United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

INARI MEDICAL, INC., Plaintiff, v. IMPERATIVE CARE, INC., et al., Defendants.	Case No. 24-cv-03117-EKL **ORDER DENYING MOTION FOR PRELIMINARY INJUNCTION** Re: Dkt. No. 83

This patent infringement action relates to medical devices used to treat blot clots in patients. Plaintiff Inari Medical, Inc. ("Inari") seeks a preliminary injunction that would require its competitor, Defendant Imperative Care, Inc. ("Imperative Care"), to stop making, using, and selling its devices in the United States. The Court reviewed the parties' briefs, the relevant authority, and the complete record, and heard argument on Inari's motion. The Court also requested and reviewed supplemental briefing on developments in the parallel *inter partes* review proceedings before the Patent Trial and Appeal Board ("PTAB"). For the following reasons, Inari's motion is DENIED.

I. BACKGROUND

The two patents asserted in Inari's motion relate to mechanical thrombectomy systems, *i.e.*, devices used to remove blood clots from veins. This section discusses the medical need for thrombectomy systems and then describes Inari's and Imperative Care's competing devices.

A. The Relevant Field

Inari and Imperative Care sell competing medical devices that treat venous thromboembolism ("VTE") – that is, blood clots that form in a patient's veins. "VTE is a significant public health risk and affects hundreds of thousands of patients every year in the

Imperative Care v. Inari Medical
IPR2025-00989
Imperative Care Ex. 1028

United States and millions worldwide." Merritt Decl. ¶ 6, ECF No. 23-4. When a blood clot forms in a vein, it can block blood flow, which in turn may cause serious health conditions, including strokes and heart attacks. Brown Decl. ¶ 32, ECF No. 23-5.

There are two types of VTE: deep vein thrombosis ("DVT") and pulmonary embolism ("PE"). A DVT clot forms in a patient's peripheral vasculature, usually in deep leg veins. Merritt Decl. ¶¶ 14, 27. The clot forms on a vessel wall and slowly grows inward to create a blockage. *Id.* ¶ 13. By contrast, a PE clot is "free floating" – not attached to a vessel wall – and is found in a patient's lungs. *Id.* Most commonly, "clots in PE patients are simply deep leg vein clots that have mobilized (meaning they have broken off and traveled to the lungs)." *Id.* ¶ 27.

Traditionally, DVT and PE have been treated with drugs such as anticoagulants (*i.e.*, blood thinners), which help prevent clot formation, and thrombolytics, which "break down and dissolve the clot over hours or days, but do not physically remove the clot material from the body." Brown Decl. ¶ 39. However, these drugs have limitations and disadvantages. Anticoagulants "are not effective against existing clots," and they have potential side effects, including "bleeding risk and loss of bone density." *Id.* ¶ 41. Thrombolytics "can take many hours to work," and "because the clots are not actually removed from the body, portions of the clot can break off and travel to a different location within the body rather than being eliminated entirely." *Id.* ¶ 40.

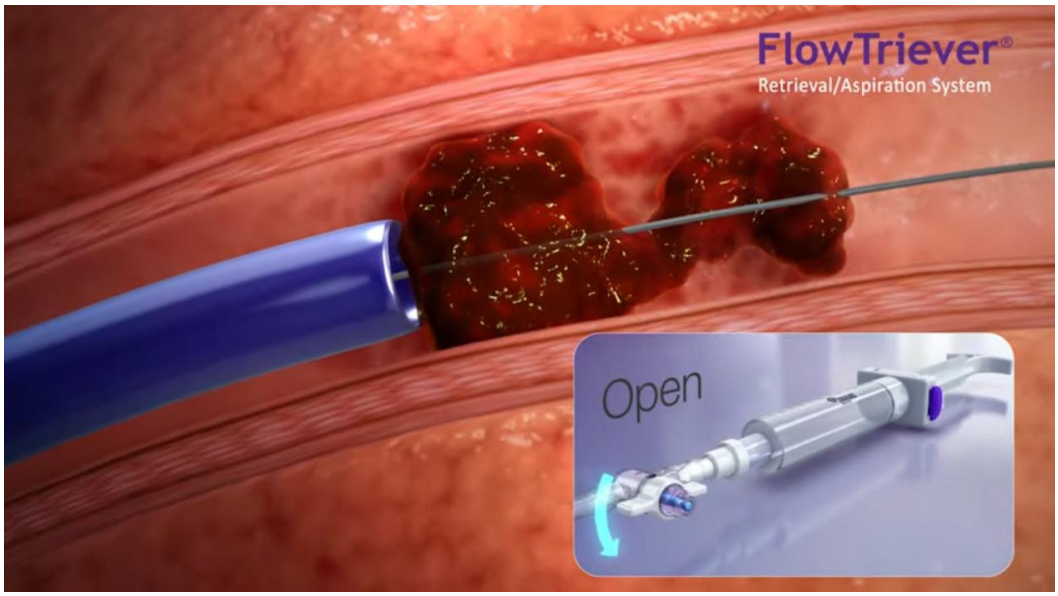
Although these traditional treatments still dominate, in recent years, thrombectomy procedures have also been used to treat DVT and PE. *Id.* ¶ 42. Thrombectomy refers to "physical removal of clotted blood . . . from the vasculature." *Id.* Here, the relevant devices are catheter-based thrombectomy systems. *Id.* ¶ 44. To use one of these devices, a doctor inserts a catheter into the patient's vasculature (*i.e.*, blood vessels) and advances the catheter until it reaches the blood clot. *Id.* ¶ 48. A doctor may use a combination of methods and tools to remove the clot, including scraping (often used for DVT clots, which are attached to vessel walls) and aspiration (*i.e.*, suction). Aspiration-based devices remove a clot by generating vacuum pressure using a pressure source to suck the clot into the catheter tip and out of the patient's vasculature. *Id.* Although "companies have long produced catheter thrombectomy systems for treating clots in smaller arteries," *id.* ¶ 44, the use of these devices for DVT and PE is a recent development.

B. Inari's Devices

Inari was founded in 2011 and focuses on "developing pioneering treatments for the removal of blood clots from veins." Hykes Decl. ¶ 4, ECF No. 23-6. Although Inari asserts many more patents in this case, for purposes of the present motion, Inari asserts that Imperative Care infringes U.S. Patent Nos. 11,844,921 ('921 Patent) and 11,974,910 ('910 Patent). The patents issued on December 19, 2023, and May 7, 2024, respectively. The relevant patent claims are discussed below. *See infra* Section III.A.

Over the years, Inari has experimented with and refined its devices based on feedback from doctors. Merritt Decl. ¶ 42; Brown Decl. ¶ 73. The Court focuses on Inari's fourth generation FlowTriever device because it incorporates the technology covered by the two patents asserted here. The FlowTriever device is a type of catheter-based thrombectomy system as described above. The following image shows the catheter of a FlowTriever device positioned next to a blood clot. The image also shows the syringe, which generates a stored vacuum. By moving the stopcock to the "open" position, the user can release the stored vacuum, which rapidly applies suction and, if successful, sucks the clot through the catheter and into the syringe. Inari refers to this deployment of suction as "WHOOSH." Merritt Decl. ¶ 34.

Image 1: Inari's FlowTriver Device with Vacuum-Generating Syringe[1]



[1] Brown Decl. ¶¶ 236-237.

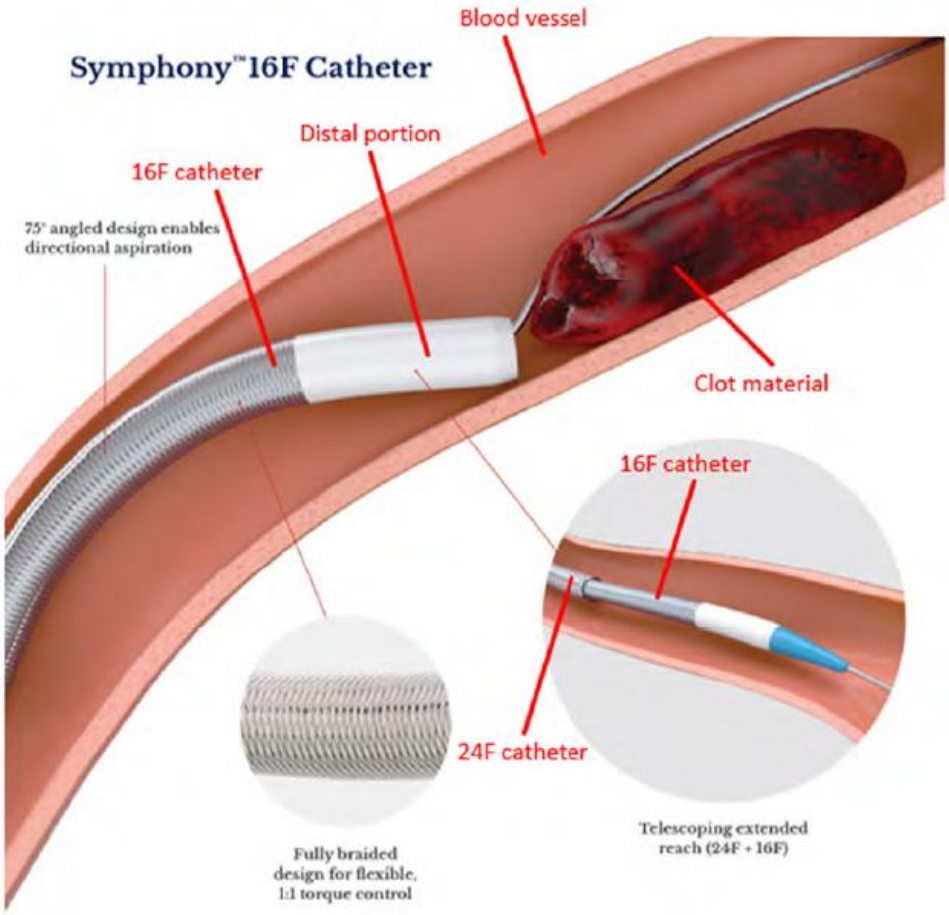
Inari explains that DVT and PE clots pose special challenges given the large size of the vessels and the location of the clot deep in a patient's vasculature. *See id.* ¶ 28. Inari claims that it developed three key innovations to address these challenges, which are relevant to its infringement claims against Imperative Care. First, Inari developed a system for "telescoping" catheters in which a smaller catheter can be advanced through a larger catheter to reach further into a patient's vasculature and to provide a second aspiration attempt. Brown Decl. ¶ 72. Second, Inari discovered that the use of 16F and 24F diameter catheters are ideal – with the 16F catheter telescoped through the larger 24F catheter.[2] Third, Inari developed an improved hemostasis valve. Among other things, a hemostasis valve prevents backflow of blood through the lumen (*i.e.*, the hollow space) of a catheter. *Id.* ¶¶ 56-57. Inari's hemostasis valve uses one or more filaments to circumferentially constrict the lumen, in a choking motion. Merritt Decl. ¶ 52 (describing how the valve forms a "garrote").

C. Imperative Care's Symphony Device

Imperative Care was founded in 2015 by a neurosurgeon who pioneered minimally invasive treatments for stroke patients. Nalbone Decl. ¶ 5, ECF No. 79. Imperative Care began developing its mechanical thrombectomy systems in late 2019 and early 2020 by investing in Truvic, which it acquired in 2021. *Id.* ¶ 8 (explaining that Truvic has now merged into Imperative Care). Imperative Care's thrombectomy system is called Symphony, and it includes multiple components, including different catheter sizes, tools, and a generator to create vacuum for suction. Scott Decl. ¶ 8, ECF No. 35-3. "Depending on the procedure and the physician's preferences, the physician may use some or all of these components to treat the patient." *Id.* The following image shows a Symphony catheter placed next to a blood clot.

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

Image 2: Symphony Catheter Removing Blood Clot[3]

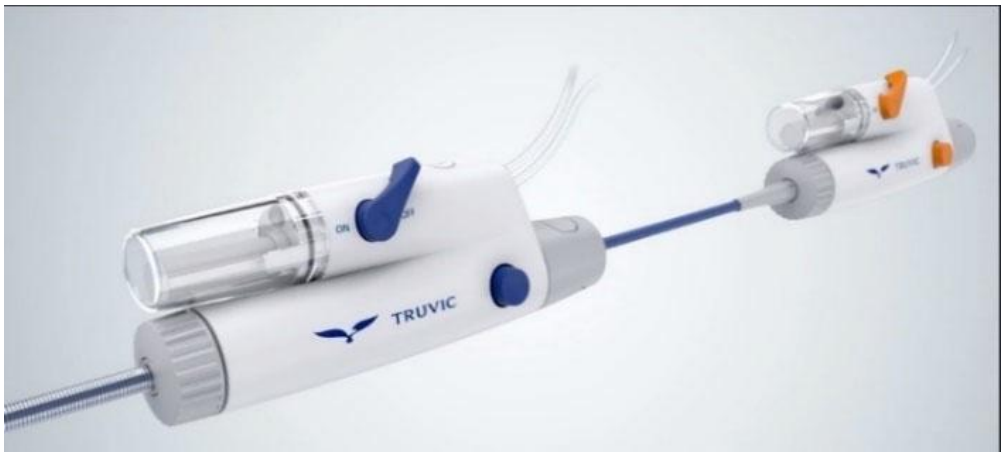


Like Inari's devices, Symphony uses aspiration to physically remove blood clots from a patient's vasculature. Unlike Inari's system, which uses a syringe that is pulled back to manually generate a stored vacuum, Symphony uses a generator to create a high-powered, on-demand, continuous vacuum. Scott Decl. ¶ 12. However, the fundamental concept is the same: The Symphony system uses suction to remove the blood clot from the patient's vasculature through a catheter. The clot material travels through the catheter to a "clot container" located in the handle of the Symphony device. The clot container is transparent and includes a filter that separates the aspirated blood from clot material. *Id.* ¶ 13. This container enables the physician to rapidly assess case progress. *Id.* The following images show these aspects of the Symphony system. Imperative Care sells 16F and 24F catheters, which can be telescoped as shown in Image 4.

[3] Brown Decl. ¶ 154.

Image 3: Diagram of the Symphony Device Handle with Vacuum Generator[4]

Image 4: Telescoping Symphony 16F and 24F Catheters[5]



In February 2023, Imperative Care obtained clearance from the U.S. Food and Drug Administration ("FDA") to sell Symphony for use in treating DVT. Nalbone Decl. ¶ 12. In August 2023, Imperative Care began selling Symphony and has sold Symphony continuously since that time. *Id.* At the time, neither of the patents asserted in this motion had issued. In October 2023, Imperative Care initiated a clinical trial to assess the safety and efficacy of the

[4] Brown Decl. ¶ 136.

[5] *Id.* ¶ 156.

Symphony system in treating PE. *Id*. On August 28, 2025, Imperative Care received FDA clearance to market Symphony for treating PE. *See* Notice of FDA Clearance at 1, ECF No. 134. Imperative Care "expects to commence a limited market release in the coming months." *Id*.

D. Inari's Request for Relief

Inari asks the Court to order that:

> Defendant Imperative Care, Inc. and its officers, agents, servants, employees, and attorneys, and any other person acting in active concert or participation with of the above, are preliminarily enjoined from making, using, selling, offering to sell, importing, marketing, or distributing its Symphony system in the United States, except to the extent that those activities relate to clinical study activity exempted from infringement liability by 35 U.S.C. § 271(e)(1).

Proposed Order, ECF No. 24-7. The practical effect of this order, if entered, would be to prevent all sales and marketing of Symphony for either DVT or PE.

II. LEGAL STANDARD

A. The *Winter* Elements

A plaintiff seeking a preliminary injunction must establish that "he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1373-74 (Fed. Cir. 2012) ("*Apple II*"). "[A] trial court need not make findings concerning the third and fourth factors if the moving party fails to establish either of the first two factors." *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 973-74 (Fed. Cir. 1996) (citation omitted); *see also Bennett v. Isagenix Int'l LLC*, 118 F.4th 1120, 1126 (9th Cir. 2024) (similar).

"A preliminary injunction is an extraordinary remedy never awarded as of right. In each case, courts 'must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief.'" *Winter*, 555 U.S. at 24 (citations omitted). The Court must also consider the scope and nature of the requested relief because "[t]he purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Lackey v. Stinnie*, 604 U.S. 192, 200 (2025) (quoting *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981)).

B. Application to Patent Infringement Cases

The parties dispute whether Inari seeks a mandatory or prohibitory injunction. "A mandatory injunction 'orders a responsible party to take action'" and "goes well beyond simply maintaining the status quo" while the litigation is pending. *Marlyn Nutraceuticals, Inc. v. Mucos Pharma GmbH Co.*, 571 F.3d 873, 878-79 (9th Cir. 2009) (citations omitted). "The inquiry is whether the party seeking the injunction seeks to alter or maintain the status quo." *Fellowship of Christian Athletes v. San Jose Unified Sch. Dist. Bd. of Educ.*, 82 F.4th 664, 684 (9th Cir. 2023). In the Ninth Circuit, mandatory injunctions are "particularly disfavored," and the movant faces a higher burden to show that "the facts and law *clearly* favor the moving party." *Id.* (first quoting *Marlyn Nutraceuticals*, 571 F.3d at 879; and then quoting *Stanley v. Univ. of S. Cal.*, 13 F.3d 1313, 1320 (9th Cir. 1994)).

Here, the pre-dispute status quo is one in which Imperative Care was selling its Symphony system – at least for DVT procedures – before Inari's two asserted patents issued. The patents had not issued in the pre-dispute status quo, thus Inari did not have a legal right to exclude Symphony from the market. *See Welker Bearing Co. v. PHD, Inc.*, 550 F.2d 1090, 1095 (Fed. Cir. 2008). Because Inari seeks to change the pre-dispute status quo by excluding Symphony from the market, Inari seeks a mandatory injunction. Inari resists this conclusion, arguing that Imperative Care's "sales are just beginning and it has not yet even been cleared to market its accused Symphony system for PE."[6] Mot. at 3, ECF No. 83. But whether Imperative Care's sales are small or large, the critical fact is that Symphony was being sold in the pre-dispute status quo, and Inari's proposed injunction would require Imperative Care to cease all sales and marketing activities. This relief is mandatory in nature.

Inari questions whether the Ninth Circuit's heightened standard for mandatory injunctions applies in patent infringement cases. Reply at 5, ECF No. 84 (arguing that "the concept of

[6] Symphony was not being sold for PE in the pre-dispute status quo because it had not yet obtained FDA clearance for such procedures. However, the same Symphony device can be used to treat both DVT and PE, so there is no question that barring all sales of Symphony would change the status quo. Inari has not identified any practical and enforceable way to tailor a potential injunction to bar sales of Symphony solely for treating PE because there is no feasible way to prevent doctors from using Symphony for PE.

'mandatory injunctions' is almost never mentioned in the dozens of preliminary injunction decisions in this District in patent cases").[7] Generally, the Federal Circuit "review[s] a grant or denial of a preliminary injunction using the law of the regional circuit" where the case originated – here, the Ninth Circuit. *Murata Mach. USA v. Daifuku Co.*, 830 F.3d 1357, 1363 (Fed. Cir. 2016) (citing *Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1165 (Fed. Cir. 2014)); *see also Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 894 (Fed. Cir. 1998) (observing that the Federal Circuit "benefit[s] from the wealth of Ninth Circuit precedent" applying the preliminary injunction standard). "However, the Federal Circuit has itself built a body of precedent applying the general preliminary injunction considerations to a large number of factually variant patent cases, and gives dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues." *Natera, Inc. v. NeoGenomics Labs., Inc.*, 106 F.4th 1369, 1375 (Fed. Cir. 2024) (quoting *Murata*, 830 F.3d at 1363).

In *Revision Military, Inc. v. Balboa Manufacturing, Co.*, the Federal Circuit limited the extent to which district courts may apply a heightened standard for issuing a preliminary injunction. 700 F.3d 524, 526 (Fed. Cir. 2012). In that case, the accused product was already on the market, thus the requested preliminary injunction would "alter the [defendant's] status." *Id.* at 525. Therefore, the district court applied the Second Circuit's requirement of a "clear and substantial likelihood of success" on the merits. The Federal Circuit reversed, holding that a heightened requirement was inconsistent with the Federal Circuit's own standard, which asks "whether success is more likely than not." *Id.* at 525-26. The Federal Circuit reasoned that, because "matters of patent infringement are unique to patent law, . . . the estimated likelihood of success in establishing infringement is governed by Federal Circuit law." *Id.* at 526. However, the Federal Circuit recognized that "the weight of the likelihood [of success] may be considered as an equitable factor, along with issues of the position of the parties with respect to the status quo, in the ultimate balance of equities." *Id.* at 526.

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[7] *But see UTTO Inc. v. Metrotech Corp.*, No. 22-cv-01904-WHO, 2022 WL 1814145, at *2 (N.D. Cal. June 2, 2022) (holding that injunction was mandatory because it would require the defendant to remove promotional materials from its website and modify its product "to remove the feature" accused of infringing).

In light of the Federal Circuit's instruction, the Court will not require Inari to make a heightened showing of its likelihood of success on its infringement claim because doing so would be inconsistent with the standard applied by the Federal Circuit.[8] *Id.* at 525-26. However, consistent with *Revision Military*, the Court will consider the mandatory nature of Inari's requested injunction when balancing the equities and considering the nature of the potential harm to Inari. *Marlyn Nutraceuticals*, 571 F.3d at 879 (holding that a mandatory injunction should not issue "unless extreme or very serious damage will result").[9]

III. DISCUSSION

Imperative Care opposes Inari's motion, arguing that Inari has failed to satisfy any of the *Winter* elements. The Court agrees. First, Imperative Care has raised a substantial question as to the validity of Inari's asserted patent claims, and therefore Inari has not shown a likelihood of success on the merits. Second, Inari has not shown that it faces a likelihood of irreparable harm in the absence of a preliminary injunction, nor that there is a causal nexus between the alleged infringement and the harm that Inari may face. Third, the balance of the hardships tips in Imperative Care's favor because Inari is unlikely to suffer irreparable harm while the case is pending, but halting all sales and marketing of Symphony would impose severe hardship on

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[8] In the Court's view, requiring a patent holder to show that the facts and the law clearly favor a mandatory injunction does not relate to a matter of patent law, and thus Ninth Circuit precedent should apply. The heightened standard for issuing a mandatory injunction does not alter the substantive legal standard for a patent infringement claim. Rather, it allows a court to weigh the strength of the movant's case *in light of* the substantive law and the evidence produced. *See Garcia v. Google, Inc.*, 786 F.3d 733, 740 (9th Cir. 2015) ("Because [plaintiff] seeks a mandatory injunction, she must establish that the law and facts clearly favor her position, not simply that she is likely to succeed."). This is an appropriate equitable consideration that seems equally applicable to patent infringement cases. *Cf. eBay Inc. v. MercExhange, L.L.C.*, 547 U.S. 388, 391 (2006) (holding that the "well-established principles of equity" apply "with equal force to disputes arising under the Patent Act").

[9] The Ninth Circuit also applies a "sliding scale" approach under which "'serious questions going to the merits' and a balance of hardships that tips sharply towards the plaintiff can support issuance of a preliminary injunction, so long as the plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the public interest." *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011). The "serious questions" standard does not apply for two reasons. First, Inari seeks a mandatory injunction. *See Doe v. Snyder*, 28 F.4th 103, 111 n.4 (9th Cir. 2022). Second, the balance of hardships does not tip sharply in Inari's favor for the reasons discussed below. *See infra* Section III.C. Additionally, to the extent the "sliding scale" approach relaxes a movant's burden to show a likelihood of infringement, it may be inconsistent with the Federal Circuit's standard as articulated by *Revision Military*.

Imperative Care. Finally, although the public interest generally favors enforcing patent rights, here, this element is neutral given the questionable validity of Inari's patent claims. Therefore, Inari has not shown that it is entitled to the extraordinary relief of a preliminary injunction – regardless of whether it seeks prohibitory or mandatory relief.

A. Likelihood of Success on the Merits

"[W]hether performed at the preliminary injunction stage or at some later stage in the course of a particular case, infringement and validity analyses must be performed on a claim-by-claim basis." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). "Therefore, in cases involving multiple patent claims, to demonstrate a likelihood of success on the merits, the patentee must demonstrate that it will likely prove infringement of one or more claims of the patents-in-suit, and that at least one of those same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer." *Id.* "In assessing whether the patentee is entitled to the injunction, the court views the matter in light of the burdens and presumptions that will inhere at trial." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009).

Here, the Court focuses on Imperative Care's invalidity challenges to Inari's asserted patents.[10] A "patent enjoys the same presumption of validity during preliminary injunction proceedings as at other stages of litigation." *Id.* at 1377. Therefore, at this stage, "the burden is on [the alleged infringer] to come forward with evidence of invalidity." *Id.* The patent holder "has the burden of responding with contrary evidence," and "must persuade the court that, . . . [it] nevertheless is likely to succeed at trial on the validity issue." *Id.* "[I]f the trial court concludes there is a 'substantial question' concerning the validity of the patent, meaning that the alleged infringer has presented an invalidity defense that the patentee has not shown lacks substantial merit, it necessarily follows that the patentee has not succeeded in showing it is likely to succeed at trial on the merits of the validity issue." *Id.* at 1378-79. "The relevant inquiry is therefore

[10] Imperative Care asserts that both patents are invalid, but argues non-infringement only with respect to the '910 Patent. Because the invalidity issues are dispositive, the Court does not reach Imperative Care's alternate position regarding non-infringement.

whether the patentee has shown it is more likely than not to prevail over an invalidity challenge." *Natera*, 106 F.4th at 1377.

Two types of validity challenges are at issue here: anticipation and obviousness. Subject matter is "'anticipated' when it is not new; that is, when it was previously known. Invalidation on this ground requires that every element and limitation of the claim was previously described in a single prior art reference, either expressly or inherently, so as to place a person of ordinary skill in possession of the invention." *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1082 (Fed. Cir. 2008). "The way in which the elements are arranged or combined in the claim must itself be disclosed, either expressly or inherently, in an anticipatory reference." *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010).

By contrast, a patent claim is invalid for obviousness "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. However, the existence of disparate pieces of prior art is not enough – the person of ordinary skill in the art must have some "motivation to combine prior art references to arrive at the claimed invention. *Natera*, 106 F.4th at 1376. The party challenging the patent's validity "must show a reason why a skilled artisan would have made the combination." *Id.*; *see also KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 417-18 (2007).

"Obviousness is a question of law with several underlying factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the field of the invention; and (4) objective considerations such as commercial success, long felt but unsolved need, and the failure of others." *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1347 (Fed. Cir. 2012). The prima facie inquiry focuses on the first three elements. *Id*. at 1348-49. "A party is also free to introduce evidence relevant to . . . objective evidence of nonobviousness, which may be sufficient to disprove or rebut a prima facie case of obviousness." *Id*. at 1349. A court must consider objective evidence of non-obviousness as part of the overall obviousness inquiry. *Id*. at 1348.

Where a movant relies on commercial success of an invention to argue that it was not obvious, the movant must show "both commercial success and that a nexus exists between that success and the merits of the claimed invention." *Id.* at 1350; *see also Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019).

1. The '921 Patent

Inari asserts independent claim 1 and dependent claim 10 of the '921 Patent, which claims a hemostasis valve. As discussed above, hemostasis valves are used to create a seal that minimizes patient blood loss and maintains a sterile environment in a patient's blood vessels. *See* Mot. at 12. Inari contends that the claimed valve was developed to solve known issues with prior art valves. "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." Mot. at 13. Inari claims that Imperative Care's Symphony system infringes because it uses 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." Mot. at 14.

Asserted claims 1 and 10 are recited below:

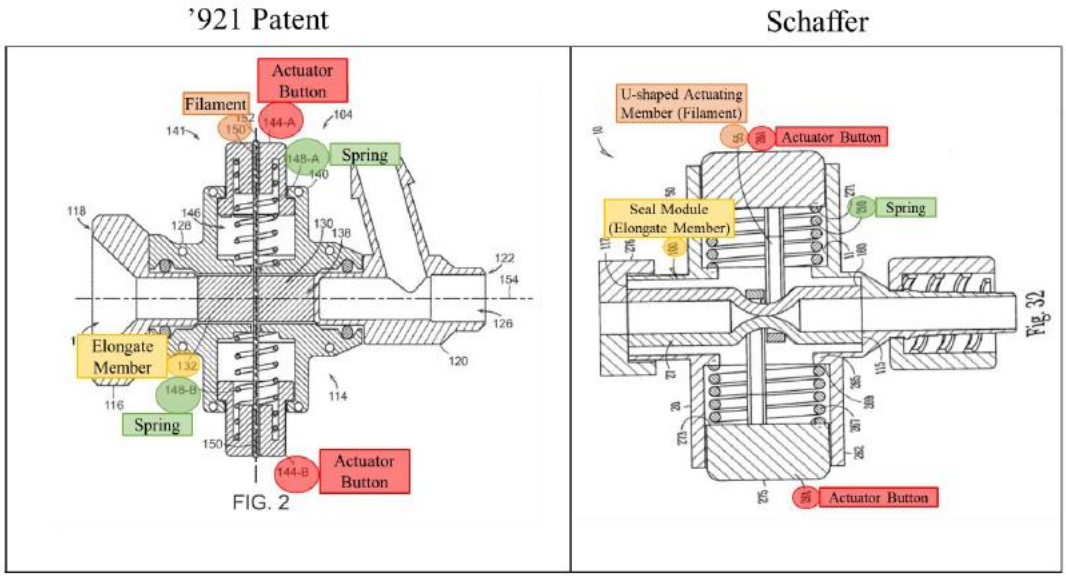
> 1. A valve, comprising:
>
> an elongate member defining a lumen;
>
> an active tensioning mechanism including an actuator coupled to the elongate member via a filament extending at least partially around the elongate member, wherein the actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and
>
> a biasing member configured to bias the actuator to the first position.
>
> [. . . .]
>
> 10. 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:
>
> a second actuator coupled to the elongate member via a second filament

> extending at least partially around the elongate member, 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
>
> a second biasing member configured to bias the second actuator to the first position.

'921 Patent at 22:12-22, 22:53-64.

Imperative Care argues that these claims are invalid because they are anticipated by, and obvious in light of, the prior art. Imperative Care argues that one prior art reference ("Schaffer") anticipates the '921 Patent claims, and the combination of Schaffer with other prior art references (especially "Hartley"), renders the claims obvious. Image 5 illustrates Imperative Care's argument that the Schaffer prior art reference has the same components, in the same arrangement, as the valve claimed by the '921 Patent. Image 6 illustrates Imperative Care's argument that combining Schaffer with the string-based constricting filament in Hartley renders the '921 Patent claims obvious.

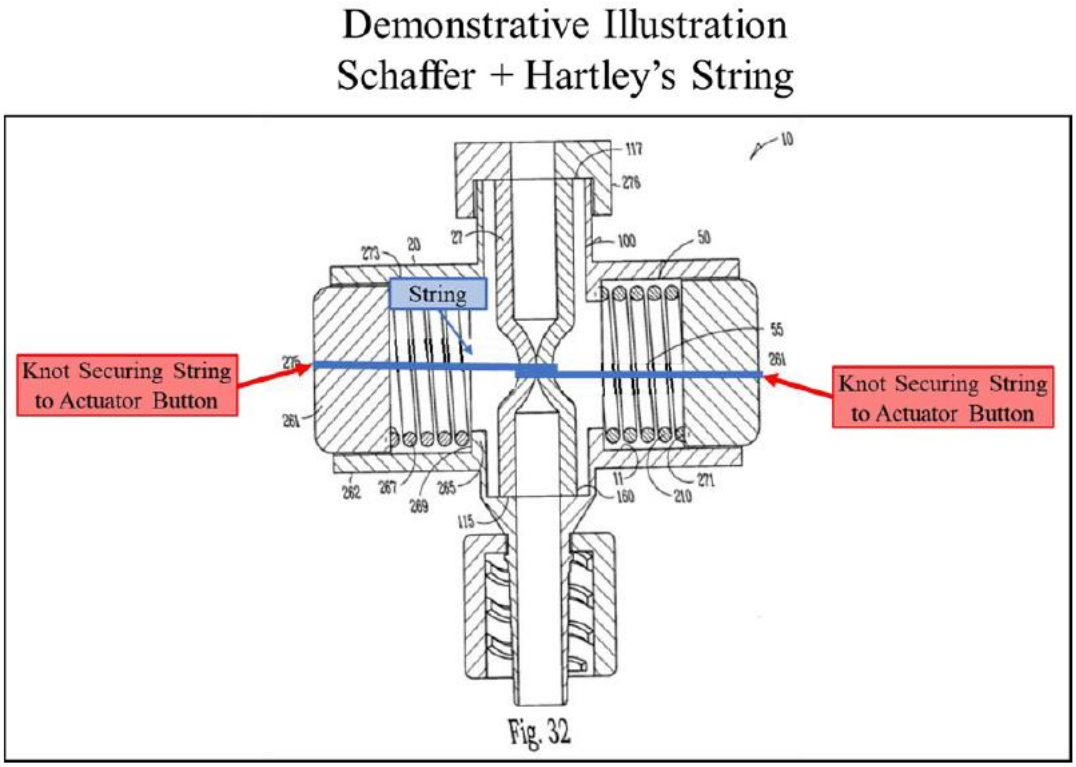
Image 5: '921 Patent Compared to Schaffer (annotated)[11]



[11] Opp. at 3, 21, ECF No. 78.

United States District Court
Northern District of California

Image 6: Proposed Combination of Schaffer and Hartley[12]



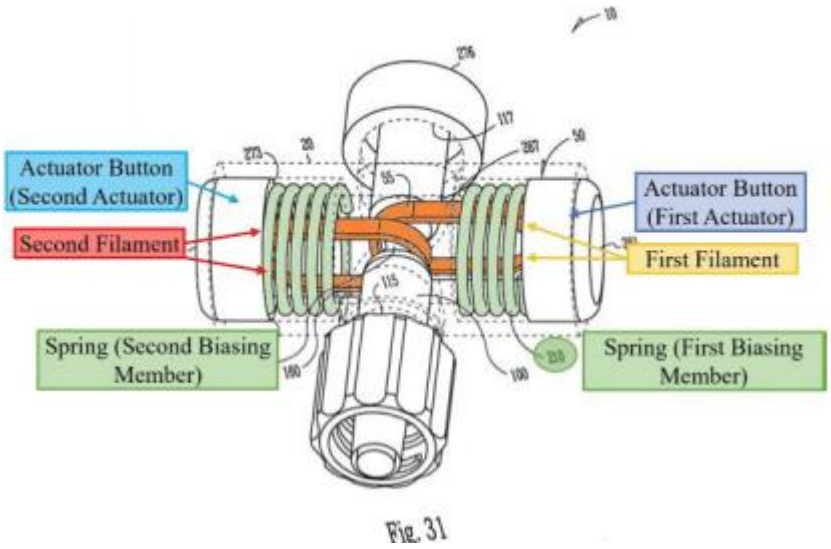
Imperative Care raised these same arguments in an *inter partes* review ("IPR") petition to the PTAB with respect to another Inari patent in the same family as the '921 Patent, and the PTAB instituted review. '011 Patent IPR Order. In instituting IPR, the PTAB concluded that Imperative Care has shown "a reasonable likelihood that it will prevail" in showing that at least one of the challenged patent claims is invalid. *Id.* at 2; *see also* 35 U.S.C. § 314(a). District courts may – and often do – consider the PTAB's rulings when determining a patent holder's likelihood of success on the merits. *See Procter & Gamble Co. v. Kraft Foods Glob. Inc.*, 549 F.3d 842, 847-48 (Fed. Cir. 2008); *see also Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prods., LLC*, 431 F. App'x 885, 889 n.3 (Fed. Cir. 2011). Many courts have found that the institution of IPR, by itself, raises a substantial question of a patent's invalidity. *Alexion Pharms., Inc. v. Samsung Bioepis Co.*, No. 24-5-GBW, 2024 WL 2111988, at *2 (D. Del. May 6, 2024); *Adidas Am., Inc. v. Skechers USA, Inc.*, No. 3:16-cv-1400-SI, 2017 WL 2604310, at *6 (D. Or. June 12, 2017)

[12] Decision Granting Institution of IPR of '011 Patent at 34, ECF No. 101-5 ("'011 Patent IPR Order").

(collecting cases). At minimum, the PTAB's ruling serves as strong circumstantial evidence that Imperative Care has raised a substantial question of validity.

The PTAB's institution decision is directly on point here. The PTAB preliminarily agreed with Imperative Care as to both the anticipation (Schaffer) and obviousness (Schaffer plus Hartley) arguments summarized above. '011 Patent IPR Order at 32-41. The PTAB concluded that Imperative Care established a "reasonable likelihood that it will prevail" on its anticipation defense, and that a person of skill in the art would be motivated to combine Schaffer and Hartley, rendering Inari's patent claim invalid for obviousness. *Id.* This analysis is persuasive for purposes of the preliminary injunction analysis because there are no relevant differences between the related patent considered by the PTAB and the '921 Patent claims asserted here. *See DNA Genotek Inc. v. Spectrum Sols. L.L.C.*, No. 16-cv-1544-JLS (NLS), 2016 WL 8738225, at *3 (S.D. Cal. Oct. 6, 2016) (holding that IPR institution on similar patent raised a substantial question of validity). Inari does not dispute the similarities between the '011 Patent claims analyzed by the PTAB and claim 1 of the '921 Patent asserted here, and acknowledges that the patents are in the same family and share a common patent application. Inari Supp. Br. at 3, ECF No. 97. Inari does argue that claim 10 of the '921 Patent is narrower than the claims analyzed by the PTAB because it requires not one but *two* actuators, filaments, and biasing structures. *Id.* at 5. This argument is not persuasive because Schaffer alone discloses these elements too, as shown below:

Image 7: Schaffer Figure 31 (annotated)[13]



Accordingly, the Court finds that Imperative Care has raised a substantial question of validity as to the asserted '921 Patent claims. The Court's conclusion rests on both the PTAB's analysis and the Court's own review of the arguments raised before the PTAB and in Inari's motion. Either the anticipation or obviousness challenge alone is sufficient to preclude Inari from showing a likelihood of success. Therefore, Inari has not shown a likelihood of success as to claims 1 and 10 of the '921 Patent.

2. The '910 Patent

The Court turns to Imperative Care's invalidity arguments with respect to asserted claim 1 of the '910 Patent. The '910 patent claims an aspiration system for intravascular removal of clot material for treating PE. Asserted claim 1 is recited below, with key limitations underlined for emphasis:

[13] Imperative Care Supp. Br. at 5, ECF No. 89.

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

a first clot aspiration assembly, including:

a first catheter;

a first pressure source; and

a first fluid control device between the first catheter and the first pressure source,

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,

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

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;

a second pressure source; and

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,

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.

’910 Patent at 35:52-36:34. Image 8 below illustrates the telescoping catheters:

Image 8: '910 Patent Figure 11 (annotated)[14]

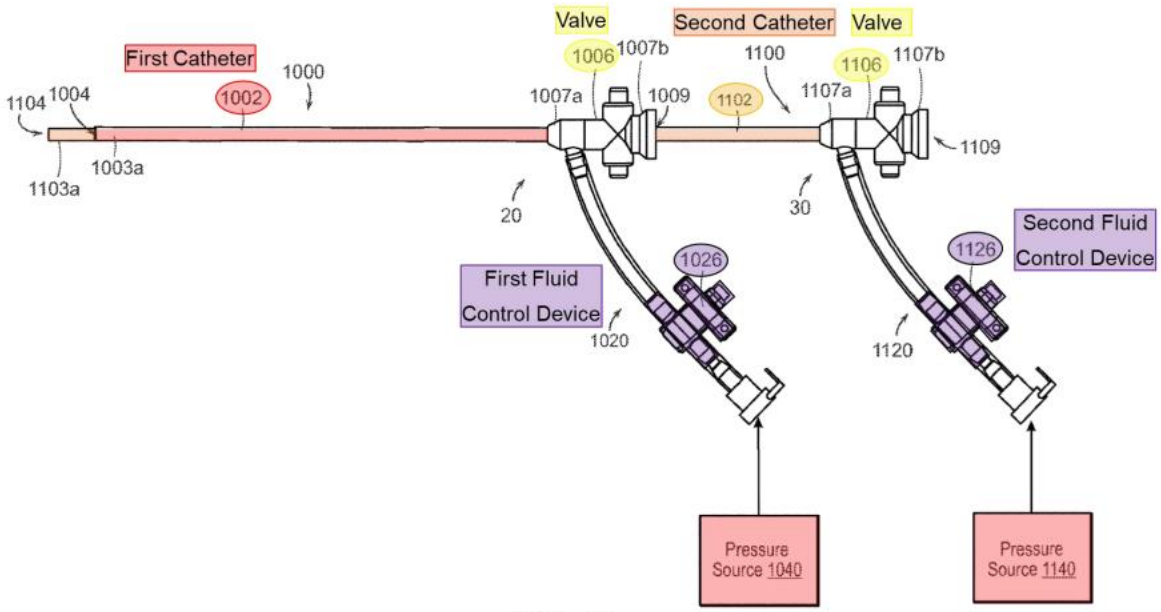


FIG. 11

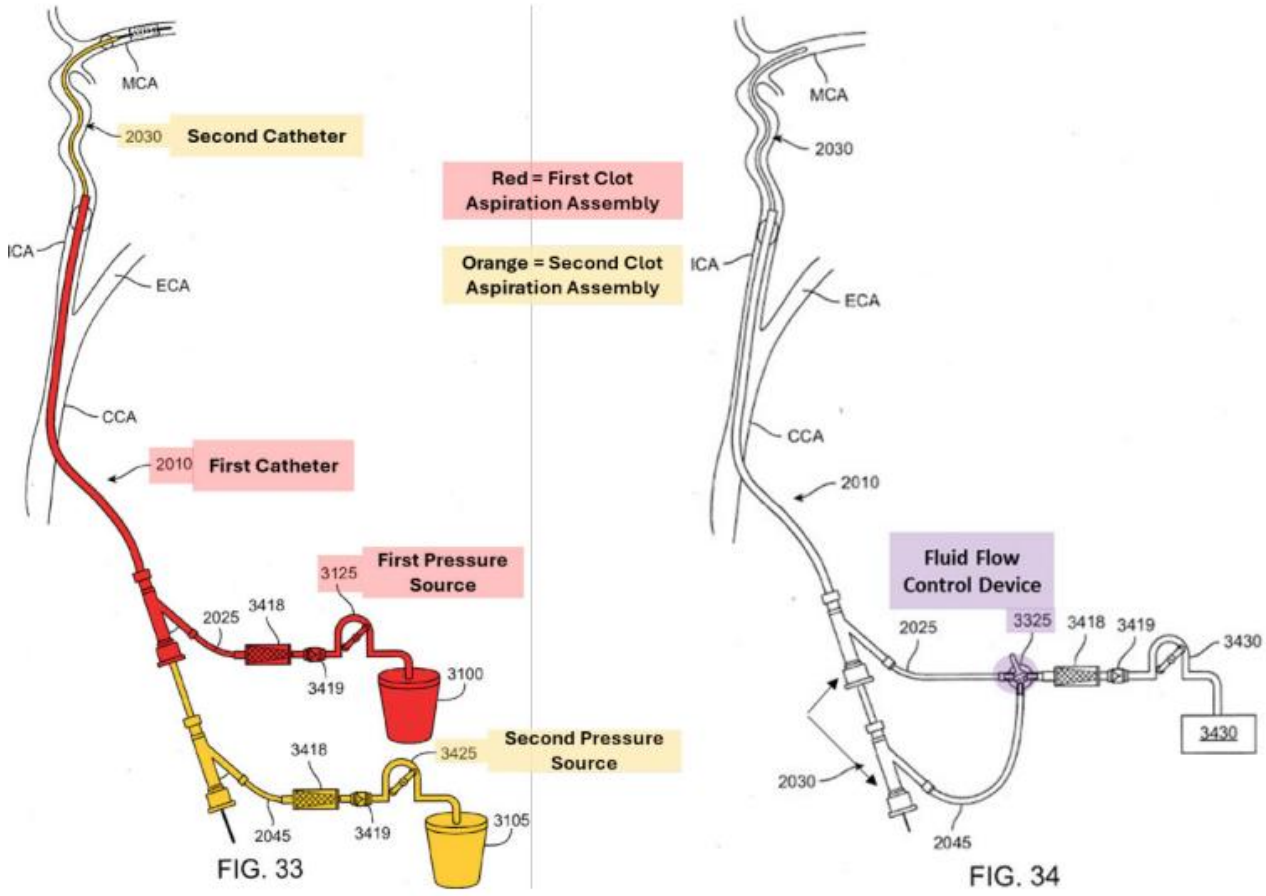
Imperative Care's invalidity arguments as to the '910 Patent focus on the combination of two prior art references: Garrison and Laub.[15] During prosecution of the '910 Patent, the Patent Examiner considered Garrison, but Laub was not presented. Garrison discloses a system to aspirate blood clots from a patient's vasculature – specifically, cerebral occlusions. The Patent Examiner concluded that Garrison discloses many of the limitations of claim 1 of the '910 Patent. *See* Brown Dep. Tr. 93:12-101:3, ECF No. 85-4 (Inari's expert agreeing with these conclusions). However, the Patent Examiner concluded that Garrison did not teach telescoping of larger and smaller catheters, nor did it teach two claim limitations that Inari added during prosecution. Brown Decl. ¶¶ 102-104. Specifically, Garrison did not disclose a system "for treating clot material comprising a pulmonary embolism" or that the second (smaller) catheter "has a size of 16 French or greater." *Id*. A diagram illustrating the Garrison aspiration system is shown below in Image 9.

[14] *See* Brown Decl. ¶ 96.

[15] Imperative Care has raised these same arguments in an IPR petition before the PTAB, and that petition is pending.

United States District Court
Northern District of California

Image 9: Garrison Figures 33 and 34 (annotated)[16]



Imperative Care persuasively argues that Garrison does, in fact, disclose telescoping catheters,[17] and that Laub supplies the two missing limitations from Garrison – that is, the use of the system for PE, and the use of a catheter sized 16F or larger. Laub, like Garrison, discloses a system for removing blood clots, but unlike Garrison, it specifically discloses that the system may be used "to remove clots from patients suffering from or at risk of pulmonary embolism." Opp. Ex. 1021 ¶ 5, ECF No. 36-16. Laub also specifically discloses the use of catheters with a "French size of at least 16." *Id.* ¶ 28.

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[16] Opp. at 15.

[17] *See* Garrison, Opp. Ex. 29 ¶ 54, ECF No. 24-36 ("A second, smaller diameter catheter may be inserted through the first catheter or exchanged for the first catheter if more distal access is desired and not possible with the initial catheter.").

Imperative Care also persuasively argues that a person of ordinary skill in the art would be motivated to combine Garrison's aspiration system for treating cerebral blood clots with Laub's teaching of an aspiration method for treating PE using larger-sized catheters, specifically 16F as claimed by the '910 Patent. These two prior art references are in the same field as Inari's claimed invention – that is, systems and methods for removing blood clots from a patient's vasculature. The closeness in field between the prior art references and the '910 Patent supports Imperative Care's obviousness position. Imperative Care's position is further supported because Garrison discloses nearly all of the limitations of the '910 Patent, and Laub alone discloses the few remaining limitations. Moreover, Laub expressly discloses the application to PE.

Inari stresses that there are significant differences between systems and methods used for removing clots from smaller vessels (as in Garrison) and those used for larger vessels, as in the case of DVT and PE. But these differences do not mean that a person of ordinary skill in the art would lack motivation to combine Garrison and Laub to use larger-sized catheters to treat PE. Indeed, Inari's expert witness acknowledged that an engineer of ordinary skill in the art could draw from her experience removing clots from smaller-diameter vessels when developing systems and methods for treating DVT and PE. *See* Brown Dep. Tr. 207:5-20, 211:15-212:3. Additionally, Imperative Care has submitted evidence that other companies in the thrombectomy market have developed PE treatment systems by adapting aspiration catheters used to remove smaller clots. Strange Dep. Tr. 31:19-25, 119:17-24, ECF No. 85-2 (testifying that competitors, such as Penumbra, took the "same core technology" used for neurovascular applications "and repurposed them to be used in veins"). This evidence that competitors were motivated to adapt other aspiration systems to treat PE undermines Inari's claims of non-obviousness based on objective evidence.[18]

[18] Inari argues that the PTAB's decision to deny institution of IPR on a related patent undermines Imperative Care's position here. *See* PTAB Decision Denying Institution of IPR, ECF No. 67-1 (denying institution as to U.S. Patent No. 11,744,691 ('691 Patent)). The Court is not persuaded. The PTAB's analysis of the '691 Patent focused on claim limitations that are not present in claim 1 of the '910 Patent. *Id.* at 25. Additionally, the PTAB primarily addressed whether Garrison *alone* anticipated the claims in the '691 Patent; it did not consider the combination of Garrison and Laub with respect to the specific claim at issue here. *Id.* at 28.

In sum, Imperative Care has raised substantial questions as to the validity of all patent claims asserted in this motion. Inari has not shown that these challenges lack substantial merit and, therefore, it has not shown a likelihood of success.

B. Likelihood of Irreparable Harm

Even when a movant establishes a likelihood of success on the merits, a court may not infer a likelihood of irreparable harm. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1148-49 (Fed. Cir. 2011). Instead, the movant "must show it is likely to suffer irreparable harm if the injunction is not granted and establish a causal nexus between the alleged infringement and the alleged harm." *Natera*, 106 F.4th at 1378 (citing *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1352 (Fed. Cir. 2016)). Here, the Court finds that Inari has not shown a likelihood of irreparable harm, nor that there is a causal nexus between the alleged infringement and Inari's claimed harm.

1. Irreparable harm

Harm is irreparable if it cannot be compensated by a final judgment – assuming that the plaintiff ultimately prevails on the merits. To be irreparable, harm must be "imminent and not remote or speculative." *Boardman v. Pac. Seafood Grp.*, 822 F.3d 1011, 1022 (9th Cir. 2016); *see also Koninklijke Philips N.V. v. Thales DIS AIS USA LLC*, 39 F.4th 1377, 1380 (Fed. Cir. 2022) (similar). Irreparable harms typically are not quantifiable, and thus "cannot be adequately compensated" with a damages award. *Natera*, 106 F.4th at 1378; *see also Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344 (Fed. Cir. 2013). By contrast, monetary losses alone, "however substantial," are "not enough." *Sampson v. Murray*, 415 U.S. 61, 90 (1974). "The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, weighs heavily against a claim of irreparable harm." *Id.*; *see also Goldie's Bookstore, Inc. v. Super. Court*, 739 F.2d 466, 471 (Fed. Cir. 1984) (same).

Many factors may be relevant to determine whether patent infringement is likely to cause irreparable harm to a patent holder. Unchecked infringement in a nascent and fast-developing market can cause irreparable harm – for example, if the patent holder is unable to establish itself, or if the alleged infringer is able to capture a dominant market position. *See Celsis In Vitro, Inc. v.*

CellzDirect, Inc., 664 F.3d 922, 931 (Fed. Cir. 2012) ("During the growth stage of a product, it is particularly crucial to be able to distinguish oneself from competitors . . . and [to] establish[]leadership in the market."); *see also Illumina, Inc. v. Qiagen, N.V.*, 207 F. Supp. 3d 1081, 1093 (N.D. Cal. 2016) (similar). The "nature of the competition between the parties undoubtedly" is relevant, too. *Robert Bosch LLC*, 659 F.3d at 1150-51. "[T]he existence of a two-player market may well serve as a substantial ground for granting an injunction – *e.g.*, because it creates an inference that an infringing sale amounts to a lost sale for the patentee." *Id.* at 1151. The presence of additional competitors, by itself, does not weigh against granting preliminary relief. *Id.*

Here, Inari primarily relies upon future lost sales, price erosion, and lost market share to show a likelihood of irreparable harm. With respect to lost sales, Inari acknowledges that Imperative Care's sales to date are "very small." Strange Dep. Tr. 58:7-18. Inari claims that nine of its hospital customers enrolled patients in Imperative Care's Symphony PE study. Hykes Decl. ¶ 26. But the use of Symphony in clinical studies is not infringement, 35 U.S.C. § 271(e)(1), and in any event, the potential harm from these limited sales is negligible. Inari also claims that there have been "dozens of Symphony cases" for treating DVT, Hykes Decl. ¶ 23, but these sales, too, are *de minimis*. Inari projects that Imperative Care will make substantial *future* sales "over the next few years." *Id.* ¶ 30. Even if these lost sales were sufficiently imminent and non-speculative, they can be compensated with a damages award, and therefore they do not establish irreparable harm. *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017) ("Evidence of potential lost sales alone does not demonstrate irreparable harm."); *see also Celsis In Vitro*, 664 F.3d at 930 ("[T]he irreparable harm inquiry seeks to measure harms that no damages payment, however great, could address.").

With respect to price erosion, the record does not support that Imperative Care frequently undercuts Inari on price. *See* Scott Decl. ¶ 27. Price comparisons between the companies' products are difficult and "depend[] on many factors." *Id.* ¶ 24. Imperative Care uses an *a la carte* pricing strategy for the components of the Symphony system, and a physician may combine different components for any particular procedure, which affects the price. *Id.* ¶¶ 21-22 (providing

examples). Based on typical cases, Symphony and Inari's devices are priced comparably. *Compare id.*, *with* Hykes Decl. ¶ 27 (summarizing Inari's pricing). In any event, sales of Symphony are not currently affecting Inari's pricing or profitability given Imperative Care's "very small" market share. Strange Dep. Tr. 58:7-18.

Even if Inari has to compete on price in the future, there is no evidence that price erosion would be irreparable if Inari later obtains a permanent injunction excluding sales of Symphony.[19] Inari's assertion as to price erosion is unsupported. *See* Hykes Decl. ¶ 30; *see also id.* ¶ 27 (similar). This conclusory assertion is not enough to establish a non-speculative likelihood of irreparable price erosion. *Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. Inc.*, 967 F.3d 1339, 1349 (Fed. Cir. 2020) (holding that bare assertions of irreparable harm based on price erosion are "never sufficient"); *cf. Celsis In Vitro*, 664 F.3d at 930 (affirming preliminary injunction premised on price erosion where movant presented "unrebutted expert testimony," fact witness testimony, specific financial records, and evidence of competitor's "significantly discounted prices" and specific lost sales).

With respect to lost market share, there is no doubt that Inari presently holds a dominant share of the market for mechanical thrombectomy devices in the United States. Strange Decl. ¶ 10 (discussing market share figures). Inari is the market leader with respect to both PE and, to a lesser extent, DVT. *Id.* Inari has maintained its dominant share despite Imperative Care's entry, and Inari's losses to date have been to other competitors, primarily Penumbra. Nalbone Decl. ¶ 17; *see also* Strange Dep. Tr. 20:16-23, 21:15-21. By contrast, Imperative Care does not have "any share in PE" given that Symphony was only just cleared by the FDA, and even with respect to DVT, its share is "very de minimis." Strange Dep. Tr. 57:14-23. Even assuming that Imperative Care establishes a greater foothold while this litigation progresses, Inari has not shown that any potential lost share would be irreparable. Instead, the market for mechanical thrombectomy devices has been dynamic, with shares fluctuating as competitors introduce new

[19] On this point, it is unclear whether Inari would reduce its price in response to continued competition from Imperative Care. *See* Strange Decl. ¶ 14.

products. *See* Strange Dep. Tr. 64:9-13. Additionally, the market is "highly underpenetrated" because most PE and DVT cases are still treated with anticoagulants and thrombolytics. *Id*. 66:5-24. Therefore, there is opportunity for both Inari and Imperative Care to expand sales, without Inari losing its relative share.

In sum, Inari has not shown that it will likely be forced to irreversibly lower its prices, or that it will lose market share that it cannot recover. Thus, Inari has not shown a likelihood that it will suffer irreparable harm in the absence of a preliminary injunction.[20]

2. Causal nexus

Even if Inari had shown a likelihood of irreparable harm, its motion would still fail for lack of a causal nexus between that harm and Imperative Care's alleged infringement. The purpose of the causal nexus requirement is to distinguish between "irreparable harm caused by patent infringement and irreparable harm caused by otherwise lawful competition – *e.g.*, sales [that] would be lost even if the offending feature were absent from the accused product." *Apple Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1361 (Fed. Cir. 2013) ("*Apple III*"). To satisfy the causal nexus requirement, the patent holder must show that the infringing features of the accused product (here, Symphony) "drive consumer demand." *Apple Inc. v. Samsung Elecs. Co*., 809 F.3d 633, 641-42 (Fed. Cir. 2015) ("*Apple IV*"). The patent holder need not show that "the infringing features were the exclusive or predominant reason why consumers bought" the accused products. *Id*. at 642. Instead, it is sufficient if there is "some connection" between the patented features and the demand for the alleged infringer's products. *Id*.

Here, the record does not support Inari's claim that the allegedly infringing aspects of Symphony drive consumer demand. Inari did not submit any direct evidence (*e.g.*, customer declarations), and its other evidence is unhelpful.[21] With respect to the hemostasis valve, Inari

[20] Inari also fails to show that Imperative Care's continued sales of Symphony are likely to cause Inari loss of goodwill or reputational harm. Inari concedes that there has been no head-to-head clinical study of the companies' devices. Hykes Dep. Tr. 270:2-271:13, ECF No. 85-3. Thus, there is no evidence that Symphony sales will somehow tarnish the reputation of Inari's technology, even if customers perceive Symphony as a copycat of Inari's devices.

[21] Imperative Care submitted a declaration from a doctor who uses both Inari's and Imperative Care's devices. The doctor uses Symphony for reasons other than the accused features. Tomalty

testified that one doctor liked "[t]he buttons, and how easy they were to use." Hykes Dep. Tr. 73:23-75:23 ("Q. The buttons. Anything else other than the buttons? A. No."). But the specific buttons that Inari uses are not claimed by the '921 Patent. Inari also testified that its customers likely do not know the details about the construction of the hemostasis valve because "it's obscured in the device. It's opaque plastic." Merritt Dep. Tr. 207:25-208:9, ECF No. 85-5. Similarly, the telescoping feature claimed by the '910 Patent has been a negligible draw for Symphony customers. Until recently, Symphony was only cleared for use in DVT procedures, and the "vast majority" of those procedures used only one Symphony catheter. Scott Decl. ¶ 9 (stating that only 1.5% of cases used the 16F and 24F catheters simultaneously).[22] Therefore, the causal nexus between the accused features of Symphony and its modest sales to date is lacking. *Genband US LLC v. Metaswitch Networks Corp.*, 861 F.3d 1378, 1384 (Fed. Cir. 2017) ("If all but an insignificant number of purchases from the infringer would have been made even without the infringing feature, the causal connection to the asserted lost-sale-based injury is missing.").

In addition to considering consumer purchasing behavior, courts may consider whether the alleged infringer copied aspects of the patent holder's product. "[E]vidence of copying does not, by itself, establish a causal nexus." *Apple IV*, 809 F.3d at 642. But copying may indicate that the alleged infringer expects a particular feature to drive demand. *Id*. Here, Inari's claims of copying are conclusory and do not satisfy the causal nexus requirement. *See* Strange Dep. Tr. 117:19-22 ("[Q.] So you really have no basis to know where [Imperative Care] learned the concepts incorporated in the Symphony device; correct? A. I have no way of knowing."); Hykes Dep. Tr. 152:22-153:1 ("Q. But you have no document, witness, any piece of evidence that actually can show that [Imperative Care] got the idea to copy a feature or attribute of an Inari device, do you? A. No."). Inari also argues that Imperative Care submitted a FOIA request to obtain information

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Decl. ¶¶ 9-17, ECF No. 36-43. This evidence is anecdotal but adds some support to Imperative Care's position that a causal nexus is lacking.

[22] To be clear, whether sales of Symphony infringe the '910 Patent is a separate question from the causal nexus inquiry. Here, the Court focuses on whether there is some connection between the allegedly infringing features of Symphony and customer demand for it. If almost no procedures use telescoping, and if Symphony is primarily used to treat DVT, these facts are relevant to the causal nexus inquiry even they do not establish non-infringement.

about its FDA application for FlowTriever, but this is not proof of copying. Hykes Decl. ¶ 20 (acknowledging that "FOIA requests are relatively common in [this] industry, and Inari has also made them").

In sum, Inari has failed to satisfy both the irreparable harm and causal nexus requirements for obtaining a preliminary injunction.

C. Balance of the Hardships and the Public Interest

Finally, the Court considers the last two *Winter* elements: the balance of the hardships and the public interest.[23] "A court must 'balance the interests of all parties and weigh the damage to each' in determining the balance of the equities." *CTIA - The Wireless Ass'n v. City of Berkeley, Cal.*, 928 F.3d 832, 852 (9th Cir. 2019) (quoting *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1138 (9th Cir. 2009)). "[T]he public interest inquiry primarily addresses impact on non-parties rather than parties." *hiQ Labs, Inc. v. LinkedIn Corp.*, 31 F.4th 1180, 1202 (9th Cir. 2022) (quoting *Bernhardt v. Los Angeles Cnty.*, 339 F.3d 920, 931-32 (9th Cir. 2003)).

The Court finds that Imperative Care presents a strong case that it would suffer hardship from a preliminary injunction. Imperative Care has made substantial investments in developing Symphony, and it continues to invest additional resources to improve the device. Nalbone Decl. ¶¶ 11, 19 (detailing Imperative Care's investments). Imperative Care is at an early stage of entry into the mechanical thrombectomy market, and blocking sales of Symphony now would have dire consequences for its business. *Id.* ¶¶ 20-22. The proposed injunction would block Imperative Care's *only* product in the mechanical thrombectomy market. Inari even acknowledges that Imperative Care "will be harmed from an injunction" and may be forced out of the market, "at least in the short term" until it can develop and obtain FDA clearance for another device. Mot. at 33. By contrast, although Inari may face competition from Imperative Care while this litigation progresses, it will not likely face irreparable harm. Therefore, the balance of hardships tips in Imperative Care's favor. *See Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir.

[23] In light of the Court's findings as to the first two elements, the Court need not reach the final two elements. *Polymer Techs.*, 103 F.3d at 973-74; *see also Reebok Int'l Ltd. v. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994). Nonetheless, the Court addresses Inari's arguments for the sake of completeness.

1990) ("The hardship on a preliminarily enjoined manufacturer who must withdraw its product from the market before trial can be devastating.").

The Court finds that the public interest element is neutral. Inari is correct that enforcing patent rights, and thereby encouraging innovation, is in the public interest. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) ("We have long acknowledged the importance of the patent system in encouraging innovation."). But this argument "has less force here because there are serious questions regarding the validity of the asserted claims" in Inari's patents. *DNA Genotek*, 2016 WL 8738225, at *5.

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Inari has not met its burden to show that any of the *Winter* elements – much less all of them – favor a preliminary injunction. Accordingly, the Court cannot award Inari the extraordinary relief of an order blocking Imperative Care from the mechanical thrombectomy market while this litigation is pending.

IV. CONCLUSION

For the foregoing reasons, Inari's motion for a preliminary injunction is DENIED.

IT IS SO ORDERED.

Dated: September 29, 2025

Eumi K. Lee
United States District Judge