to a clot, such as a PE, then generating vacuum pressure in a chamber and opening a valve to apply the vacuum pressure to the catheter to aspirate and remove the clot through the catheter. *E.g.*, *id.* Claim 1 describes a combination of components with telescoping aspiration catheters (the smaller being 16F or larger in size) suitable for treating PE and that are configured to generate a stored vacuum for each catheter (the telescoping configuration is also appropriate for treating DVT), *see id.* at 35:52-36:34. A team of Inari engineers and doctors worked long and hard to develop, iterate, and perfect these ideas for optimal patient outcomes, with much creativity, brainstorming, and trial-and-error involved. Merritt Dec. ¶¶12, 17-22.

Each of the '910 inventors came to Inari with different backgrounds and perspectives: the team included both engineers and clinicians who contributed key concepts, and they focused on different aspects of the ideal thrombectomy device that they combined into a system with particularly effective results. *Id.* Thus, for instance, Dr. Tu, a medical doctor and Inari's Chief

Medical Officer, came up with the "WHOOSH" concept that is incorporated into the claims of the '910 Patent. With "WHOOSH," a doctor advances a catheter that is disconnected from a vacuum source to a clot, uses a vacuum pressure source (e.g., a locking syringe or pump) to generate a stored vacuum, and then connects the catheter to the stored vacuum (causing a rapid pressure drop) to aspirate the clot. *E.g.*, *id.* at ¶15, Ex. 1 at Fig. 1, Fig. 8-9C, 7:28-41, 16:33-20:52. Dr. Tu tried this approach because, as a practicing physician before he joined Inari, he was dissatisfied with the earlier versions of Inari devices that used retraction-aspiration techniques, where a clot was suctioned partially into the end of a catheter and then the catheter retracted back through the patient. Merritt Dec. ¶34. He conceived the solution of using higher vacuum pressure to "WHOOSH," *i.e.*, to suction, more of the clot into and back through a catheter. *E.g.*, *id.*; Ex. 1. at 4:34-50.

Mr. Strauss and Ms. Macias worked on the use of telescoping catheters (where a smaller catheter is advanced inside of a larger diameter one) with Inari's thrombectomy devices. *See, e.g.*, Merritt Dec. ¶40; Ex. 1 at Figs. 11-16E, 20:58-28:10. By telescoping, they hoped to (and did) provide additional reach for the catheter to get deeper into the patient's veins, regardless of how they might twist and turn inside a patient's body. Merritt Dec. ¶¶43-45. Beyond providing longer reach, telescoping also creates the opportunity for a second aspiration pass (a second "WHOOSH") to increase the odds of successfully and completely aspirating an entire clot (or multiple clots). *Id.* The seal created between the telescoping catheters by withdrawing a clogged smaller catheter through the larger catheter while applying vacuum also provided a piston effect that captured more clot. *Id.* Mr. Strauss and Ms. Macias (along with Mr. Merritt) also conceived inventions for filtering blood from clots and returning filtered blood to the patient, which are claimed in relatives of the '910 Patent. *See, e.g.*, *id.* ¶46 at Figures 19-23, 30:61-34:63.

Messrs. Merritt, Thress and Lubock also focused on the novel hemostasis valves used in Inari's FlowTriever and ClotTriever systems. Merritt Dec. ¶¶47-58; *see also, e.g.*, Ex. 1 at 5:37-61, Claim 7. These structures are memorialized in, for instance, U.S. Patent Application No 16/117,519 (the parent to the '921 Patent), which is—in turn—incorporated by reference into the '910 specification. *Id.* at 5:56-61. By way of background, hemostasis valves have long been

known in the art. Merritt Dec. ¶48. Thus, there are commercially available, off-the-shelf valves that are commonly used in a variety of medical devices, including thrombectomy devices designed for removal of clots from small arteries. *Id.* Wanting a better seal and easier-to-operate valves, Messrs. Merritt, Thress, and Lubock set out to design a more effective, Inari-specific hemostasis valve, *see id.* ¶¶47-58, described more below in connection with the '921 Patent.

Claim 1 of the '910 Patent combines the work that these engineers and doctor inventors were doing individually into a single, streamlined system that works unexpectedly well in patients. Brown Dec. ¶¶204-206. This claim focuses a system that uses vacuum aspiration with multiple catheters that can telescope, multiple pressure sources, and fluid control devices that can be toggled between different positions, among other components. Ex. 1 at Claim 1.

2. Claim 10 Of The '921 Patent

Naming Messrs. Merritt, Thress and Lubock as inventors, the Patent Office issued Inari's '921 Patent, titled "Hemostasis Valves and Methods of Use," in late 2023. Ex. 2. The '921 Patent expires on November 2, 2038. *See* MPEP § 2733 (term adjustment per 37 CFR § 1.705).

The '921 Patent discloses improved hemostasis valves and methods of their use. Ex. 2 at Abstract, 1:58-62. Hemostasis valves are used to create a seal that, in turn, minimizes patient blood loss and maintains sterility in patients' bodies, such as in blood vessels. *Id.* at 1:28-44. This is critical for preventing patients from losing blood unnecessarily and air from entering the vasculature (which can cause bubbles) and for reducing infection. *See id.* at 1:18-26. Improved hemostasis valves are important to patient outcomes, including by providing ease of use (*e.g.*, one-handed use) for doctors and minimizing dangerous blood loss. *See id.* at 1:45-54, 5:49-67.

As shown in Figure 2 of the '921 Patent (pictured, next page), its invention relates to the structure for an improved garrote-structure hemostasis valves that meets these goals. *Id.* Abstract, Fig. 1, 2:8-25, 5:49-67, Claims 1 & 10. Inari's hemostasis valve (104) has an internal elongate member or tube (132, aqua) having a lumen (an inner cavity through which a catheter can be inserted). *Id.* at Fig. 2, 7:65-8:9. The elongate member (132) can be constricted by an active tensioning mechanism having one or more filament(s) (150, red) wrapped around the elongate tube (132). *Id.* In some embodiments there are two or more constricting filaments. *Id.*

at Fig. 7, 13:54-14:22. The hemostasis valve's tensioning mechanism has one or more actuators (such as button control mechanisms 144a and 144b, orange) that actuate the valve between a closed and open position, and a structure (such as springs 148a and 148b, purple) to bias the actuators to the closed position. *Id.* at Fig. 2, 8:33-40.

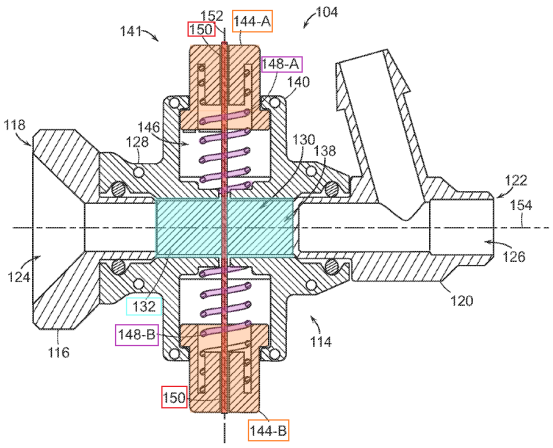

FIG. 2

Messrs. Merritt, Thress, and Lubock came up with this design to solve known issues with prior art valves. *See, e.g.*, *id.* at 5:49-6:18; Merritt Dec. ¶¶47-58. Specifically, those prior art valves did not adequately seal around a variety of catheters—which increases the odds that patients will experience dangerous blood loss—or provide for ease of use (*e.g.*, one-handed operation, easily controlled force) during complicated procedures. *E.g.*, *id.*; Ex. 2 at 5:49-6:18, 8:34-67. These concerns were especially acute for valves for larger diameter vessels that have pressure differentials (such as 16F or 24F aspiration catheters used in VTE treatments, where blood loss from an open valve can be dangerous and life-threatening) and for valves used with telescoping catheters (because of advantages in insertion and because it can better withstand the rapid drop in pressure that occurs during a WHOOSH). Merritt Dec. ¶¶50, 63.

Because doctors want thrombectomy systems that have easy-to-use and easy-to-control hemostasis valves that minimize patient blood loss (leading to better outcomes), Inari's valve provides an important competitive advantage. Merritt Dec. ¶61. A valve that seals quickly and easily is particularly important to doctors performing VTE procedures, because the time that a valve is unsealed can cause material blood loss. *Id.* Prior art valves, such as Tuohy-Borst valves, required more time (and force) to fully open and close, meaning that the blood lost during the longer times for actuating the valve could be significant. *Id.* ¶62; Brown Dec. ¶59.

E. Truvic's Copying Of Inari's Business And Products

Truvic Medical, Inc. was incorporated in Delaware in 2020, many years after Inari was formed, for the purpose of developing medical devices that provide "single-session thrombus

removal without the use of thrombolytics" in February 2020. Ex. 11.[8]

Truvic's Symphony devices are strikingly similar to Inari's FlowTriever and ClotTriever devices. *See* §IV.A.1, below. Symphony uses 16F and 24F telescoping catheters, just like Inari's FlowTriever. *Id.* Truvic touts to customers its "catheters [that] optimize navigation" and the Symphony systems' "telescoping extended reach (24F + 16F)," descriptions that apply equally to Inari's FlowTriever. *Id.* Truvic likewise uses its large-diameter telescoping catheters for aspiration with stored (pre-charged) vacuum. *Id.* Truvic's Symphony system also has an intervening member (the dual action pressure control) between the pressure source and catheter to disconnect the catheter from the pressure source while vacuum is generated and then to connect to rapidly apply the stored vacuum to the catheter to aspirate the clot (i.e., suck it into the catheter, as with WHOOSH). *Id.* Truvic also has a garrote hemostasis valve with an active tensioning mechanism biased to a constricted position, in which a central tubular piece is constricted by filament lines, just like the unique hemostasis valve design of both FlowTriever and ClotTriever. *Id.*; *see also* Merritt Dec. ¶¶65, 66. This is consistent with Truvic's attempt to mimic and leverage Inari's entire VTE business, rather than building something of its own.

When it had only been in business for a few months, in August 2020, Truvic submitted two Freedom of Information Act ("FOIA") requests to obtain access to Inari's FDA applications for the FlowTriever device (Ex. 9; Hykes Dec. ¶20), presumably in hopes of obtaining technical information about Inari's product. Although FOIA requests are not uncommon in the medical device industry and Inari has even used them itself (*id.*), Truvic's requests here are consistent with Truvic's deliberate copying of parts of Inari's products and business.

Truvic obtained FDA approval to market its Symphony system for the treatment of DVT in February 2023. Ex. 10. In just three years—i.e., a notably short time—Truvic had completed design and testing for its product (using a third-party design firm, Ex. 15), cleared all regulatory

[8] Eighteen months later, in July 2021, Defendant Imperative Care, Inc. acquired Truvic. Ex. 13 (press release). Founded in 2016, Imperative Care develops products in a wide array of disparate health-related areas, such as for strokes, vascular disease, digital health, and robotics. *Id.* After Inari filed this case, Imperative Care informed Inari that Truvic had been merged into Imperative Care, so Inari has removed Truvic as a separately named defendant. Dkt. 20. That said, Inari continues to refer to Imperative Care as "Truvic" to avoid confusion.

hurdles, arranged for suppliers and manufacturers, selected a product name and pricing structure, and begun assembling a sales force.

After receiving FDA clearance to market its Symphony system for treatment of clots in the peripheral vasculature (which includes DVT) in early 2023, Truvic quickly began to market the system to doctors: Truvic launched its Symphony website soon after FDA approval and distributed product brochures at an industry conference in March 2023. Hykes Dec. ¶21. At that same industry conference, Truvic's CTO commented to an Inari engineer that Trvuic appreciated Inari "paving the way for us [Truvic]." *Id.*

On the sales front, Truvic has recruited at least six ***Inari*** sales reps (and attempted unsuccessfully to recruit more), a large portion of Truvic's initial sales force. *Id.* ¶25. These former Inari salespeople, who are familiar with Inari's products, are now approaching Inari's customers on Truvic's behalf to convince them to use Symphony instead of Inari's products. *Id.*

Truvic's sales representatives (both those hired from Inari and others) have also interfered with Inari's customer relationships. Inari's sales representatives typically attend procedures using Inari products, especially the initial uses by a doctor, to ensure that products are used properly and safely. Hykes Dec. ¶25. Truvic, however, has in at least one instance convinced a doctor ***not*** to tell Inari that he was going to use FlowTriever so that Truvic representatives (including senior leadership and R&D personnel) could attend to observe how Inari's devices work. *Id.* This is highly unusual. Not only that, but Truvic has offered and given doctors meaningful amounts of equity in Imperative Care to induce them to try the Symphony system, which is not something that Inari has ever done. *Id.* ¶26.

Though unclear, it appears that Truvic did not begin selling its Symphony system until the second half of 2023. Strange Dec. ¶15. In August 2023, for instance, Truvic announced that Symphony would launch "in the coming months." Ex. 13. By the Fall of 2023, Inari began hearing reports that customers were purchasing and trying Truvic's system, particularly for DVT. *See, e.g.*, Ex. 12 (reporting first use for DVT in LA).

Truvic's business model is also notable: rather than attempting to persuade the thousands of doctors who continue to use traditional treatments today to try Truvic's Symphony system,

Truvic has focused its efforts on stealing doctors that ***Inari*** has already won over—using Truvic's lower prices (and Imperative Care's wider credibility and stock incentives) to sweeten the deal. *See* Strange Dec ¶13; Hykes Dec. ¶¶24-26. In other words, Truvic has followed the (far easier) path of leveraging the work that Inari has done to build a market, rather than trying to pave its own way in the wider market for VTE treatment as a whole.

F. Inari Is Already Losing Sales To Truvic; It Will Lose Many More When Truvic Gets Its PE Approval

Truvic's business model is to target doctors who are already Inari customers, meaning that every sale of a Symphony system is a lost sale for Inari. As Truvic resolves rumored supply chain issues (Hykes Decl. ¶30) and ramps up its sales, this becomes an increasing problem, and Inari expects the bulk of this case to focus on future sales and harms, rather than the more limited initial/past sales that Truvic has made.

Truvic is already selling its Symphony system, which can be used for either DVT ***or*** PE, and it is already cleared by the FDA to specifically market for the treatment of DVT. Exs. 10, 12. Truvic has not yet obtained FDA clearance to market Symphony for the treatment of PE, doctors are already making "off-label" use for that purpose. Hykes Dec. ¶30.

Moreover, Truvic is seeking FDA clearance to specifically market Symphony for treatment of PE. In October 2023, it announced clinical trials for PE treatment with the Symphony system. From December 2023 to July 2024, it announced trial sites at ten hospitals in Alabama, California, Michigan, New York, Texas, Indiana, and Ohio. Ex. 14. Notably, [redacted]. Hykes Dec. ¶26. Truvic anticipates completing these studies in early 2025 (Ex. 14), with FDA clearance presumably soon to follow.[9]

In short, Inari is already beginning to lose sales of both FlowTriever (cleared for PE, but sometimes also used by doctors for DVT) and ClotTriever (DVT). If and when Truvic resolves supply chain issues, gets its sales force deployed in earnest, and gets its PE approval, [redacted]

[9] Although Inari cannot and does not allege that use of devices in FDA trials is an infringement, these clinical studies are relevant as to the operation of Truvic's products, its intent to specifically market Symphony for PE, and its ability to woo away Inari's customers. [redacted]

[redacted] Kevin Strange, Inari's VP of Finance, Strategy & Business Development, describes [redacted]. Strange Dec. ¶¶13-14. Mr. Strange [redacted]. Strange Dec., ¶14. [redacted]. *Id.* [redacted]. Hykes Dec. ¶30. [redacted]. *Id.* The effects on Inari from these lost opportunities are impossible to quantify and extend far in the future. *Id.*

G. Inari Attempted To Get Truvic To Desist Infringement Before It Filed This Suit

On September 29, 2023, Inari gave notice to Truvic of certain Inari patents and asked for a sample of the Symphony device to test for infringement of other patents. Ex. 22. Inari requested that that the parties meaningfully address the infringement issues and avoid an unnecessary lawsuit. Al-Salam Dec. ¶2. After waiting months, Truvic responded by claiming that its Symphony device, which it was already distributing to doctors at the time, was "proprietary," and refused to provide a sample. Ex. 24. Then, in January 2024, it provided its first substantive response: it did not contest infringement for three of the four patents that Inari had identified in another December email, but instead asserted that the Inari patents were invalid based on prior art that it identified. Ex. 25. Inari then promptly disclosed that prior art to the Patent Office in connection with pending applications to see whether the Patent Office agreed with Truvic. Al-Salam Decl. ¶6. Inari also explained to Truvic's counsel in a letter in April

2024 why Truvic's cited prior art did not invalidate Inari's patent claims—and explained that the Patent Office had agreed with Inari. Ex. 26. Inari also asked, again, that Truvic cease its sales of the Symphony product. *Id*. Truvic refused to do so, thus necessitating this lawsuit.

PRELIMINARY INJUNCTION LEGAL STANDARDS

This case is the poster child for injunctive relief. "The essential attribute of a patent grant" is the right to exclude competitors from infringing. *Acumed LLC v. Stryker Corp*., 551 F.3d 1323, 1328 (Fed. Cir. 2008). This is particularly true where the parties are direct competitors in a two-supplier market, and even holds true where additional competitors are present in the market. *See, e.g.*, *Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1378 (Fed. Cir. 2020) (affirming-in-part injunction where "district court found that [parties] are direct competitors, and [patentee] would suffer irreparable competitive harm absent an injunction," even where some products did not compete); *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1151 (Fed. Cir. 2011) (remanding for entry of injunction where lower "court's first legal error lies in its conclusion that the presence of additional competitors, without more, cuts against a finding of irreparable harm").

A patentee seeking a preliminary injunction must establish 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 [its] favor;" and (4) an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1356 (Fed. Cir. 2002).[10]

To demonstrate a "reasonable likelihood of success on the merits," a patentee must show

[10] The Federal Circuit has explained that "the factors are not applied mechanically" and that the movant must establish both of the first two factors to be entitled to a preliminary injunction. *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1005-06 (Fed. Cir. 2009); *see also Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prods., LLC*, 431 Fed. Appx. 884 (Fed. Cir. 2011); *Amazon.com, Inc. v. Barnesandnoble.com, Inc.,* 239 F.3d 1343, 1350 (Fed. Cir. 2001). The Ninth Circuit has additionally (or perhaps alternatively) taken a "sliding scale" approach, where preliminary injunction factors are balanced, such that a stronger showing on one element may offset a weaker showing of another. "For example, a stronger showing of irreparable harm to plaintiff might offset a lesser showing of likelihood of success on the merits." *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131-32 (9th Cir. 2011); *Flathead-Lolo-Bitterroot Citizen Task Force v. Montana*, 98 F.4th 1180, 1190 (9th Cir. 2024) (quoting *id.*). Regardless of which test applies, Inari has met it.

that: (1) it will likely prove infringement;[11] and (2) its infringement claim will likely withstand challenges to the patent's validity and enforceability.[12] *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001). This requires a clear showing that at least one claim is infringed.[13] *Abbott Labs. v. Andrx Pharms., Inc*., 473 F.3d 1196, 1213 (Fed. Cir. 2007). An accused infringer cannot defeat a patentee's showing of likelihood of success on the merits without raising a "substantial question" concerning infringement, validity, or enforceability. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1364 (Fed. Cir. 2008).

III. THIS COURT SHOULD GRANT A PRELIMINARY INJUNCTION

A. Inari Is Likely To Succeed On Its Patent Infringement Claims

1. Truvic's Copycat Symphony System Infringes The '910 And '921 Patents

To meet its burden on infringement, Inari provides a detailed declaration from expert Brian A. Brown. Mr. Brown has a degree in mechanical engineering and over 30 years of R&D experience in the cardiovascular and medical device industries across a variety of applications, including neurovascular, cardiovascular, peripheral vascular, and pulmonary aspiration thrombectomy devices. Mr. Brown's declaration explains, with images, explanation, and claim charts, how Truvic's Symphony system meets each limitation of the three featured claims and therefore directly infringes. Due to space constraints, Inari provides an only an abbreviated explanation here of where each element of the three claims are found in the Symphony system.

a. There Is Only One Claim Construction Issue To Resolve

Preliminarily, the only claim term of the three featured claims that requires claim construction is "filament," which should be given its plain and ordinary meaning of "a thin, flexible length of material formed by one or more strands of material." Brown Dec. ¶¶90-91;

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[11] It is an act of infringement to make, use, sell, offer to sell, or import an invention covered by the claims of a patent without the authority of the patentee. 35 U.S.C. § 271(a). Infringement requires a two-step analysis: first, the Court determines scope and meaning of the asserted patent claims, and second, the Court compares the properly construed claims to the accused infringing device. *CommScope Technologies LLC v. Dali Wireless Inc.*, 10 F.4th 1289, 1295 (Fed. Cir. 2021) (citation omitted).

[12] Patents are presumed valid. 35 U.S. Code § 282. Inari does not rest on that assumption here, however, but instead comes forward with affirmative evidence of validity. *See* §III.A.2, *supra*.

[13] Inari focuses on three claims (from two separate and unrelated patents) in this motion, but it need only prevail on one of them to be entitled to a preliminary injunction.

Ex. 39 (defining "filament" as "a single thread or a thin flexible threadlike object, process, or appendage" as of the priority date); Ex. 40 (defining "filament" as "a very fine thread or threadlike structure; a fiber or fibril" as of the priority date). The '921 specification makes clear that the filament uses thin, flexible materials, "the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape." '921 Patent at 9:15-17, *see also id.* at Fig. 7, Fig. 8, 4:3-6, 9:13-17.

The only reason that this term needs to be construed is because Truvic has tried to apply an indefensibly overbroad meaning to it already—removing the requirement of flexibility, for instance—in an *inter partes* review ("IPR") petition that it filed for a patent related to the '921 Patent. Ex. 28 at 13-14. Truvic's attempt to misconstrue this term to sweep in the prior art for purposes of its invalidity argument should be rejected: Inari's patents are valid and infringed.

b. Truvic Infringes Claim 1 Of The '910 Patent

i. Preamble: "A clot treatment system for treating clot material comprising a pulmonary embolism in a vasculature of a patient, comprising:"

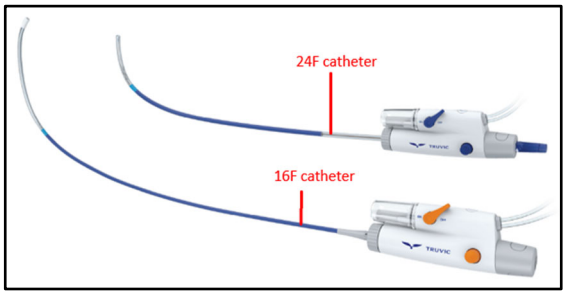
As set forth in Mr. Brown's declaration and the attached chart, the Truvic Symphony system is a clot treatment system. Brown Dec. ¶¶131-32. To the extent that the preamble is deemed limiting, Truvic's own documentation and marketing materials make abundantly clear that Symphony is an aspiration-based clot treatment system used to perform treatments with "next generation thrombus removal" via "powerful, focused aspiration." Ex. 7 at 2-4.

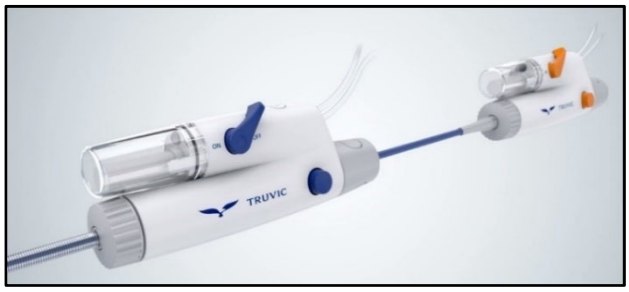
The Symphony system also is designed for treating embolism in a patient's pulmonary (lung system) blood vessel, *e.g.*, in the pulmonary arteries. Truvic has instituted a study for using Symphony products to treat PE, for instance. Ex. 14. What is more, the Symphony system is already competing with FlowTriever for PE treatment with customers using Symphony off-label, despite the lack of explicit FDA clearance for PE. Hykes. Dec. ¶30.

ii. Element 1[a][i]: "a first clot aspiration assembly, including: a first catheter;"

As Mr. Brown explains (Brown Dec. ¶¶133-36), the Truvic Symphony system includes a 24F aspiration catheter and 24F controller handle to perform aspiration via the 24F catheter. Truvic's marketing materials and demo video (clipped below) show that the Symphony system

is designed with two aspiration assemblies and two telescoping aspiration catheters: a first 24F controller handle (with blue controls) and first 24F catheter, as well as a second 16F controller handle (with orange controls) and a second 16F catheter. Truvic further teaches to use the two catheters in a telescoping configuration where the 16F catheter is advanced through 24F catheter.





iii. Elements 1[a][ii]: "a first pressure source;" and 1[a][iii]: "a first fluid control device between the first catheter and the first pressure source,"

The Truvic Symphony system includes a first pressure source, specifically a Truvic Generator (an electric vacuum pump) and the clot canister on the first controller handle, which together form a first pressure source. Brown Dec. ¶¶133-36. The Truvic Generator (labeled "Vacuum pump") and the clot canister are annotated below. The Truvic Symphony system also has a first fluid control device, a Dual-Action Vacuum Control (first fluid control device) operated by the blue lever (labeled, right). *Id.* This is used to disconnect the vacuum in the pressure source (clot canister and vacuum pump) from the 24F aspiration catheter when the lever is in the "off" position and connects the vacuum to the 24F aspiration catheter when the lever is in the "on" position. *Id.*

iv. Element 1[b]: "wherein the first fluid control device is movable between (a) a first position in which the first pressure source is fluidly disconnected from the first catheter and (b) a second position in which the first pressure source is fluidly connected to the first catheter,"

The Symphony system's first fluid control device (specifically, the Dual-Action Vacuum Control operated by the blue lever) is moveable between a first "off" position to a second "on" position by rotating the lever. Brown Dec. ¶¶137-43. Rotating the lever to the "off" position

fluidly disconnects the vacuum pump and clot canister from the aspiration catheter, while rotating the lever to the "on" position fluidly connects the vacuum to the aspiration catheter. *Id.*

v. Element 1[c]: "wherein the first pressure source is configured to generate vacuum pressure while the first fluid control device is in the first position, and wherein, upon movement of the first fluid control device from the first position to the second position, the vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first catheter; and"

As Mr. Brown explains, the Symphony system meets this limitation. Brown Dec. ¶¶144-50. Truvic's Instructions For Use expressly teach to set the Dual Action Vacuum to the "off" position in a series of steps (#12-15), to allow the vacuum pressure to build to -20 inHg (20 inches of mercury or ~68,000 Pascals) or greater, to confirm the stored pressure and the positioning of the aspiration catheter's distal end, and only then to rotate the Dual Action Vacuum to the "on" position to apply aspiration at the distal tip of the first catheter. Ex. 8 at 5.

vi. Element 1[d]: "a second clot aspiration assembly, including: a second catheter advanceable through the first catheter, wherein the second catheter has a distal portion, wherein the second catheter has a size of 16 French or greater, and wherein the second catheter is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism;"

The second clot aspiration assembly functions essentially the same as the first, but with a second catheter (the 16F aspiration catheter) and a 16F controller handle (controls in orange). Brown Dec. ¶¶151-54. As can be seen in the images below and in Element 1[a][i] above, the second 16F catheter is used in a telescoping configuration where the 16F catheter is advanced through the first 24F catheter and a patient's vasculature until the distal end is positioned

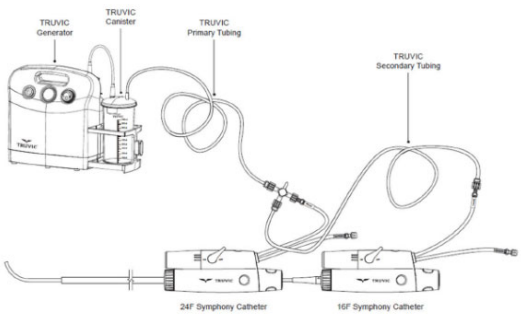
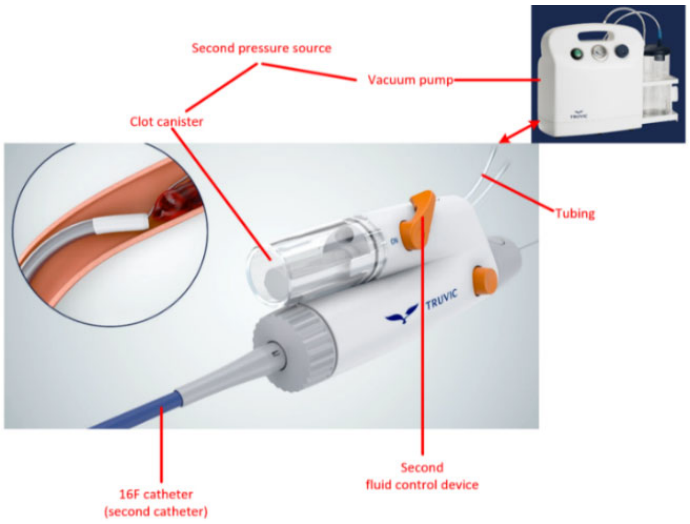


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

proximate to the clot material, *e.g.*, at the PE. *Id.* This telescoping configuration is specifically taught in the above Symphony brochure and Instructions for Use, as well. Ex. 7 at 4; Ex. 8 at 8.

vii. Elements 1[e][i]: "a second pressure source; and" 1[e][ii]: "a second fluid control device between the second catheter and the second pressure source, wherein the second fluid control device is movable between (a) a first position in which the second pressure source is fluidly disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter,

As with the first pressure source, Truvic's system has a second pressure source: the Truvic Generator electric vacuum pump and the clot canister on the 16F controller handle (shown right). Brown Dec. ¶¶155-63. The second fluid control device, specifically the Dual-Action Vacuum Control operated by the orange lever, functions the same as the blue lever that operates the first fluid control device (*see* Element 1[a][iii]). *Id.*



viii. Element 1[f]: "wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the first position, and wherein, upon movement of the second fluid control device from the first position to the second position, the vacuum pressure is applied to the second catheter to generate suction at the distal portion of the second catheter to aspirate blood and at least a portion of the pulmonary embolism into the second catheter."

As Mr. Brown describes, the Symphony system meets this limitation. Brown Dec. ¶¶164-70. Truvic's Instructions For Use regarding the telescoping configurations teach to set the Dual Action Vacuum Controls to the "off" position on both the 16F and 24F handles, to allow the vacuum pressure to build to -20 inHg (20 inches of mercury or ~68,000 Pascals) or greater, to confirm the stored pressure and the positioning of the 16F aspiration catheter's distal end, and only then to rotate the Dual Action Vacuum Control on the 16F handle to the "on" position to apply aspiration at the distal tip of the 16F second catheter. Ex. 8 at 8.

In short, there can be no legitimate dispute that Truvic's Symphony system practices all

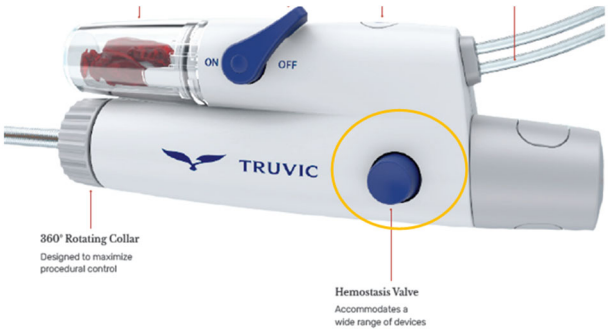
elements of Claim 1 of the '910 Patent, as described here and in Mr. Brown's Declaration.

c. Truvic Also Infringes Claims 1 and 10 Of The '921 Patent

Dependent Claim 10 depends from and incorporates all elements of independent Claim 1.

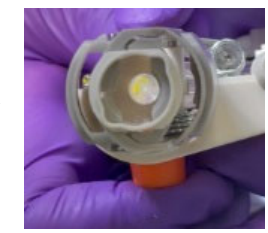
i. Preamble [1]: "A valve, comprising:"

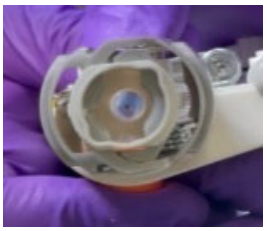
As Mr. Brown and his attached chart explain, the Truvic Symphony system includes hemostasis valves in each of the 16F and 24F Symphony controller handles, to the extent that the preamble to Claim 1 is deemed limiting. Brown Dec. ¶¶175-77; Ex. 7 at 6 (circle added to highlight hemostasis valve, right).

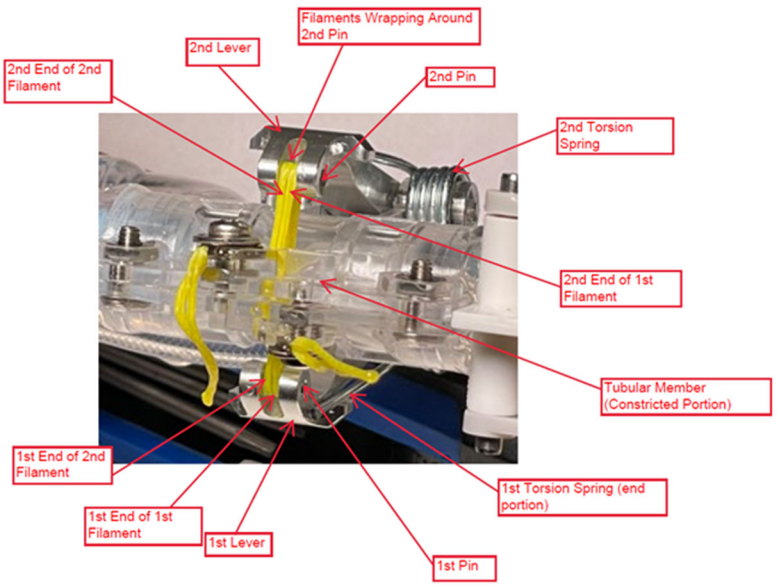


ii. Element 1[a]: "an elongate member defining a lumen;"

The hemostasis valves in Truvic's 16F and 24F controller handles are garrote hemostasis valves with an elongate (tubular) member defining a lumen in the inner central area of the elongate (tubular) member. Brown. Dec. ¶¶178-80. Images of a Symphony handle teardown (above) show the elongate member of the hemostasis valve in the open (buttons depressed, above right) and constricted (buttons un-depressed, above left) positions. *See* Al-Salam Dec. ¶36 (teardown authentication). An annotated teardown image of the Symphony controller handle below further shows the hemostasis valve, including the elongate (tubular) member (shown right).

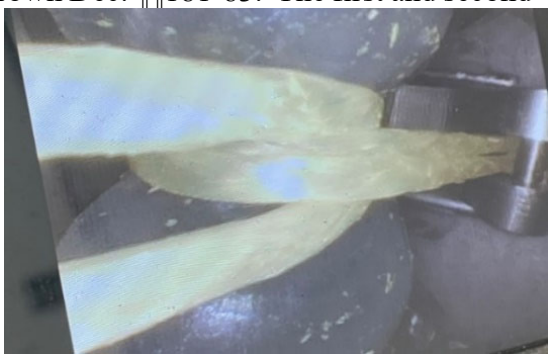






iii. Element 1[b][i]: "an active tensioning mechanism including an actuator coupled to the elongate member via a filament extending at least partially around the elongate member,"

The hemostasis valve of the Symphony system has an active tensioning mechanism including a first actuator (a first lever and first pin (labeled above), and first button that pushes against the first lever) and a second actuator (a second lever and second pin (labeled above), and second button that pushes against the second lever). Brown Dec. ¶¶181-83. The first and second actuators of the hemostasis valve are coupled to the elongate member via first and second yellow filaments that extend (loop) around the elongate member (teardown image, right, is zoomed in on the filaments wrapped around the elongate member).



iv. Element 1[b][ii]: "wherein the actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and

Truvic's hemostasis valve has a first actuator (a first lever, first pin, and first button that pushes against the first lever) and a second actuator (a second lever, second pin, and second button that pushes against the second lever) that are moveable between a first position (un-depressed button, the lumen constricted) to a second position (depressed button, the lumen at least partially open). Brown Dec. ¶¶181-83. Releasing (un-depressing) the first (or second) button returns the first (or second) actuator to the first position. *Id.*

v. Element 1[c]: "a biasing member configured to bias the actuator to the first position."

As can be seen in the annotated teardown image above (Element 1[a]), the active tensioning member has two biasing members: specifically, first torsion spring(s) and second torsion spring(s) (two for each of the first lever and second levers). Brown Dec. ¶¶184-85. The first torsion spring(s) push against the first actuator (specifically, the first lever), and the second torsion spring(s) push against the second actuator (specifically, the second lever); the torsion springs push the levers outward (to the buttons' undepressed position), tensioning the yellow filaments and constricting the elongate member. *Id.* The springs bias the actuators to the first

(undepressed, valve constricted) position until the buttons are pushed inward with enough force to move the actuator to the second position (button depressed). *Id.*

vi. Element 10[pre]: "The valve of claim 1 wherein the actuator is a first actuator, wherein the filament is a first filament, wherein the biasing member is a first biasing member, and wherein the active tensioning mechanism further comprises:"

Truvic's hemostasis valves in the controller handles meet this limitation. *See* Claim 1.

vii. Element 10[a][i]: "a second actuator coupled to the elongate member via a second filament extending at least partially around the elongate member,"

Truvic's hemostasis valves in its 16F/24F handles have a first actuator (a first lever and first pin, labeled above, and first button that pushes against the first lever) and a second actuator (a second lever and second pin, labeled above, and second butto§n that pushes against the second lever) coupled to the elongate member via first and second filaments. *See* Element 1[b][i].

viii. Element 10[a][ii]: "wherein the second actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and"

As set forth above for Element 1[b][ii], the hemostasis valves in the 16F and 24F handles of the Symphony system have a second actuator that is moveable between a first position (button un-depressed button, the lumen constricted) and a second position (depressed button, the lumen at least partially open). The second actuator and the first actuator are moved from the first position (wherein the lumen is constricted) to the second position (wherein the lumen is at least partially open) by pressing the first button and the second button and are moved from the second position to the first by releasing the buttons.

ix. Element 10[b]: "a second biasing member configured to bias the second actuator to the first position."

Truvic's hemostasis valves have a second biasing member, a second torsion spring(s) that push against the second lever of the second actuator to bias the second actuator to the first (un-depressed position, the lumen constricted). *See* Element 1[c].

2. Truvic Cannot Raise A Substantial Question On Validity

When Inari gave Truvic notice of many of its patents in September of 2023, Truvic's response (sent four months later) did not even attempt to argue noninfringement for most of

Inari's patents. Instead, Truvic focused on arguments that Inari's patents are supposedly invalid based on prior art. Ex. 25. Moreover, as mentioned above, Truvic recently filed an IPR petition challenging the validity of a patent related to the '921 patent, relying on the same references (plus one more, Eller) that Truvic had previously identified in its letter to Truvic. Inari thus expects that Truvic will concentrate its opposition to this motion on such arguments.

In litigation, the burden is ordinarily on the accused infringer to prove invalidity by clear and convincing evidence, and patents are presumed to be valid. *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir., 2009). For preliminary injunction motions, however, there is a greater burden on the patentee, who should come forward with affirmative evidence of validity. *Id.* at 1376-77. But the accused infringer must show a "substantial question" as to validity—meaning that it must show that it is "more likely than not" that it will prevail on its invalidity challenge—to defeat the first preliminary injunction factor. *Id.* at 1377, 1380; *see also Natera, Inc. v. Neogenomics Labs., Inc.*, No. 2024-1324, 2024 WL 3381916 (Fed. Cir. July 12, 2024) (affirming grant of preliminary injunction; clarifying burdens for validity).

Inari welcomes the increased burden because of the strength of its patent claims and the ingenuity of its inventors. Indeed, to eliminate any validity questions, Inari has already taken the prior art patents cited in Truvic's January letter (the "Garrison I" reference, for the '910 Patent) to the Patent Office to confirm that the Examiner agreed (she did) that these references do ***not*** render Inari's claims invalid. Similarly, the principal reference cited by Truvic for Inari's hemostasis valve patents (the "Hartley" reference) was specifically considered by the Examiner during prosecution, and she determined that it did not anticipate or render the '921 Patent obvious. Additional references recently cited by Truvic (*see* Exs. 25, 28), such as Schaffer (Ex. 32) and Eller (Ex. 33), also considered by the Examiner, likewise do not solve Truvic's problem.

The Examiner allowed Inari's claims for good reason. The prior art, including the art relied on by Truvic, relates to far different systems than in the asserted claims. As detailed in Section II.C above, Inari's innovations solved problems that are far more complicated than simply "sizing up" systems such as Garrison I from arterial thrombectomy devices or making insignificant tweaks to existing hemostasis valve designs. Instead, the Inari patents in this

motion (along with others in the FAC that focus on other aspects of thrombectomy devices) solved important and challenging problems to the (often life-saving) benefit of patients suffering from VTE clots who otherwise would have only limited and less effective treatment options.

Garrison I, and other references like it that Truvic might cite, disclose thrombectomy systems for neurovascular applications (i.e., for small arteries in the brain) that focus on treating acute ischemic stroke. Brown Dec. ¶¶207-17. But, as discussed above, this is significantly different than Inari's claimed purpose-built system for treating VTE because of the different challenges posed and techniques required to treat complex clots in large pulmonary arteries, including due to blood vessel size; blood loss concerns; clot size, age, and geometry; and clot location. Thus, as the Examiner specifically determined during prosecution, it is not (and would not have been in 2018) obvious to modify Garrison I's system to treat PE in far larger pulmonary vasculature because of the dangers and differences such a shift requires. *Id.*; Ex. 5. The '910 Patent demands a 16F or greater second catheter and an even larger first catheter that the second catheter telescopes through, in stark contrast to the much smaller 6F and 8F sheaths in Garrison I. Brown Dec. ¶208-16. Additionally, Garrison I does not disclose or render obvious the telescoping configuration recited by the claims, which the Examiner also cited as reasons the pending claims of the '910 Patent were not anticipated or obvious. *Id.*; Ex. 4.

Likewise, for the '921 Patent, Hartley (and Schaffer and Eller) disclose hemostasis valves that have far different structures than those in Claim 10 of the '921 Patent. Brown Dec. ¶¶221-30. None of these references, by themselves, anticipates. Hartley discloses a rotational actuator hemostasis valve that is inactive, meaning that it is not actively biased to a closed position; instead, it can retain its position at multiple intermediate levels of constriction, meaning that it is not necessarily fully open or closed. *Id.* Eller also discloses a single rotational actuator. *Id.* Hartley also discloses a single actuator, not two or more, as Claim 10 requires. *Id.*; Exs. 2, 31. Schaffer, for its part, discloses a valve with rigid u-shaped plastic or aluminum members, rather than a flexible filament to constrict the valve. Brown Dec. ¶221-30. These are important distinctions: An active valve biased to a closed position, such as Inari claims in the '910 Patent and uses in its products, helps to quickly and easily seal the valve when it should not be open,

thus reducing blood loss, and a non-flexible "filament" would not work. *Id.*

The combination of Hartley and Schaffer, or Hartley and Eller, fares no better than these references do individually. *Id.* A person of skill in the art would not have modified Hartley's valve to add a biasing member to bias the valve to a first (closed) position, as in Schaffer, because doing so would require overriding the ball/recess structure in Hartley and would remove the ability for the valve to retain intermediate positions. *Id.* Hartley and Schaffer disclose very different structures, with Schaffer disclosing rigid u-shaped constricting members that pinch, rather than circumferentially constrict, the valve's lumen, unlike the filament constricting member in Hartley. And these are both different from the active circumferential constriction provided by Inari's '921 filaments, which help to better seal the valve, reducing blood loss compared to Truvic's cited art. *See id.* (describing assembly that requires deconstruction without continued engagement filaments provide). Indeed, Schaffer teaches using rigid U-shaped constricting member rather than using flexible filaments, meaning that there is no motivation to combine Schaffer with any reference that uses a flexible filament. *Id.* (using flexible filaments is contrary to Schaffer because device would open with the filament still engaged around the containment structure outside the elastomer member); Ex. 32 at ¶83. Hartley and Eller, likewise, fail to disclose (individually or together) having multiple actuators and/or multiple biasing members. Brown Dec. ¶¶221-30.

Additionally, in evaluating obviousness, the law permits courts to consider "secondary indicia of nonobviousness," such as commercial success, long-felt but unsolved needs, skepticism by experts, praise by others, unexpected results, and copying. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012). In short, a court can look at real-world conditions and market reactions as evidence that innovations ***are*** improvements.

Here, secondary indicia of nonobviousness strongly support that both Inari's aspiration-based thrombectomy devices as a whole and its hemostasis valve design specifically are valid—i.e., that they are novel and nonobvious. If it had been so simple and obvious to treat patients with PE and DVT through the types of award-winning aspiration-mechanical thrombectomy

devices at issue here, then someone would surely would have done so sooner, and with less effort than Inari has had to invest into solving these problems (not to mention that Truvic would not have needed to copy Inari had it had been easy to come up with solutions). *See* §II.C, *supra*. Given the pervasiveness of VTE and its associated mortality risks, one would think that public health concerns (i.e., long-felt need), if nothing else, would have driven the solution on which Inari has landed. Instead, more than five decades have passed with little to no improvement in patient mortality rates before Inari's devices. Brown Dec. ¶205; Hykes Dec. ¶5. Not only that, if Inari's solution had been so easy and straightforward, medical professionals—and the associations that write the guidelines—would not be so skeptical about adopting Inari's approach. *See* § II.C, *supra*. Indeed, much of the market continues to rely on more expensive and less effective lytics precisely because of that skepticism of Inari's solution. *Id.* ¶16; Brown Dec. ¶¶39-47. All of these and other secondary indicia of nonobviousness support that Inari's asserted patents are valid.

In short, Inari has made a strong showing of likelihood of success on the merits (i.e., infringement and validity), and the first preliminary injunction factor weighs heavily in its favor.

B. Inari Will Be Irreparably Harmed If Truvic Is Not Enjoined

A patentee suffers harm when it is "forced to compete against products that incorporate and infringe its own patented inventions." *See Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344-45 (Fed. Cir. 2013). Critically important here, "[t]he purpose of an injunction is not to remedy irreparable harm that has already occurred (plainly, it could not), but ***to prevent that harm from occurring in the first place***." *Illumina, Inc. v. Qiagen, N.V.*, 207 F. Supp. 3d 1081, 1094 (N.D. Cal. 2016) (emphasis added). Inari seeks a preliminary injunction for exactly that reason.

There can be no serious question that Inari will suffer irreparable harm if Truvic is not enjoined. [redacted] It does so by targeting Inari's

customers specifically with devices that are similar to Inari's, but cheaper. *Id.* These similarities, notably, exist for features that drive the demand for Truvic's products, such as its unique and more effective hemostasis value and the combination of system-level components claimed in its patents. Merritt Dec. ¶46; *see also Natera*, 2024 WL 3381916, at *7 (affirming preliminary injunction where patented feature drove demand).

If allowed to proceed, particularly once Truvic obtains its FDA clearance for PE in early 2025, [redacted]. Strange Dec. ¶14. This is true even if the market for thrombectomy devices continues to grow overall as a result of Inari's efforts to convert more doctors from other treatments. [redacted] *See Douglas Dynamics*, 717 F.3d at 1345 ("Douglas's reputation would be damaged if its dealers and distributors believed it did not enforce its intellectual property rights.").

Although Inari has attempted to estimate the amount of lost revenues to Truvic over the coming years, those estimates are based on conservative assumptions that may not prove to be correct. Strange Dec. ¶14. Moreover, even if those estimates were exactly right, many of Inari's harms from those lost revenues are impossible to quantify. That difficulty in quantifying damages further supports an injunction. *See Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) (irreparable harm inquiry attempts to measure the type of harm "that no damages payment, however great, could address"; "There is no effective way to measure the

loss of sales or potential growth.").

This Court need not sort out all of these complicated issues to find that Inari has shown irreparable harm. Another court in this District has already found that the loss of some portion of a growing market to be a basis to grant a preliminary injunction in a similar like that here:

> The market for DNA sequencing in clinical laboratories is expected to grow substantially in the near future, and [defendant] has a foothold in that market …. Now, as the doors to the market have swung open, [defendant] seeks to usurp [patentee's] position in that market with pirated technology.… ***At this crucial inflection point in the development of the market …, [patentee] would suffer irreparable harm if [defendant] were allowed to capture and define the market with pirated technology alongside its preexisting relationships and disruptive business model***.

Illumina, 207 F.Supp.3d at 1093 (emphasis added); *see also Douglas Dynamics*, 717 F.3d at 1344-45 (reversing denial of preliminary injunction; "[T]he fact that Douglas's market share increased 1% a year after Buyers introduced its infringing snowplow is … immaterial. The record shows that Douglas dedicates significant amounts of time and money towards marketing and sales, engineering, and research and development. Over the years, it has earned itself a reputation in the marketplace as an innovator and trusted supplier of quality snowplows."); *Celsis*, 664 F.3d at 930 (affirming finding of irreparable harm in part because the patentee's products were its "flagship products" and were "in their growth phase and will soon be entering the mature phase with the highest revenues and strongest market position"). Further, as in *Illumina*, the market for VTE thrombectomy devices here is at a "crucial inflection point" and, just like in that case, it would not be right here to allow Truvic "to capture and define the market with pirated technology." *Illumina*, 207 F. Supp. 3d at 1093.

Many of the other types of irreparable harm that the Federal Circuit has traditionally found support a preliminary injunction are also unquestionably present here, including the potential for price erosion, damage to customer relationships, loss of customer goodwill, and loss of business opportunities. *E.g.*, *Celsis*, 664 F.3d at 930; *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1063; (Fed. Cir. 2010); *Abbot Labs.*, 544 F.3d at 1361-62 ("[L]oss of revenue, goodwill, and research and development support constitute irreparable harm."). This authority, too, mandates relief for Inari. Indeed, when a Court in this District applied these and other

similar authorities in a medical device case involving facts directly analogous to those here, it granted an injunction:

> It is undisputed that Hologic took market share away… Hologic's marketing strategy, in part, was to take away physicians using Essure because they were already trained in hysteroscopy ... This strategy siphoned off Conceptus's prior investments in creating the market for transcervical hysteroscopic sterilization. Prior to Adiana's launch, Essure was the only FDA-approved product in the market. But since Adiana's launch, Conceptus has had to compete. This led to loss of market share, loss of customers, and loss of access to potential customers. This is indicative of irreparable harm.

Conceptus, Inc. v. Hologic, Inc., No. 09-cv-2280, 2012 WL 44064, at *2 (N.D. Cal. Jan. 9, 2012). Those principles apply identically here.

In short, the evidence is strong that it will be irreparable, particularly in the PE space. The second factor weighs in Inari's favor.

C. The Balance Of The Hardships Favors Inari

In deciding whether to grant a preliminary injunction, the court must balance the hardships of the parties. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988). Undeniably, Truvic will be harmed from an injunction. It wants to continue its entry into the market, and its inability to do so might force Truvic out of the VTE thrombectomy business, at least in the short term. But the Federal Circuit long ago determined that even an injunction that might put an alleged infringer out of business—something far more severe than here, where Imperative Care has multiple other product lines—"cannot justify denial of that injunction." *Windsurfing Int'l Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986).

Moreover, Inari's harm here is greater and of a different type than Truvic's for multiple reasons. First, Truvic is now owned by Imperative Care, which has a diversified portfolio of products. Imperative Care and Truvic are not wholly dependent on Symphony, whereas Inari's company and mission are inseparable from its VTE products.

Second, Truvic's newness in VTE thrombectomy mitigates in Inari's favor. Inari has been dedicatedly working for many years to build a market for its products and turn the corner. Truvic, by contrast, is a relative newcomer to the scene and has fewer years invested to lose.

Third, courts regularly find that a potential infringer's interest in entering a market pending a patent lawsuit does not outweigh the plaintiff's interest in its patents. *See Abbott Labs.*, 544 F.3d at 1362-63; *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005). This is so even where, as here, a new entrant to a market could benefit the public by bringing medically important products to market. *Illumina, Inc. v. BGI Genomics Co.*, No. 19-cv-3770, 2020 WL 3186921, at *11 (N.D. Cal. June 15, 2020).

Fourth, Truvic's slow launch of the Symphony system belies any claim that there is urgency to its own need to be on the market immediately, before this suit can be resolved.

Inari submits that this factor weighs in its favor. Even if that were not true, however, and if the Court found the harms to be equal, this factor still favors Inari: ties on this factor go to the patentee. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1458 (Fed. Cir. 1988).

D. The Public Interest Is Served With A Preliminary Injunction Here

"[T]he public is best served by enforcing patents that are likely valid and infringed." *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006)); *see also Abbott*, 544 F.3d at 1362 (where court finds "a substantial likelihood that the [patent] is valid and enforceable, there can be no serious argument that public interest is not best served by enforcing it") (internal citation and quotation marks omitted).

This general principle is particularly true—and important—when medical devices are concerned. The Federal Circuit has specifically recognized the importance of protecting patent rights in the medical field because this "provides incentive to the innovative drug companies to continue costly development efforts." *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006). Thus, for instance, another court in this District has found that the public interest weighs in favor of granting an injunction in a medical device case. *LifeScan, Inc. v. Shasta Techs., LLC*, 933 F. Supp. 2d 1243, 1263 (N.D. Cal. 2013) (reversed on other grounds in *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361 (Fed. Cir. 2013)).

[redacted] to create the market it now serves, and it did so relying on the patent system to protect it and allow it to make a profit. Hykes Dec. ¶17. Allowing Truvic to copy Inari's inventions will "have the effect of

inhibiting innovation and incentive." *Douglas Dynamics*, 717 F.3d at 1346. This is particularly true because Truvic is poaching sales from Inari rather than growing the pie.

Inari stands ready and willing to supply an increased capacity of its systems to meet an expanding market demand, and Inari's systems are already cheaper than conventional lytics treatments. Hykes Dec. ¶32; *see also Natera*, 2024 WL 3381916, at *8 (public interest weighed in patentee's favor where infringing product treated same conditions and patentee could meet full patient demand). The public, moreover, still has the option to use all of the conventional treatments for embolisms that existed before Inari made its breakthroughs; indeed, those are still—for better or worse—what is recommended by the leading medical associations. In the circumstances, it is difficult to see how the public is disadvantaged by not having Truvic's copycat systems available. No patients will be harmed by an injunction here. *Id.* (customer preference should not play significant role in public interest analysis when choice is between patented and infringing products). Instead, the "detrimental effect" of inhibiting innovation like Inari's, paired with the "public's general interest in the judicial protection of … rights in inventive technology" outweighs any public interest public in cheaper infringing products. *Douglas*, 717 F.3d at 1346.

The fourth factor for a preliminary injunction thus favors Inari.

IV. CONCLUSION

For the reasons above, Inari respectfully requests that the Court grant its motion for a preliminary injunction and enjoin Truvic from further infringement of the '921 and '910 Patents.

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