IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INARI MEDICAL, INC., a Delaware Corporation,	)	
	)	C.A. No.
Plaintiff,	)	
v.	)	**DEMAND FOR JURY TRIAL**
INQUIS MEDICAL, INC., a Delaware Corporation,	)	
Defendant.	)	

COMPLAINT

1. Plaintiff Inari Medical, Inc. ("Inari") files this Complaint against Defendant Inquis Medical, Inc. ("Inquis") for the misappropriation of Inari's trade secrets, patent infringement, and intentional interference with contractual relations.

2. Inari is a pioneering healthcare company with a mission of improving outcomes for patients suffering from life-threatening conditions. As the result of its years of effort and sustained investment, Inari successfully developed, proved the efficacy of, and received regulatory (FDA) clearance for several transformational (and award-winning) medical devices to treat conditions involving blood clots. Inari's innovations have been repeatedly recognized by the United States Patent and Trademark Office, which has awarded Inari over 50 United States patents.

3. Inquis, a start-up with no history of marketing similar devices, hired Inari's Vice President of Regulatory Affairs & Quality Assurance, Kit Cariquitan, to provide consulting services for Inquis and help secure FDA clearance for Inquis' competing products ***while Cariquitan was still employed by Inari***. Soon after he was hired by Inquis, Cariquitan downloaded from Inari's network several of Inari's most confidential FDA documents containing numerous Inari trade secrets and copied them to a folder on a thumb drive titled ***"Inquis Medical."*** On information and belief, Inquis, through Cariquitan, then used Inari's confidential files as a shortcut

to secure FDA clearance for devices that directly compete with Inari's devices and infringe Inari's patents.

THE PARTIES

4. Plaintiff Inari Medical, Inc. is a Delaware corporation having its principal place of business and headquarters at 6001 Oak Canyon, Suite 100, Irvine, California.

5. Defendant Inquis Medical, Inc. is a Delaware corporation, and on information and belief, has a principal place of business and headquarters at 127 Independence Drive, Menlo Park, California.

JURISDICTION AND VENUE

6. Inari brings this action for, among other claims, trade secret misappropriation under 18 U.S.C. § 1836, *et seq.* and patent infringement under the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

7. This Court has subject matter jurisdiction over this action pursuant to at least 28 U.S.C. §§ 1331 and 1338(a), and supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a).

8. This Court has personal jurisdiction over Inquis because, for example, (1) it is incorporated and therefore resides in Delaware, (2) it maintains a registered agent in Delaware, (3) on information and belief and as discussed in this Complaint, it has used Inari's trade secrets to receive numerous FDA clearances to market and sell its products throughout the United States, including in Delaware, (4) on information and belief and as discussed in this Complaint, it markets and/or sells the Accused Products that infringe Inari's patents throughout the United States, including in Delaware, and (5) on information and belief, it derives revenue from its marketing and/or selling of the Accused Products throughout the United States, including in Delaware.

9. Venue is proper in this District pursuant to at least 28 U.S.C. § 1391(b) and 28 U.S.C. § 1400(b) because, for example, Inquis (1) is incorporated in and therefore resides in Delaware, (2) on information and belief and as discussed in this Complaint, has used Inari's trade secrets to receive numerous FDA clearances to market and sell its products throughout the United States, including in Delaware, (3) on information and belief and as discussed in this Complaint, markets and/or sells the Accused Products that infringe Inari's patents throughout the United States, including in Delaware, and (4) on information and belief, derives revenue from its marketing and/or selling of the Accused Products throughout the United States, including in Delaware.

FACTUAL ALLEGATIONS UNDERLYING INARI'S CLAIMS

Inari's Thrombectomy Systems

10. Venous thromboembolism ("VTE") is a disease caused by blood clot formation in the veins of the body, and is, unfortunately, a leading cause of both death and disease worldwide. Pulmonary embolism and deep vein thrombosis are common types of VTE. Deep vein thrombosis is a type of blood clot that typically forms in the deep veins of a limb, such as the leg, and can develop into pulmonary embolism if portions of the clot break off, migrate to, and become lodged in the arteries of the lungs.

11. Inari is the world's leading developer of catheter-based mechanical thrombectomy devices that treat pulmonary embolism and deep vein thrombosis through aspiration (*e.g.*, by using suction to remove clot material) and/or mechanical mechanisms of action (*e.g.*, by using mechanical objects to disrupt clot material). Inari was and is a pioneer in changing the standard of care for pulmonary embolism and deep vein thrombosis from conservative medical management with anticoagulation alone and thrombolytics-based

treatments (*i.e.*, treatments with drugs called "lytics" that break down blood clots that have formed in blood vessels)—which have been plagued with drawbacks relating to effectiveness and side effects—to treatment with mechanical systems. Inari's lifesaving products, including its FlowTriever, FlowSaver, and ClotTriever systems, have received widespread acclaim for their efficacy in treating pulmonary embolism and/or deep vein thrombosis. Inari markets these products from its headquarters in California and sells them to hospital systems throughout the United States and internationally.

The 510(k) Process

12. In the United States, each person who wants to market a Class I, II, or III medical device intended for human use must submit to the FDA a "Premarket Notification 510(k)" unless the device is exempt, or a Premarket Approval application is required. A 510(k) is a premarket submission made to the FDA to demonstrate that a device to be marketed is as safe and effective as—*i.e.*, substantially equivalent to—an existing, legally marketed device. Submitters must compare their device-to-be-marketed to one or more similar legally marketed devices to make and support their substantial equivalence claims. The legally marketed device(s) to which equivalence is drawn is (are) commonly known as the "predicate" device(s). Any legally marketed device may be used as a predicate.

13. To establish that a device-to-be-marketed is substantially equivalent to the predicate device where the devices have different technological characteristics, the submitter must show that the differences in characteristics do not raise different questions of safety and effectiveness, and the information submitted to the FDA must demonstrate that the device-to-be-marketed is as safe and effective as the legally marketed predicate device.

14. To determine if a device-to-be-marketed is as safe and effective as a predicate device, the FDA reviews: (1) the scientific methods used to evaluate differences in technological characteristics; and (2) performance data. This performance data can include clinical data and non-clinical bench performance data, including engineering performance testing, sterility, electromagnetic compatibility, software validation, and biocompatibility evaluation, among other data. The company submitting a 510(k) is responsible for designing the scientific methods and ultimately generating the performance data needed for FDA clearance.

15. Until the submitter receives an order from the FDA declaring its new device "substantially equivalent," the submitter may not market the device in the United States. To receive FDA clearance for a 510(k), there are often multiple rounds of correspondence with the FDA required, serving to: (1) correct deficiencies identified by the FDA; (2) provide additional information requested by the FDA; or (3) report on the running of additional or refined tests. This correspondence is typically not made public due to the trade secret, confidential commercial, and/or personal nature of such information.

16. Although the FDA will make a 510(k) summary of the safety and effectiveness data available to the public within 30 days of clearance, the full premarket 510(k) submission (*e.g.*, showing the detailed scientific methods, product design information and testing data) is typically not made public due to the trade secret, confidential commercial, and/or personal nature of such information.

17. To receive FDA clearance for its FlowTriever, FlowSaver, and ClotTriever Systems, Inari prepared and submitted several Premarket Notification 510(k)s to the FDA.

Inari's FlowTriever

18. Inari's first product, its FlowTriever system, represented a major leap forward in treatment for venous thromboembolism, including pulmonary embolism. During procedures, FlowTriever applies aspiration (*i.e.*, negative vacuum pressure) directly to the thrombus (*i.e.*, the blood clot) via catheters. Inari's FlowTriever may be used to facilitate aspiration and removal of the thrombus through variously sized catheters, aspirating at least a portion of the clot material.

19. Inari began working on the FlowTriever product in 2011[1] and invested millions of dollars in its development prior to bringing the first-generation product to market in 2015. In May 2018, the FlowTriever became the first mechanical thrombectomy system to receive FDA 510(k) clearance specifically for the treatment of pulmonary embolism, which can be life threatening if not addressed quickly.

Inari's FlowSaver

20. Inari continued to improve the performance of FlowTriever over the years, including by developing accessory devices to be used in connection with the FlowTriever. One such product was Inari's FlowSaver.

21. The FlowSaver minimizes blood loss when using the FlowTriever by allowing for autologous blood transfusion of aspirated blood from the FlowTriever procedure using a syringe and dual layer 40-micron/200-micron blood filter. In other words, after the FlowTriever removes the clot, the FlowSaver then filters the clot from the extracted blood and allows that filtered blood (without the clot) to be returned to the patient to minimize blood loss during the procedure.

[1] Inari was formed under the laws of the state of Delaware in July 2011 under the name Inceptus Newco1 Inc. and changed its name to Inari Medical, Inc. in September 2013.

22. Inari submitted its 510(k) for the FlowSaver on November 10, 2020 (the "FlowSaver 510(k)").[2] The FlowSaver 510(k) was cleared by the FDA on July 22, 2021.[3] This clearance, however, included a requirement that after passing through Inari's FlowSaver filter, the filtered blood needed to be filtered a second time (through a suitable transfusion filter) before being reintroduced to the patient. With a goal to remove this second filter, Inari met with the FDA on September 9, 2021. Inari then prepared and submitted a 510(k) with the second filter removed on May 20, 2022, which was cleared by the FDA on February 17, 2023.[4] Thus, in total, Inari's FlowSaver 510(k)s were pending with the FDA almost seventeen months (from November 10, 2020 through January 5, 2021, from January 21, 2021 to July 22, 2021, and then again from September 9, 2021 through February 17, 2023).[5]

23. As is typical, in the process of reviewing the FlowSaver 510(k)s, the FDA made several requests for additional information (known as "deficiency letters"). These included specific requests for additional information regarding performance and comparative testing of the FlowSaver to demonstrate it was as safe and effective as the predicate device. Over the course of more than sixteen months, Inari provided detailed (and satisfactory) responses to the FDA's deficiency letters, and the FDA cleared Inari's FlowSaver 510(k)s. The details of this correspondence with the FDA contains Inari trade secret information and is not public.

24. This process of the FDA requesting additional information before clearing a 510(k)

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[2] Inari originally submitted the FlowSaver 510(k) as K203324 on November 10, 2020. After discussion with the FDA regarding proper classification and testing, Inari withdrew the initial FlowSaver 510(k) on January 5, 2021, and resubmitted it as K210176 on January 21, 2021.

[3] *See* FDA 510(k) Premarket Notification (K210176) (available at https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210176.pdf).

[4] *See* FDA 510(k) Premarket Notification (K221483) (available at https://www.accessdata.fda.gov/cdrh_docs/pdf22/K221483.pdf).

[5] Or, approximately fourteen months if you omit the time K203324 was pending.

submission is often time consuming but is extremely common. Indeed, it would be an anomaly for the FDA to not request additional testing and data rationales to establish substantial equivalence to reach 510(k) clearance, especially for a newer company on its first Traditional 510(k) submission.

Inari's ClotTriever

25. Separate from its work on FlowTriever, Inari also received FDA clearance for its ClotTriever system in February 2017. ClotTriever was designed for clot removal from the peripheral vasculature using nitinol mesh structures to engage and then withdraw clots.

26. Inari has continued to improve the performance of ClotTriever over the years. By December 2017, Inari had developed and received FDA clearance for the ClotTriever including a collapsible clot collection bag. On September 9, 2020, Inari received FDA clearance to market ClotTriever specifically for the treatment of deep vein thrombosis.

27. On April 27, 2023, the FDA cleared Inari's 510(k) for a new iteration of the ClotTriever system called the ClotTriever XL Catheter (the "ClotTriever XL 510(k)"). The ClotTriever XL was a new catheter purpose-built for clot removal from the Inferior Vena Cava that is larger in diameter and longer in length than the previous catheter.[6]

Cariquitan's Employment with Inari

28. On May 24, 2021, Inari hired Cariquitan as its Vice President of Regulatory Affairs & Quality Assurance. One of Cariquitan's primary job responsibilities at Inari included providing guidance in preparing 510(k)s for Inari and being the liaison between Inari and the FDA regarding

[6] *See* FDA 510(k) Premarket Notification K223210 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf22/K223210.pdf).

the same. Cariquitan also participated in the management of the company, including by providing guidance to senior management regarding regulatory compliance for the company.

29. While working for Inari, Cariquitan led the 510(k) process for several Inari products, including the ClotTriever XL 510(k), and assisted with responding to the FDA in connection with other 510(k)s including the FlowSaver 510(k).

30. As with all Inari regulatory personnel, Cariquitan was required to and completed several trainings related to the handling of confidential information.

31. As a condition of employment at Inari, Cariquitan executed and agreed to Inari's Employee Handbook (the "Employee Handbook") on May 18, 2021, and again on April 5, 2022.

32. Through the Employee Handbook, Cariquitan acknowledged and agreed, among other things, that he would:

a. Disclose any outside employment and get written approval from his immediate supervisor;

b. Not engage in outside employment that creates a conflict of interest;

c. "Act in Inari Medical's best interest in fulfilling its mission and take care to avoid the potential or appearance of conflict of interest," which is defined as "any circumstance that impedes an employee's ability to act with total objectivity regarding Inari Medical interest"; and

d. "Preserve and protect confidential information, agreements or materials from unauthorized disclosure and use."

33. Specifically, as to conflicts of interest, Cariquitan agreed he would not create any conflicts of interest, including by working for a competitor or using confidential Inari information for personal gain or to Inari's detriment.

34. Similarly, as to Inari's confidential information, Cariquitan agreed to "not use or disclose any proprietary or confidential information [he] obtain[ed] during employment with Inari Medical" and to "keep proprietary and confidential information secure from outside visitors and all other persons who do not have a legitimate reason to see or use such information."

35. Like all employees, Cariquitan was also required to agree to Inari's Confidential Information and Invention Assignment Agreement (the "Confidentiality Agreement"). Cariquitan executed the Confidentiality Agreement on May 18, 2021.

36. Through the Confidentiality Agreement, Cariquitan agreed to protect the confidentiality of Inari's "Company Confidential Information," which is defined as "information that [Inari] has or will develop, acquire, create, compile, discover or own, that has value in or to [Inari's] business which is not generally known and which [Inari] wishes to maintain as confidential." "Company Confidential Information" specifically includes but is not limited to:

> any and all non-public information that relates to the actual or anticipated business and/or products, research or development of the Company, or to the Company's technical data, trade secrets, or know-how, including, but not limited to, research, product plans, or other information regarding the Company's products or services and markets therefor, customer lists and customers (including, but not limited to, customers of the Company on which I called or with which I may become acquainted during the term of my employment), software, developments, inventions, processes, formulas, technology, designs, drawings, engineering, hardware configuration information, marketing, finances, and other business information disclosed by the Company either directly or indirectly in writing, orally or by drawings or inspection of premises, parts, equipment, or other Company property.

37. Cariquitan agreed "during and after" his employment with Inari to "hold in the strictest confidence, and take all reasonable precautions to prevent any unauthorized use or disclosure of Company Confidential Information."

38. He further agreed to not "(i) use the Company Confidential Information for any purpose whatsoever other than for the benefit of the Company in the course of [his] employment,

or (ii) disclose the Company Confidential Information to any third party without the prior written authorization of the President, CEO, or the Board of Directors of the Company."

39. Cariquitan also agreed that while employed by Inari, he would not "engage in or undertake any other employment, occupation, consulting relationship, or commitment that is directly related to" Inari's current or planned future business, and that he would not "engage in any other activities that conflict with [his] obligations to the Company."

Cariquitan Begins Working with Inquis

40. Inquis is a recently-founded medical device company. Since early 2023, Inquis has been working to obtain FDA approval and clearance for two devices related to the removal of emboli and thrombi from blood vessels and a blood return system, the Aventus Thrombectomy System and the Aventus Clot Management System.

41. Inquis' Aventus Thrombectomy System and Aventus Clot Management System have the same purpose as Inari's FlowTriever and FlowSaver combination: to remove emboli and thrombi (*i.e.*, clot material) from the peripheral vasculature of the patient and perform autologous blood transfusion (*i.e.*, blood return to the patient) after the filtration of the clot material.

42. In early 2023, Inquis submitted an application to the FDA for an Investigational Device Exemption for the Inquis Aventus Thrombectomy System (the "Inquis IDE"). An IDE application is a document submitted to the FDA that asks for permission to use a device in a clinical study in humans in order to collect safety and effectiveness data on the device.

43. In or around March 2023, Inquis retained Cariquitan as a "consultant" to help Inquis secure FDA clearance for the Aventus products that are directly competitive with Inari's FlowTriever, FlowSaver, and ClotTriever devices. Inquis continued to work with Cariquitan through at least September 2023, all while he was employed full-time by Inari.

44. On information and belief, Inquis hired Cariquitan expressly because he had worked with Inari on the FlowTriever, FlowSaver, and ClotTriever FDA clearances. On information and belief, Inquis was hoping to use confidential information, including trade secrets, relating to Inari's path to FDA clearance to enable and shorten Inquis' path to clearance.

45. Inquis knew Cariquitan had an employment relationship with Inari. On information and belief, Inquis thus knew that Cariquitan had contracts with Inari requiring Cariquitan to (1) not disclose Inari confidential information to Inquis or other third parties and (2) not engage in employment or consulting that conflicted with Cariquitan's employment with Inari.

46. Inquis may contend that it did not know Cariquitan was still working for Inari when he began working with Inquis. However, if Inquis had conducted even a cursory background investigation as to Cariquitan's employment history or FDA filings, it would have seen from numerous public documents that Cariquitan was a full-time employee of Inari. Cariquitan's picture and biography was also clearly listed on Inari's website as a member of the Executive Leadership Team. Moreover, a simple phone call to Inari's main phone number asking to speak with Cariquitan would have revealed that Cariquitan was an employee. Therefore, Inquis, at minimum, was willfully blind to Cariquitan's employment with Inari.

47. Even if Inquis did not and could not have known about Cariquitan's employment, Inquis unquestionably knew that Cariquitan had previously been affiliated with Inari. Inquis therefore was clearly seeking to benefit from Cariquitan's Inari-specific knowledge and knowingly assumed the risk that Cariquitan would be using confidential Inari information on Inquis' behalf.

48. Moreover, since Inquis knew Cariquitan had worked for Inari at least at some point, Inquis knew (or should have known) that Cariquitan had confidentiality obligations to Inari.

Inquis' Thrombectomy IDE Application

49. On March 31, 2023, *two days after he was retained by Inquis*, Cariquitan downloaded dozens of Inari's highly confidential FlowSaver files containing Inari trade secrets from a secure Inari network location.

50. Cariquitan inserted a personal thumb drive into his Inari laptop, created a folder called "Inquis Medical," and downloaded the entire, unredacted Inari folder for the FlowSaver 510(k) into the Inquis Medical folder, including but not limited to drafts of the 510(k), the submitted 510(k), numerous FlowSaver test protocols and test results, FlowSaver design details, and several confidential communications with the FDA regarding the 510(k), including Inari's deficiency responses. Cariquitan then removed the thumb drive from his Inari laptop and inserted it into his personal laptop so he could access the documents there without being detected by Inari.

51. The files Cariquitan downloaded were not publicly available, and Inari protected them in several ways, including by: (1) clearly designating them as "confidential"; (2) storing them behind two layers of password protections with access restricted to only Inari employees that needed access to the documents; (3) requiring employees to sign and agree to confidentiality agreements; and (4) housing them in a secure facility. The files Cariquitan downloaded also included Inari's highly confidential trade secrets, including but not limited to, its product designs, assembly instructions, testing protocols, and the very path that Inari followed to successfully gain FDA 510(k) clearance for the FlowSaver. These trade secrets derive independent economic value from not being generally known, including because developing medical devices and obtaining FDA clearance for them is a time consuming and expensive process. Accordingly, a competitor with access to these Inari trade secrets would be able to avoid significant time and expense when developing the information necessary to obtain FDA clearance of a comparable medical device.

52. For instance, the test protocols and test results Cariquitan downloaded contained highly confidential information regarding what tests Inari ran to respond to deficiencies and secure 510(k) clearance, what the protocols were for those tests (*e.g.*, what variables were used in testing), and the results of those tests. Those tests took Inari several years to develop and run in a manner sufficient to receive FDA clearance. Having access to the documents Cariquitan took would give any competitor, such as Inquis, a significant head start in developing a similar product and securing FDA clearance.

53. Likewise, Inari's confidential communications with the FDA in response to the FDA's requests for additional information would be invaluable to a competitor attempting to secure FDA clearance for a similar product. Those communications would essentially provide a roadmap of what the FDA requires for 510(k) clearance, and how to meet those requirements. This trade secret information includes, for instance, the issues the FDA is focused on in clearing similar devices, what information, evidence, or revised testing the FDA deems sufficient to respond to those issues, and similar information necessary to gain clearance for similar devices.

54. And of course, seeing an unredacted, full version of Inari's 510(k)—which includes descriptions and analysis of various test protocols and results necessary to achieve clearance and which the FDA had already cleared—would similarly provide a roadmap for a competitor to secure clearance for its own 510(k). After all, it took Inari almost seventeen months to secure clearance for its FlowSaver 510(k)s, including months developing responses to the FDA's requests for additional information.

55. Cariquitan has since told Inari that Inquis initially hired him to work on a then-pending Inquis IDE. On information and belief, Cariquitan then used Inari's trade secrets in connection with his work on the Inquis IDE.

56. In June 2023, Inquis received FDA approval for the Inquis IDE.

57. On information and belief, Inquis either (a) intentionally sought Inari trade secrets through Cariquitan, or (b) knew or should have known that Cariquitan had improper access to and was unlawfully using Inari trade secrets in the course of performing work for Inquis. Despite this actual or constructive knowledge that it was benefiting from Inari trade secrets, Inquis chose to continue its work with Cariquitan and to continue to reap the benefits of his misappropriation.

58. On information and belief, Inquis' use of Inari's trade secrets helped Inquis secure FDA approval for the Inquis IDE. At a minimum, Inquis' use of Inari's trade secrets materially reduced the time between application and approval, and saved Inquis time, money, and resources while freeriding off of Inari's hard work.

Inquis' Aventus Thrombectomy System 510(k)

59. Inquis' Aventus Thrombectomy System 510(k) (K232730, the "Aventus Thrombectomy 510(k)") covers a device highly similar to Inari's FlowTriever and related to the ClotTriever. Like the FlowTriever, for instance, the Aventus Thrombectomy System is a catheter-based mechanical thrombectomy system that utilizes a 60-cc syringe for aspiration, which is designed for the non-surgical removal of emboli and thrombi from a blood vessel. Notably, the Aventus Thrombectomy 510(k) uses the Malibu Aspiration Catheter cleared by the FDA under K223929 as its predicate device, and the Malibu Aspiration Catheter cleared under K223929 used *Inari's* FlowTriever Retrieval/Aspiration System cleared under K211013 as its predicate device.

60. Inquis submitted the Aventus Thrombectomy 510(k) on September 7, 2023, and received FDA clearance less than two months later on November 1, 2023. On information and belief, Cariquitan, who Inquis had hired to assist it with securing FDA clearance for its Aventus products, and who worked for Inquis through at least September 2023, worked directly on the

Aventus Thrombectomy 510(k) in at least the August 2023-September 2023 time period.

61. On August 30, 2023, Cariquitan used his Inari work email address—which he had access to because he was still an Inari employee—to send himself a copy of Inari's confidential, unredacted ClotTriever XL 510(k). Knowing this was prohibited, Cariquitan attempted to hide his actions by sending the ClotTriever XL 510(k) to his *personal* email address.

62. Like the FlowSaver 510(k) materials that Cariquitan downloaded, Inari's ClotTriever XL 510(k) is also replete with Inari's confidential, trade secret information, including information regarding Inari's test protocols, results, and product design. Also like the FlowSaver materials, the ClotTriever XL 510(k) was not publicly available, and was protected by Inari in several ways, including by being clearly designated as "confidential," being stored behind two layers of password protections with access restricted to only Inari employees that needed access to the documents, being available only to employees who had signed and agreed to confidentiality agreements, and otherwise being housed in a secure facility.

63. On information and belief, Cariquitan used Inari's ClotTriever XL 510(k) while he was consulting for and to the benefit of Inquis, in association with his work on the Aventus Thrombectomy 510(k), and did so with the knowledge and/or approval of Inquis.

64. On information and belief, Inquis' use of Inari's trade secrets made it possible for Inquis to secure FDA clearance for the Aventus Thrombectomy 510(k) while saving Inquis time, money, and resources. At a minimum, Inquis' use of Inari's trade secrets materially reduced the time between submission and clearance.

Inari Discovers the Misappropriation

65. Cariquitan, of course, kept his work for Inquis secret from Inari. Inari first learned of it in or around November 2023 from an employee of a company that Inari had recently acquired.

That employee told an Inari executive that he had learned from Inquis' Chief Technical Officer, who was a close personal friend, that Cariquitan was working as a consultant for Inquis. That employee further explained that Inquis retained Cariquitan expressly because of his affiliation with Inari and his work on Inari's 510(k) applications, and that Cariquitan had shared confidential Inari documents with Inquis.

66. Shortly after learning this information, Inari began investigating the allegations and interviewed Cariquitan, who admitted his affiliation with Inquis. Inari promptly terminated Cariquitan's employment that same day. Inari also immediately confiscated Cariquitan's laptop and ensured chain of custody by depositing the laptop with its law firm, Perkins Coie, minutes later. Perkins Coie provided the laptop directly to Berkeley Research Group ("BRG").

67. Inari then reached out to both Cariquitan and Inquis to put them on notice of the investigation and request they preserve all documents. Inquis contended it did not know Cariquitan had been an employee of Inari when working with Inquis and pledged support for the investigation.

68. Inari hired BRG to conduct a forensic analysis of Cariquitan's Inari laptop. BRG quickly identified the "Inquis Medical" folder into which Cariquitan had copied Inari's FlowSaver 510(k) materials.

69. Inari once again contacted Cariquitan and Inquis, to let them know about this clear evidence that Cariquitan had used Inari trade secret information in connection with his work for Inquis. Inari sought and obtained their agreement to analyze Cariquitan's personal devices and e-mail to determine where the Inari documents had been saved, opened or transmitted. Inari, Inquis, and Cariquitan negotiated and signed a Forensic Protocol pursuant to which BRG was permitted to analyze Cariquitan's personal laptop, thumb drives, and email ("Repositories").

70. Pursuant to the terms of the Forensic Protocol, party information was to be shared with counsel for the parties in a particular order, and certain information shared would be treated as "HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY." Although contemplated by the agreement as a possible Phase II, no documents or information from Inquis were evaluated as part of BRG's analysis.

71. By signing the Forensic Protocol, Inari, Inquis, and Cariquitan agreed that:

- "BRG shall conduct a forensic analysis of the Repositories to identify any evidence related to the presence, usage, replication, transmission, or deletion of any Inari Content";
- Inari, Inquis, and Cariquitan would "work together in good faith to share information necessary for [Inari, Inquis, and Cariquitan] to understand whether and what Inari information may have been used or shared by Cariquitan with Inquis or third parties while balancing the need to protect each party's competitively sensitive information"; and
- If the investigation "reveals that Cariquitan may have accessed Inari confidential information during the time he was consulting with Inquis, Inari will likely request access to Cariquitan's work product for Inquis and other communications between Inquis and Cariquitan."

72. Pursuant to the Forensic Protocol, BRG conducted a forensic analysis of the Repositories and reported results therefrom. After BRG's forensic analysis of the Repositories, in accordance with what was set forth in the Forensic Protocol, Inari made the follow-up request for Inquis to provide communications (for example, email communications) between Inquis and Cariquitan so Inari's counsel could see what information was transmitted back and forth and

review the final and complete versions of relevant FDA filings "to understand whether and what Inari information may have been used or shared by Cariquitan with Inquis[.]" Inquis refused.

73. By agreement of the parties, BRG's investigation (as detailed in the Forensic Protocol) currently concludes September 15, 2024. Unless Inari files this suit before BRG's investigation concludes on September 15, BRG will no longer be obligated by the Forensic Protocol to "preserve the images and information it has gathered for use in the litigation as may be appropriate and agreed by the Parties, or ordered by the court[.]"

74. If Inquis is allowed to continue using Inari's confidential and trade secret information, Inari will continue to suffer (and has suffered) irreparable competitive harm. Unless Inquis is stopped, it will be impossible to restore the parties to their respective competitive positions as if no misappropriation had occurred.

Inquis' Aventus Clot Management System 510(k)

75. While Inari's investigation was underway, Inquis submitted its Aventus Clot Management System 510(k) (K240426, the "Aventus Clot Management 510(k)") to gain FDA clearance to market the device, using Inari's FlowSaver as the predicate device. It was soon after Inquis submitted the Aventus Clot Management 510(k) that Inquis stopped cooperating in the Forensic Protocol.

76. The Aventus Clot Management System is a device similar in purpose to Inari's FlowSaver, used for blood return to the patient after the removal of a thrombus or embolus. Inquis describes the similarity between the two devices in its Aventus Clot Management System 510(k), stating:

> The [Aventus Clot Management System] and [Inari's FlowSaver] share the same technological characteristics in that both devices include an aspiration syringe that connects to the aspiration catheter and injects the blood/clot into the blood return device using positive pressure and a second syringe for removing the filtered blood

> via negative pressure. Both devices have a dual layer filtration for separating clot from aspirated blood. Both devices use a suitable blood transfusion filter (not provided). Both devices can be opened to remove clot and flushed between filtrations. Both devices utilize a dedicated "inlet" for aspirated blood and "outlet" to remove filtered blood.

77. Notably, the FDA cleared the Aventus Clot Management 510(k) after just three months. This is a highly unusual turnaround time by the FDA for a first attempt to achieve 510(k) clearance for an autologous blood return device of this type. In comparison and as discussed above, it took Inari more than sixteen months to obtain clearance for its FlowSaver.

78. On information and belief, this abnormality is easily explained, however, by Inquis having access to Inari's FlowSaver 510(k), product designs, test protocols and results, and Inari's responses to the FDA's deficiency letters requesting additional information on the FlowSaver.

79. Indeed, many of the tests supporting Inquis' Aventus Clot Management 510(k) were identical in purpose to the FlowSaver testing documents which Cariquitan took from Inari to help Inquis, including testing documents for mechanical hemolysis, filtration efficiency, hematocrit, and biocompatibility. Inari spent significant time, money, and resources developing and successfully running these tests.

80. On information and belief, Inquis had access to those and other Inari trade secrets through the documents Cariquitan took and used them to draft and refine the Aventus Clot Management 510(k) and secure FDA clearance for the same.

81. On information and belief, Inquis' use of Inari's trade secrets made it possible for Inquis to secure FDA clearance for the Aventus Clot Management 510(k). At a minimum, Inquis' use of Inari's trade secrets materially reduced the time between submission and clearance.

Inari's Patent Portfolio

82. As outlined above, Inari has spent many years of effort and sustained investment to develop, prove the efficacy of, and receive regulatory (FDA) clearance for its transformational thrombectomy devices. It has also spent significant time and money protecting its intellectual property through its trade secrets and patents.

83. To date, the United States Patent and Trademark Office has awarded Inari's innovation with over 50 United States patents.

84. Inari's thrombectomy devices differ significantly from any prior thrombectomy treatments. For example, Inari offers a host of product features that are separately and collectively innovative, including, but not limited to Inari products' use of stored vacuum pressure for aspiration (the "Whoosh"™ technology), their "hemostasis valve" design, their flow rates, the size of the catheters involved, and their blood filtering and return systems.

85. It has not been a trivial process to educate and win over, one-by-one, the multitude of cardiologists, vascular surgeons, interventional radiologists, and other doctors charged with treating patients via thrombectomy procedures, who are accustomed to the less-effective, traditional treatments for blood clots. This has taken extraordinary effort. Through investment, persistence, and superior products, however, Inari has single-handedly created and supplied a market for its mechanical thrombectomy devices, saving patient lives in the process.

86. Having worked so hard to develop and protect its intellectual property, and having worked so hard to win over doctors to create a market for those products, Inari cannot stand idly by as other companies—wanting to replicate Inari's success—copy Inari's products and use Inari's patented inventions. This is exactly the model that Inquis has followed here.

87. Inari uses a virtual marking website to provide notice to the public that its products are patented: https://www.inarimedical.com/inari-patents.

88. Inari sent Inquis a cease-and-desist letter notifying Inquis of its infringement described in this Complaint and the supporting exhibits on September 10, 2024.

Inquis' Infringing Products

89. As shown in detail below and in the attached claim charts, Inquis infringes numerous Inari patents with its Aventus Thrombectomy System and Aventus Clot Management System (collectively, the "Accused Products").

90. The Aventus Thrombectomy System, cleared by the FDA under K232730, is indicated for (a) the non-surgical removal of emboli and thrombi from blood vessels, and (b) injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. It is intended for use in the peripheral vasculature.

91. The Aventus Clot Management System, cleared by the FDA under K240426, is indicated for use with the Aventus Thrombectomy System for autologous blood transfusion.

92. Like Inari's FlowTriever and ClotTriever, the Aventus Thrombectomy System is intended for the non-surgical removal of emboli and thrombi from blood vessels. Also like Inari's FlowSaver, the Aventus Thrombectomy System is designed to remove thrombus/embolus using aspiration. The Aventus Thrombectomy System uses a catheter that is navigated to the site of the thrombus. Upon reaching the thrombus, negative pressure is applied through the catheter to aspirate the thrombus, causing the thrombus and blood to flow into a container. When the Aventus Thrombectomy System is used in connection with the Aventus Clot Management system, the "aspirant," *i.e.*, aspirated clot material and blood, from the Aventus Thrombectomy System procedure is injected into a clot canister, and the blood then passes through a dual-layer filter in

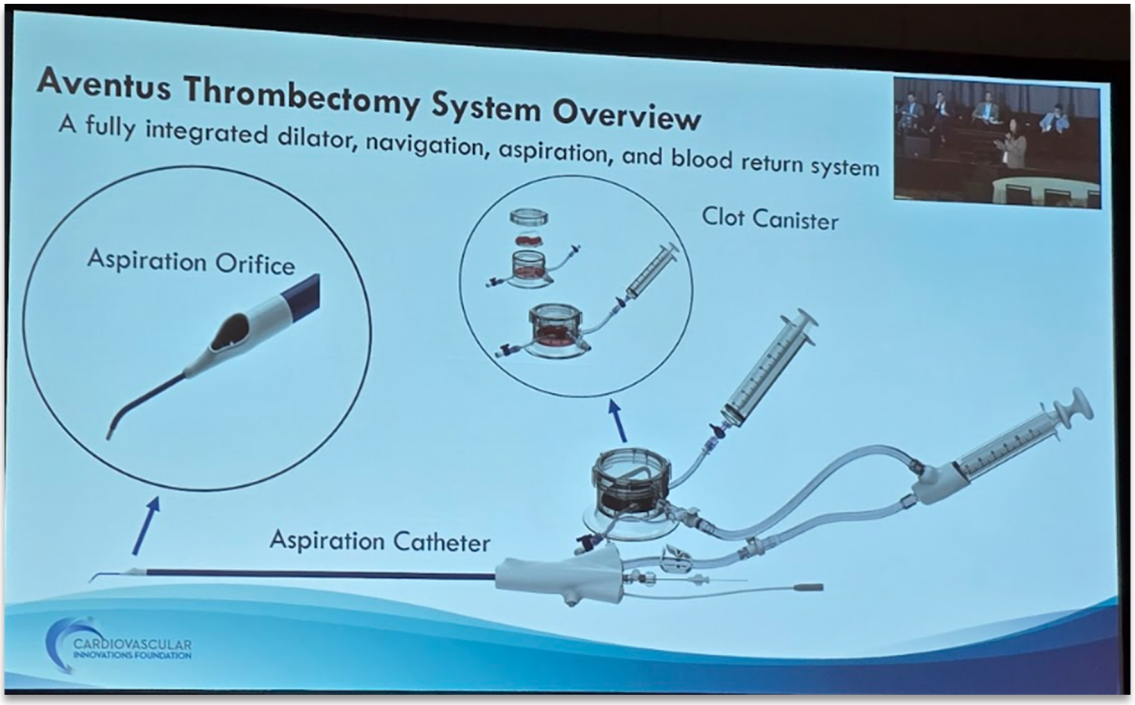
the clot canister, filling a syringe connected to the filter assembly. The filtered blood may then be returned to the patient.

93. Inquis received FDA 510(k) clearance to market the Aventus Thrombectomy System (K232730) and the Aventus Clot Management System (K240426) in November 2023 and May 2024, respectively. On information and belief, Inquis has been making, using, selling, and/or offering for sale the Accused Products since before receiving FDA clearance for them. On information and belief, it has also been instructing its customers how to use them in infringing ways.

94. For example, since receiving its FDA clearances, Inquis' LinkedIn and X pages regularly post "Congratulations" to customers across the country who have used one or both of the Accused Products.

95. As another example, an Endovascular Today article sponsored by Inquis described the Aventus Thrombectomy System as "Featured Technology." *See* "Unmet Needs in the PE Thrombectomy Space," Insert to Endovascular Today (May 2024) Vol. 23, No. 5, available at https://assets.bmctoday.net/evtoday/pdfs/et0524_FT_Inquis.pdf. And in July 2024, Inquis presented the Accused Products at the Cardiovascular Innovations Foundation Conference in Denver, CO:[7]

[7] Although this image is titled "Aventus Thrombectomy System," the device shown appears to include both the Aventus Thrombectomy System and the Aventus Clot Management System (which can be used together).



96. On information and belief, Inquis has been producing, using, promoting, selling, and inducing physicians and hospitals to buy and use the Accused Products. Inari has not been able to obtain a sample or Inquis' instructions for use of either of the Accused Products and, thus, has conducted a reasonable inquiry based on the available public information for its infringement analysis. On information and belief, the Accused Products are available only by sale directly to physicians or hospital providers.

97. Moreover, on information and belief, Inquis itself has performed infringing procedures, or directed or controlled the performance of others in the infringing procedures, or acted as part of a joint enterprise in the performance of the infringing procedures. Inquis works in close association with at least one doctor who, on information and belief, has worked on behalf of or in association with Inquis in using the Accused Products in an infringing manner during development and/or testing of the Accused Products.

The Asserted Patents

98. On February 6, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,890,180 ("the '180 Patent"), entitled "System for Treating Embolism and Associated Devices and Methods." Inari owns all rights, title, and interest in and to the '180 Patent and possesses all rights of recovery under the '180 Patent. A true and correct copy of the '180 Patent is attached as Exhibit A.

99. The '180 Patent is valid and enforceable.

100. On April 30, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,969,332 ("the '332 Patent"), entitled "System for Treating Embolism and Associated Devices and Methods." Inari owns all rights, title, and interest in and to the '332 Patent and possesses all rights of recovery under the '332 Patent. A true and correct copy of the '332 Patent is attached as Exhibit B.

101. The '332 Patent is valid and enforceable.

102. On May 7, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,974,909 ("the '909 Patent"), entitled "System for Treating Embolism and Associated Devices and Methods." Inari owns all rights, title, and interest in and to the '909 Patent and possesses all rights of recovery under the '909 Patent. A true and correct copy of the '909 Patent is attached as Exhibit C.

103. The '909 Patent is valid and enforceable.

104. On May 21, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,986,382 ("the '382 Patent"), entitled "System for Treating Embolism and Associated Devices and Methods." Inari owns all rights, title, and interest in and to

the ’382 Patent and possesses all rights of recovery under the ’382 Patent. A true and correct copy of the ’382 Patent is attached as Exhibit D.

105. The ’382 Patent is valid and enforceable.

FIRST CAUSE OF ACTION

Violation of Defend Trade Secrets Act (18 U.S.C. § 1836)

106. Inari realleges and incorporates by reference, as if fully set forth herein, each of the allegations set forth above.

107. Inari was and continues to be the owner of certain confidential and proprietary information, as alleged above, which constitutes trade secrets under the Defend Trade Secrets Act. Inari has invested significant time and resources in the research, development, and protection of this trade secret information.

108. The Inari documents downloaded by Cariquitan, including the FlowSaver and ClotTriever XL 510(k)s and related documents, contain information that constitutes Inari’s confidential trade secrets. On information and belief, Cariquitan shared Inari trade secrets with Inquis during his work for Inquis. On information and belief, Inquis used the Inari trade secrets shared by Cariquitan at least to advance Inquis’ regulatory objectives, as discussed in this Complaint.

109. The Inari trade secrets in the documents downloaded by Cariquitan and, on information and belief, shared with and used by Inquis at least to advance its regulatory objectives, including the FlowSaver and ClotTriever XL 510(k)s and related documents, are highly sensitive, derive significant economic value from not being generally known, and are not readily ascertainable by proper means.

110. At all times, Inari's trade secrets have been subject to reasonable efforts to maintain their secrecy including by being protected behind several layers of passwords, with access permitted only to authorized personnel who have agreed to Confidentiality Agreements, and otherwise being stored in a secured facility.

111. The Inari documents downloaded by Cariquitan and, on information and belief, shared with and used by Inquis at least to advance its regulatory objectives, including the FlowSaver and ClotTriever XL 510(k)s and related documents, relate to interstate commerce and are regarding products sold in interstate commerce and FDA clearance of the same.

112. On information and belief, Inquis misappropriated Inari's confidential trade secrets as alleged above, including by wrongfully, and without the authorization of Inari: acquiring Inari's trade secrets by hiring Cariquitan to gain access to Inari's trade secrets, and using those trade secrets in connection with Inquis' own products and for its own benefit, including in connection with securing FDA approval for the Inquis IDE application and FDA clearance for the Aventus Thrombectomy 510(k) and Aventus Clot Management 510(k). Inquis knew or should have known the information taken by Cariquitan constituted Inari's trade secrets.

113. Inari has been and will continue to be harmed by Inquis' conduct, in an amount to be proven at trial, including actual damages (such as lost profits).

114. On information and belief, Inquis has also been unjustly enriched including by avoiding the risk and investment required to develop their own FDA clearance materials through legitimate means, and because their conduct has provided Inquis a significant and unfair head start in FDA approval and clearance for the testing and marketing of devices that directly compete with Inari's business.

115. Inari's damages include without limitation Inquis' unjust enrichment for the use of Inari's trade secrets (including avoidance costs), Inari's lost profits, and/or the cost of Inari's remedial efforts resulting from Inquis' misappropriation.

116. Inquis' actions were deliberate, willful, malicious, and in bad faith. Accordingly, Inari is entitled to reasonable attorneys' fees and costs, and double damages under 18 U.S.C. §§ 1836(b)(3)(C)-(D).

117. Inquis' use of Inari's trade secrets has caused and will continue to cause irreparable harm to Inari for which Inari has no adequate remedy at law. Inari is entitled to injunctive relief to prevent the continued misuse and misappropriation of its trade secrets and to prevent further irreparable harm to Inari.

SECOND CAUSE OF ACTION

Violation of California's Uniform Trade Secrets Act (Cal. Civ. Code §§ 3426-3426.11)

118. Inari realleges and incorporates by reference, as if fully set forth herein, each of the allegations set forth above.

119. Inari was and continues to be the owner of certain confidential and proprietary information, as alleged above, which constitute trade secrets under California's Uniform Trade Secret Act. Inari has invested significant time and resources in the research, development, and protection of this trade secret information.

120. The Inari documents downloaded by Cariquitan, including the FlowSaver and ClotTriever XL 510(k)s and related documents, contain information that constitutes Inari's confidential trade secrets. On information and belief, Cariquitan was located in California when he downloaded these documents.

121. On information and belief, Cariquitan shared Inari trade secrets with Inquis during his work for Inquis. On information and belief, Inquis used the Inari trade secrets shared by Cariquitan at least to advance Inquis' regulatory objectives, as discussed in this Complaint.

122. The Inari documents downloaded by Cariquitan and, on information and belief, shared with and used by Inquis at least to advance its regulatory objectives, including the FlowSaver and ClotTriever XL 510(k)s and related documents, are highly sensitive and derive significant economic value from not being generally known and not being readily ascertainable by proper means.

123. At all times, Inari's trade secrets have been and are subject to reasonable efforts to maintain their secrecy including by being protected behind several layers of passwords, with access permitted only to authorized personnel who have agreed to Confidentiality Agreements, and otherwise being stored in a secured facility.

124. On information and belief, Inquis misappropriated Inari's confidential trade secrets as alleged above, including by wrongfully, and without the authorization of Inari: acquiring Inari's trade secrets by hiring Cariquitan to gain access to Inari's trade secrets, and using those trade secrets in connection with Inquis' own products for its own benefit, including in connection with securing FDA approval for the Inquis IDE application and FDA clearance for the Aventus Thrombectomy 510(k) and Aventus Clot Management 510(k). Inquis knew or should have known the information taken by Cariquitan constituted Inari's trade secrets. On information and belief, the persons at Inquis who prepared and submitted the Inquis IDE application and the Aventus Thrombectomy and Aventus Clot Management 510(k)s (including Cariquitan) were based in California at the time of the alleged conduct.

125. Inari has been and will continue to be harmed by Inquis' conduct, in an amount to be proven at trial, including actual damages (such as lost profits).

126. On information and belief, Inquis has also been unjustly enriched including by avoiding the risk and investment required to develop their own FDA clearance materials through legitimate means, and because their conduct has provided Inquis a significant and unfair head start in FDA clearance for the testing and marketing of devices that directly compete with Inari's business.

127. Inari's damages include without limitation Inquis' unjust enrichment for the use of Inari's trade secrets (including avoided costs), Inari's lost profits, and/or the cost of Inari's remedial efforts resulting from Inquis' misappropriation.

128. Inquis' actions were deliberate, willful and malicious. Accordingly, Inari is entitled to attorneys' fees and costs, and double damages under Cal. Civ. Code §§ 3426.3(c), 3426.4.

129. Inquis' use of Inari's trade secrets has caused and will continue to cause irreparable harm to Inari for which Inari has no adequate remedy at law. Inari is entitled to injunctive relief pursuant to Cal. Civ. Code § 3426.2 to prevent the continued misuse and misappropriation of its trade secrets and to prevent further irreparable harm to Inari.

THIRD CAUSE OF ACTION

Intentional Interference with Contractual Relations

130. Inari realleges and incorporates by reference, as if fully set forth herein, each of the allegations set forth above.

131. As a condition of employment, Inari and Cariquitan entered into valid and enforceable contracts that governed Cariquitan's conduct both while he was employed by Inari

and after his employment ceased, including the Employee Handbook and the Confidentiality Agreement.

132. Among other obligations, the Employee Handbook and Confidentiality Agreement required Cariquitan to disclose any outside employment and get written approval from his immediate supervisor, forego any outside employment that would create a conflict of interest, act in Inari's best interest in fulfilling its mission, take care to avoid the potential or appearance of conflict of interest, and not engage in any other activities that would conflict with Cariquitan's obligations to Inari.

133. The Employee Handbook and Confidentiality Agreement that Cariquitan agreed to are valid and enforceable.

134. Inari performed its duties under these contracts, including by paying Cariquitan's agreed annual salary.

135. Inquis knew that Cariquitan had an employment relationship with Inari. Given that, Inquis necessarily knew that Cariquitan had a contractual obligation to avoid conflicts of interest.

136. To the extent Inquis contends it did not know Cariquitan was still employed by Inari when Inquis hired him, even a cursory background investigation as to Cariquitan's employment history or FDA filings would have revealed numerous public documents indicating Cariquitan was a current, full-time employee of Inari. Moreover, Cariquitan's picture and biography was also clearly listed on Inari's website as a member of the Executive Leadership Team, and a simple phone call to Inari's main phone number asking to speak with Cariquitan would have likewise revealed that Cariquitan was still an employee.

137. Accordingly, on information and belief, Inquis knew that Cariquitan had contractual obligations to Inari to forego any outside employment that would create a conflict of interest when Inquis hired Cariquitan.

138. Inquis intentionally interfered with Inari's contractual relationship with Cariquitan by knowingly employing Cariquitan in violation of Cariquitan's contracts with Inari.

139. Cariquitan breached the Employee Handbook and the Confidentiality Agreement when he engaged in the conduct described in this Complaint, including but not limited to by working for a direct competitor, Inquis, while employed by Inari.

140. As a direct and proximate result of Inquis' intentional interference with Inari's contractual relationship with Cariquitan, Inari has been and will continue to be harmed, in an amount to be proven at trial, including because (1) Cariquitan's work for Inquis diluted the time spent on and quality of his work for Inari and (2) Inquis' interference allowed Inquis to secure a significant and unfair head start in FDA clearance for the testing and marketing of devices that directly compete with Inari's business, thus entitling Inari to profits lost due to Inquis' disruption and early market entrance.

FOURTH CAUSE OF ACTION

Infringement of U.S. Patent No. 11,890,180

141. Inari realleges and incorporates by reference, as if fully set forth herein, each of the allegations set forth above.

142. The '180 Patent is titled "System for treating embolism and associated devices and methods." The '180 Patent discloses improved systems and methods for removing clot material from a blood vessel of a human patient via a catheter intravascularly positioned within a blood vessel, including by fluidly coupling the catheter to a pressure source via a valve or other fluid

control device positioned outside the patient and applying a vacuum to the catheter via the pressure source to aspirate at least a portion of the clot material from the blood vessel. *See* Ex. A at 2:45-46, 4:17-34.

143. As evidenced below and in the exemplary claim chart attached as Exhibit E, Inquis directly infringes—literally and/or under the doctrine of equivalents—one or more claims of the '180 Patent by making, using, selling, offering for sale, and/or importing into the United States the Aventus Thrombectomy System.

144. As evidenced in the exemplary claim chart attached as Exhibit E, Inquis has also induced infringement of one or more of the claims of the '180 Patent by encouraging direct infringement by its customers (e.g., hospitals and/or physicians). Specifically, operation of the Aventus Thrombectomy System directly infringes one or more method claims of the '180 Patent. By selling the Aventus Thrombectomy System and, on information and belief, providing instructions regarding how to use the Aventus Thrombectomy System, Inquis has induced its customers to directly infringe the '180 Patent. Inquis has done so with the knowledge that its actions have encouraged direct infringement by its customers. Inquis specifically intended and was aware that the ordinary and customary use of the Aventus Thrombectomy System would infringe the '180 Patent.

145. Inquis has also engaged in contributory infringement by, on information and belief, offering to sell, selling, and/or importing into the United States the Aventus Thrombectomy System (and components thereof), knowing that it is an apparatus for use in a patented process and constitutes a material part of the invention that is especially made for use in a patented process and constitutes a material part of the invention that is especially made or adapted for infringement of

claims of the '180 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

146. The Aventus Thrombectomy System satisfies each limitation of at least claim 22 of the '180 Patent.

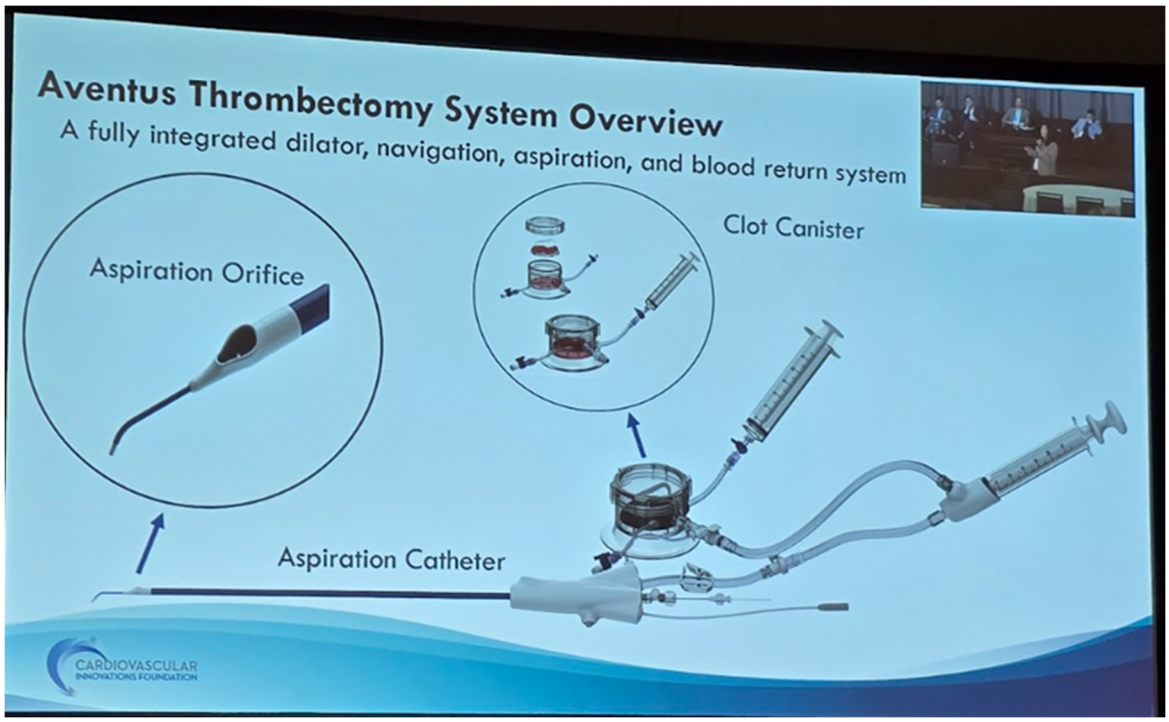
147. Claim 22 of the '180 Patent recites:

> 22. A system for the intravascular treatment of clot material from within a vasculature of a patient, the system comprising:
>
> a catheter configured to be positioned at least partially within the vasculature proximate to the clot material;
>
> a pressure source configured to generate negative pressure; and
>
> a fluid control device fluidically coupled between the pressure source and the catheter, wherein—
>
> > the fluid control device is configured to be closed to fluidically disconnect the pressure source from the catheter when the pressure source generates the negative pressure; and
> >
> > the fluid control device is configured to be opened to fluidically connect the pressure to the catheter after the pressure source generates the negative pressure to generate a flow rate within the catheter of greater than about 60 cubic centimeters per second to thereby aspirate at least a portion of the clot material into the catheter.

148. The Aventus Thrombectomy System "is a catheter-based manual aspiration system designed for minimally invasive removal of emboli and thrombi from the peripheral vasculature[.]" K232730 510(k) Summary. Thus, to the extent the preamble of claim 22 is construed to be limiting, the Aventus Thrombectomy System is "[a] system for the intravascular treatment of clot material"—*i.e.*, emboli and thrombi—"from within a vasculature of a patient[.]"

149. The Aventus Thrombectomy System includes "a catheter" that is "configured to be positioned at least partially within the vasculature proximate to the clot material." As described in the K232730 510(k) Summary, the Aventus Thrombectomy System comprises an Aspiration

Catheter. Moreover, as shown in the image below, the Aventus Thrombectomy System includes an Aspiration Catheter:



150. Further, Inquis' patents and patent applications describe the aspiration catheter as "having a proximal portion, a distal portion, and a lumen extending therebetween" where "the distal portion is configured to be positioned at a treatment site within a lumen of a pulmonary blood vessel, proximate a clot material." U.S. Patent No. 11,376,028 at 46:10-15.

151. On information and belief, the Accused Products embody the Inquis patents and patent applications cited herein, and the patents and patent applications thus evidence the features and functions of the Accused Products.

152. The Aventus Thrombectomy System further includes "a pressure source" that is "configured to generate negative pressure." For example, the Aventus Thrombectomy System "is provided with a 60-cc dual action manual syringe which allows for directional flow control and directs aspirated blood and clot into [a] Clot Canister." K232730 510(k) Summary. As another

example, the Aventus Thrombectomy System includes "a vacuum source" that is configured for "'charging' the cannister 3225 to a vacuum at the desired vacuum level," *i.e.*, configured to generate negative pressure. WIPO Patent Application Publication No. WO 2023/205815 at ¶¶ [0200]-[0201]; *see also*:

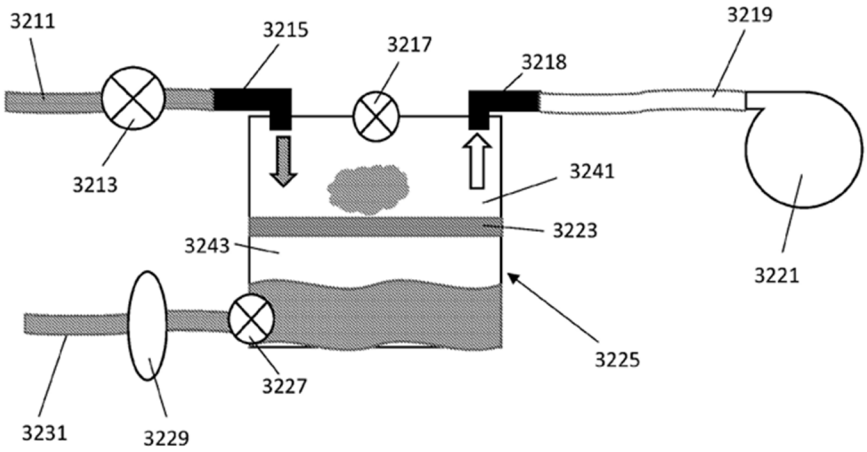


FIG. 32

WIPO Patent Application Publication No. WO 2023/205815 at Fig. 32.

153. The Aventus Thrombectomy System further includes "a fluid control device" that is "fluidically coupled between the pressure source and the catheter[.]" For example, the Aventus Thrombectomy System uses "flow-control valves to direct the flow of fluids." K232730 510(k) Summary. As another example, "[t]here is an on/off valve 3213 on the aspiration line [3211]" "that connects to an aspiration catheter." WIPO Patent Application Publication No. WO 2023/205815 at ¶¶ [0200]-[0201], [0205]. As shown in the figure above, on/off valve 3213 fluidically couples the aspiration line 3211 and aspiration catheter to cannister 3225, which is itself coupled to vacuum source 3221. Accordingly, on/off valve 3213 is a "fluid control device" that is "fluidically coupled between the pressure source and the catheter[.]"

154. Moreover, "the fluid control device" of the Aventus Thrombectomy System "is configured to be closed to fluidically disconnect the pressure source from the catheter when the pressure source generates the negative pressure[.]" For example, on/off valve 3213 is configured to be closed to fluidically disconnect the catheter from the vacuum source so the vacuum source may "'charg[e]' the cannister 3225 to a vacuum at the desired vacuum level." WIPO Patent Application Publication No. WO 2023/205815 at ¶¶ [0200]-[0201]; *see also* K232730 510(k) Summary (use of flow-control valves).

155. Additionally, "the fluid control device" of the Aventus Thrombectomy System "is configured to be opened to fluidically connect the pressure to the catheter after the pressure source generates the negative pressure to thereby aspirate at least a portion of the clot material into the catheter." For example, as shown in the figure below, "once charged, the pump may be turned off, holding the charged vacuum in the canister. Once the aspiration catheter is positioned at a target site in the vasculature, the aspiration valve 3313 may be opened, and fluid blood 3343 and thrombus material (clot material) 3344 may be drawn out of the vasculature through the aspiration catheter." WIPO Patent Application Publication No. WO 2023/205815 at ¶ [0201]; *see also* K232730 510(k) Summary (use of flow-control valves).

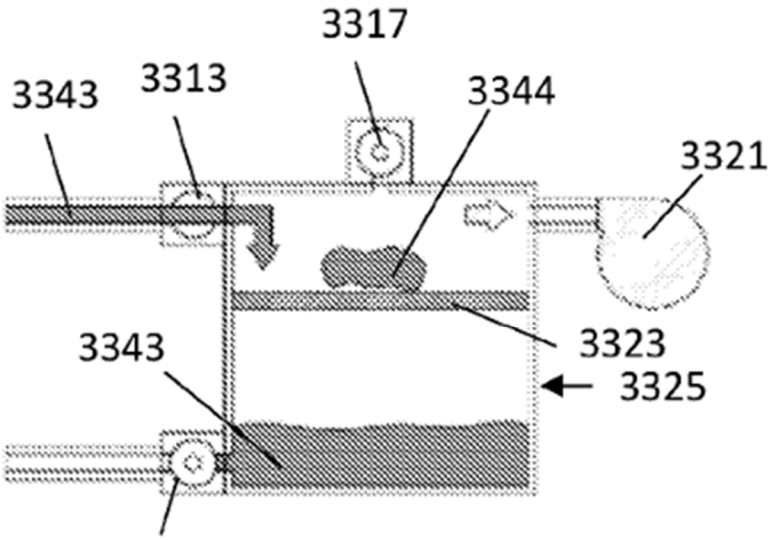


FIG. 33D

WIPO Patent Application Publication No. WO 2023/205815 at Fig. 33D; *see also* K232730 510(k) Summary (use of flow-control valves).

156. On information and belief, when the aspiration valve is opened and blood and thrombus material are drawn out of the vasculature through the Aventus Thrombectomy System's aspiration catheter, the negative pressure generates a flow rate within the catheter of greater than about 60 cubic centimeters per second, at least due to the size of the catheter and volume of the pressure source of the Aventus Thrombectomy System. *See* K232730 510(k) Summary.

157. Inquis has had knowledge of the '180 Patent and Inquis' infringement since receiving Inari's cease and desist letter and/or the filing of this Complaint. To the extent Inquis continues its infringing activities and inducing infringement after the filing of this Complaint, such post-filing infringement and inducement is intentional and with knowledge of the '180 Patent and infringement thereof.

158. With respect to 35 U.S.C. § 287, Inari does not currently seek pre-filing damages as to the '180 Patent.

159. Inquis' infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

160. Inquis' infringement of the '180 Patent has been and continues to be willful and deliberate at least since receiving Inari's cease and desist letter and/or the filing of this Complaint, entitling Inari to an award of treble damages and attorneys' fees pursuant to 35 U.S.C. §§ 284-285.

FIFTH CAUSE OF ACTION

Infringement of U.S. Patent No. 11,969,332

161. Inari realleges and incorporates by reference, as if fully set forth herein, each of the allegations set forth above.

162. The '332 Patent is titled "System for treating embolism and associated devices and methods." The '332 Patent discloses improved systems and methods for removing clot material from a blood vessel of a human patient via a catheter intravascularly positioned within a blood vessel, including by fluidly coupling the catheter to a pressure source via a valve or other fluid control device positioned outside the patient and applying a vacuum to the catheter via the pressure source to aspirate at least a portion of the clot material from the blood vessel. *See* Ex. B at 2:45-46, 4:17-34.

163. Inquis directly infringes—literally and/or under the doctrine of equivalents—one or more claims of the '332 Patent by making, using, selling, offering for sale, and/or importing into the United States the Accused Products. As evidenced below and in the exemplary claim chart attached as Exhibit F, use of the Accused Products together practices each limitation of at least claim 1 of the '332 Patent. In addition, as described above, Inquis works in close association with at least one doctor who uses the Accused Products. On information and belief, Inquis employed doctors, or has directed or controlled the actions of doctors, or has acted as part of a joint enterprise

with doctors, in the use of the Accused Products in an infringing way during development and/or testing of the Accused Products.

164. To the extent Inquis contends another entity (*e.g.*, the doctors working with Inquis) perform one or more of the claimed method steps, Inquis infringes the '332 Patent jointly and/or vicariously. Inquis engages or participates in a joint enterprise and/or collective conduct of making, using, offering to sell, selling, and/or importing of the Accused Products with at least one or more subsidiaries and affiliates, customers, and/or other third parties. On information and belief, Inquis provides the direction and/or control of one or more different parties. The infringing acts of subsidiaries, affiliates, customers and other third parties are attributable to Inquis.

165. As evidenced below and in the exemplary claim chart attached as Exhibit F, Inquis has also induced infringement of one or more of the claims of the '332 patent by encouraging direct infringement by its customers (*e.g.*, hospitals and/or physicians). Specifically, operation of the Accused Products together directly infringes one or more method claims of the '332 Patent. By selling the Accused Products and, on information and belief, providing instructions regarding how to use those Accused Products, Inquis has induced its customers to directly infringe the '332 Patent. Inquis has done so with the knowledge that its actions have encouraged direct infringement by its customers. Inquis specifically intended and was aware that the ordinary and customary use of the Accused Products would infringe the '332 Patent.

166. Inquis has additionally engaged in contributory infringement by, on information and belief, offering to sell, selling, and/or importing into the United States the Accused Products (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of

claims of the ’332 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

167. Use of the Accused Products together involves each limitation of at least claim 1 of the ’332 Patent.

168. Claim 1 of the ’332 Patent recites:

> 1. A method for the treatment of clot material within a vasculature of a patient, the method comprising
>
> positioning a first catheter at least partially within the vasculature proximate to the clot material;
>
> aspirating at least a portion of the clot material and blood through the first catheter and into a first container coupled to the first catheter;
>
> decoupling the first container from the first catheter;
>
> coupling the first container to a filter assembly;
>
> driving the portion of the clot material and the blood from the first container into the filter assembly, wherein the filter assembly is configured to filter the portion of the clot material from the blood to produce filtered blood;
>
> receiving the filtered blood from the filter assembly within a second container coupled to the filter assembly;
>
> decoupling the second container from the filter assembly;
>
> coupling the second container to a second catheter at least partially positioned within the vasculature; and
>
> driving the filtered blood from the second container through the second catheter into the vasculature.

169. The Aventus Thrombectomy System “is a catheter-based manual aspiration system designed for minimally invasive removal of emboli and thrombi from the peripheral vasculature[.]” K232730 510(k) Summary. “The Aventus Clot Management System is indicated for use with the Aventus Thrombectomy System for autologous blood transfusion.” K240426 510(k) Summary. Thus, to the extent the preamble of claim 1 is construed to be limiting, use of

the Accused Products together involves "[a] method for the treatment of clot material within a vasculature of a patient."

170. Use of the Accused Products involves "positioning a first catheter at least partially within the vasculature proximate to the clot material[.]" For example, Inquis' patents and patent applications describe "[a] method of removing material from the vascular anatomy . . . comprising . . . advancing a distal section of a catheter . . . adjacent to unwanted material," *i.e.*, a clot, "within vascular anatomy." U.S. Patent No. 11,376,028 at 6:63-67.

171. On information and belief, the Accused Products embody the Inquis patents and patent applications cited herein, and the patents and patent applications thus evidence the features and functions of the Accused Products.

172. Use of the Accused Products further involves "aspirating at least a portion of the clot material and blood through the first catheter and into a first container coupled to the first catheter." For example, the Aventus Clot Management System "is provided with a 60-cc dual action manual syringe which allows for directional flow control and directs aspirated blood and clot into [a] Clot Canister." K232730 510(k) Summary. The Aventus Thrombectomy System comprises a "large bore aspiration catheter[] which utilize[s] a 60-cc manual syringe as the aspiration source." *Id*.

173. Use of the Accused Products further involves "decoupling the first container from the first catheter." During use of the Accused Products together, "aspirant," *i.e.*, aspirated clot material and blood, "from the Aventus Thrombectomy System procedure is injected into the Clot Cannister" via the manual syringe. K240426 510(k) Summary. The "use of flow-control valves [] direct the flow of fluids." K232730 510(k) Summary. "[T]he manual syringe [] allows for directional flow control and directs aspirated blood and clot into the Clot Canister." *Id*. "The Clot

Cannister connects to the Aspiration Syringe via quick disconnect connector at the inlet port on the side of the Canister." K240426 510(k) Summary. For example, prior to injecting the aspirant into the clot cannister, the manual syringe is decoupled from the aspiration catheter. *See* K232730 510(k) Summary; K240426 510(k) Summary.

174. Use of the Accused Products further involves "coupling the first container to a filter assembly." "[T]he manual syringe [] allows for directional flow control and directs aspirated blood and clot into the Clot Canister." K232730 510(k) Summary. For example, the manual syringe filled with aspirant is coupled to the Clot Canister in order to inject the aspirant into the clot canister. K240426 510(k) Summary. Moreover, the Clot Canister includes a "dual layer nominal 40µ/200µ polyester screen filter." *Id.* Accordingly, the Clot Canister includes a filter assembly.

175. Use of the Accused Products further involves "driving the portion of the clot material and the blood from the first container into the filter assembly." For example, during use of the Accused Products, "aspirant from the Aventus Thrombectomy System" contained in the manual syringe "is injected into the Clot Canister." K240426 510(k) Summary.

176. The "filter assembly" of the Accused Products "is configured to filter the portion of the clot material from the blood to produce filtered blood[.]" "The blood passes through the Clot Canister dual layer nominal 40µ/200µ polyester screen filter," and the resulting material passed through the filter is "filtered blood." K240426 510(k) Summary.

177. Use of the Accused Products further involves "receiving the filtered blood from the filter assembly within a second container coupled to the filter assembly." For example, during use of the Accused Products "blood passes through the Clot Canister . . . filling a syringe pre-connected to the female luer lock that is positioned below the filter assembly." K240426 510(k) Summary.

178. Use of the Accused Products further involves "decoupling the second container from the filter assembly." For example, during use of the Accused Products, after the syringe has been filled with the filtered blood, the syringe may be decoupled from the filter assembly so that the "clinician can then return the filtered blood back to the patient" using a "suitable blood transfusion filter." K240426 510(k) Summary. The filtered blood is returned to the patient via "a blood return circuit place[d] in the vasculature." WIPO Patent Application Publication No. WO 2023/205815 at ¶ [0194].

179. Use of the Accused Products further involves "coupling the second container to a second catheter at least partially positioned within the vasculature." For example, after the syringe has been filled with the filtered blood, the syringe may be decoupled from the filter assembly so that the "clinician can then return the filtered blood back to the patient" using a "suitable blood transfusion filter." K240426 510(k) Summary. The filtered blood is returned to the patient via "a blood return circuit place[d] in the vasculature." WIPO Patent Application Publication No. WO 2023/205815 at ¶ [0194].

180. Use of the Accused Products further involves "driving the filtered blood from the pressure source through the second catheter into the vasculature." For example, after the syringe has been filled with the filtered blood, the syringe may be decoupled from the filter assembly so that the "clinician can then return the filtered blood back to the patient" using a "suitable blood transfusion filter." K240426 510(k) Summary at 1. The filtered blood is returned to the patient via "a blood return circuit place[d] in the vasculature." WIPO Patent Application Publication No. WO 2023/205815 at ¶ [0194].

181. Inquis has had knowledge of the '332 Patent and Inquis' infringement since receiving Inari's cease and desist letter and/or the filing of this Complaint. To the extent Inquis

continues its infringing activities and inducing infringement after the filing of this Complaint, such post-filing inducement and infringement is intentional and with knowledge of the '332 Patent and infringement thereof.

182. With respect to 35 U.S.C. § 287, the '332 Patent includes only method claims, and thus imposes no marking requirement.

183. Inquis' infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

184. Inquis' infringement of the '332 Patent has been and continues to be willful and deliberate at least since receiving Inari's cease and desist letter and/or the filing of this Complaint, entitling Inari to an award of treble damages and attorneys' fees pursuant to 35 U.S.C. §§ 284-285.

SIXTH CAUSE OF ACTION

Infringement of U.S. Patent No. 11,974,909

185. Inari realleges and incorporates by reference, as if fully set forth herein, each of the allegations set forth above.

186. The '909 Patent is titled "System for treating embolism and associated devices and methods." The '909 Patent discloses improved systems and methods for removing clot material from a blood vessel of a human patient via a catheter intravascularly positioned within a blood vessel including by fluidly coupling the catheter to a pressure source via a valve or other fluid control device positioned outside the patient and applying a vacuum to the catheter via the pressure source to aspirate at least a portion of the clot material from the blood vessel. *See* Ex. C at 2:45-46, 4:17-33.

187. Inquis directly infringes—literally and/or under the doctrine of equivalents—one or more claims of the '909 Patent by making, using, selling, offering for sale, and/or importing

into the United States the Accused Products. As evidenced below and in the exemplary claim chart attached as Exhibit G, use of the Accused Products together practices each limitation of at least claim 1 of the ’909 Patent. In addition, as described above, Inquis worked in close association with at least one doctor who uses the Accused Products. On information and belief, Inquis employed doctors, or has directed or controlled the actions of doctors, or has acted as part of a joint enterprise with doctors, in the use of the Accused Products in an infringing way during development and/or testing of the Accused Products.

188. To the extent Inquis contends another entity (e.g., the doctors working with Inquis) perform one or more of the claimed method steps, Inquis infringes the ’909 Patent jointly and/or vicariously. Inquis engages or participates in a joint enterprise and/or collective conduct of making, using, offering to sell, selling, and/or importing of the Accused Products with at least one or more subsidiaries and affiliates, customers, and/or other third parties. On information and belief, Inquis provides the direction and/or control of one or more different parties. The infringing acts of subsidiaries, affiliates, customers and other third parties are attributable to Inquis.

189. In addition, as evidenced below and in the exemplary claim chart attached as Exhibit G, Inquis has induced infringement of one or more of the claims of the ’909 Patent by encouraging direct infringement by its customers (e.g., hospitals and/or physicians). Specifically, operation of the Accused Products together directly infringes one or more method claims of the ’909 Patent. By selling the Accused Products and, on information and belief, providing instructions regarding how to use those Accused Products, Inquis has induced its customers to directly infringe the ’909 Patent. Inquis has done so with the knowledge that its actions have encouraged direct infringement by its customers. Inquis specifically intended and was aware that the ordinary and customary use of the Accused Products would infringe the ’909 Patent.

190. Inquis has also engaged in contributory infringement by, on information and belief, offering to sell, selling, and/or importing into the United States the Accused Products (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of claims of the '909 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

191. Use of the Accused Products together practices each limitation of at least claim 1 of the '909 Patent.

192. Claim 1 of the '909 Patent recites:

> 1. The A [sic] method for the treatment of clot material within a vasculature of a patient, the method comprising:
>
> positioning an aspiration catheter at least partially within the vasculature proximate to the clot material, wherein a lumen of the aspiration catheter is fluidly coupled along a flow path to a clot canister and an aspiration source proximal of the clot canister;
>
> with a valve positioned along the flow path between the aspiration catheter and the clot canister in a closed position, generating vacuum pressure within the clot canister via the aspiration source;
>
> moving the valve to an open position to apply the vacuum pressure to the lumen of the aspiration catheter to aspirate at least a portion of the clot material and blood into the clot canister, wherein the clot canister includes a filter configured to filter the blood from the portion of the clot material;
>
> receiving the filtered blood through a fluid outlet of the clot canister; and
>
> reintroducing the filtered blood into the vasculature of the patient.

193. The Aventus Thrombectomy System "is a catheter-based manual aspiration system designed for minimally invasive removal of emboli and thrombi from the peripheral vasculature[.]" K232730 510(k) Summary. "The Aventus Clot Management System is indicated

for use with the Aventus Thrombectomy System for autologous blood transfusion." K240426 510(k) Summary. Thus, to the extent the preamble of claim 1 is construed to be limiting, use of the Accused Products together involves "[a] method for the treatment of clot material within a vasculature of a patient[.]"

194. Use of the Aventus Thrombectomy System practices "positioning an aspiration catheter at least partially within the vasculature proximate to the clot material, wherein a lumen of the aspiration catheter is fluidly coupled along a flow path to a clot canister and an aspiration source proximal of the clot canister[.]" For example, Inquis' patents and patent applications describe "[a] method of removing material from the vascular anatomy . . . comprising . . . advancing a distal section of a catheter . . . adjacent to unwanted material," *i.e.*, a clot, "within vascular anatomy." U.S. Patent No. 11,376,028 at 6:63-67. Inquis' patents and applications further describe a catheter that is fluidically coupled to a "vacuum source 3221," *i.e.*, an aspiration source, and a "clot canister 3325." *See, e.g.*, WIPO Patent Application Publication No. WO 2023/205815 at ¶ [0200].

195. Moreover, "[t]here is an on/off valve 3213 on the aspiration line [3211]" "that connects to an aspiration catheter" and the lumen thereof. WIPO Patent Application Publication No. WO 2023/205815 at ¶¶ [0200]-[0201], [0205]. As shown in the figure below, on/off valve 3213 fluidically couples the aspiration line and the lumen of the aspiration catheter to cannister 3225, which is itself coupled to vacuum source 3221 that is proximal of the clot canister. Accordingly, the lumen of the aspiration catheter, the clot canister 3325, and the vacuum source 3321 are fluidically coupled along a flow path.

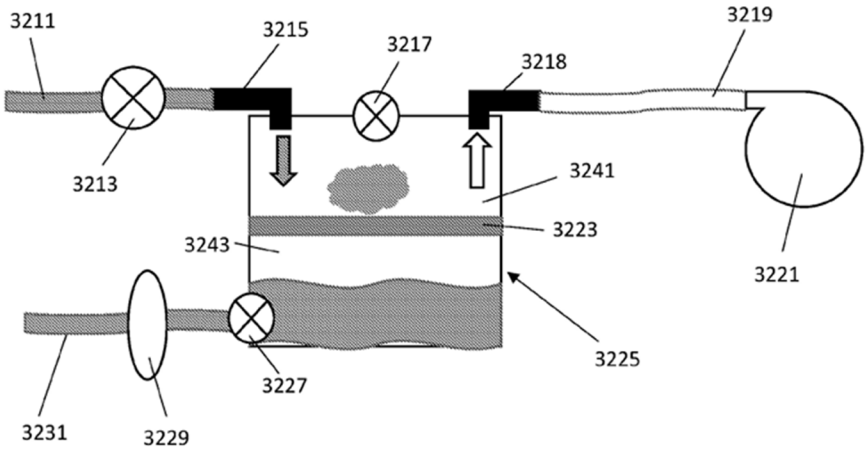


FIG. 32

WIPO Patent Application Publication No. WO 2023/205815 at Fig. 32.

196. On information and belief, the Accused Products embody the Inquis patents and patent applications cited herein, and the patents and patent applications thus evidence the features and functions of the Accused Products.

197. Use of the Accused Products together practices "with a valve positioned along the flow path between the aspiration catheter and the clot canister in a closed position, generating vacuum pressure within the clot canister via the aspiration source." For example, with on/off valve 3213 closed, use of the Accused Products includes "'charging' the cannister 3225 to a vacuum at the desired vacuum level (e.g., less than 1 atm)" via "vacuum source 3321." WIPO Patent Application Publication No. WO 2023/205815 at ¶ [0201].

198. Use of the Accused Products further practices "moving the valve to an open position to apply the vacuum pressure to the lumen of the aspiration catheter to aspirate at least a portion of the clot material and blood into the clot canister, wherein the clot canister includes a filter configured to filter the blood from the portion of the clot material." For example, after charging the canister and "[o]nce the aspiration catheter is positioned at a target site in the

vasculature, the aspiration valve 3313 may be opened, and fluid blood 3343 and thrombus material (clot material) 3344 may be drawn out of the vasculature through the aspiration catheter and aspiration line and into the canister." WIPO Patent Application Publication No. WO 2023/205815 at ¶ [0201]. Moreover, the clot canister includes a filter where "[c]lot material 3344 from the aspiration catheter may collect on the top of the aspiration filter (e.g., coarse filter) 3323, while fluids (e.g., blood 3343) may pass through the filter and collect in the bottom portion of the canister." *Id.*; *see also*:

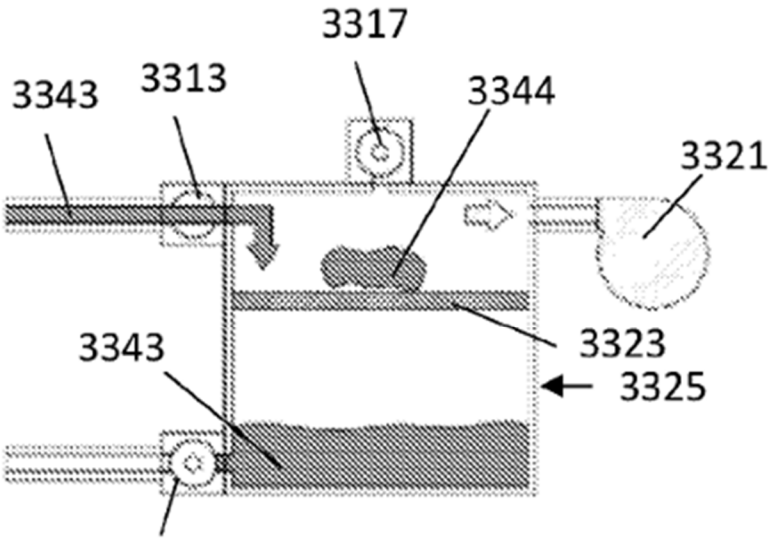


FIG. 33D

WIPO Patent Application Publication No. WO 2023/205815 at Fig. 33D.

199. Use of the Accused Products further practices "receiving the filtered blood through a fluid outlet of the clot canister." For example, once "the blood passes though the Clot Canister dual layer . . . filter" it "fil[s] a syringe preconnected to the female luer lock that is positioned below the filter assembly." K240426 510(k) Summary.

200. Finally, use of the Aventus Clot Management System practices "reintroducing the filtered blood into the vasculature of the patient." For example, once "the blood passes though [the

Accused Products'] Clot Canister dual layer . . . filter" it "fil[s] a syringe preconnected to the female luer lock that is positioned below the filter assembly." K240426 510(k) Summary. "The clinician can then return the filtered blood back to the patient." *Id.* The filtered blood is returned to the patient via "a blood return circuit place[d] in the vasculature." WIPO Patent Application Publication No. WO 2023/205815 at ¶ [0194].

201. Inquis has had knowledge of the '909 Patent and Inquis' infringement since receiving Inari's cease and desist letter and/or the filing of this Complaint. To the extent Inquis continues its infringing activities and inducing infringement after the filing of this Complaint, such post-filing inducement and infringement is intentional and with knowledge of the '909 Patent and infringement thereof.

202. With respect to 35 U.S.C. § 287, the '909 Patent includes only method claims, and thus imposes no marking requirement.

203. Inquis' infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

204. Inquis' infringement of the '909 Patent has been and continues to be willful and deliberate at least since receiving Inari's cease and desist letter and/or the filing of this Complaint, entitling Inari to an award of treble damages and attorneys' fees pursuant to 35 U.S.C. §§ 284-285.

SEVENTH CAUSE OF ACTION

Infringement of U.S. Patent No. 11,986,382

205. Inari realleges and incorporates by reference, as if fully set forth herein, each of the allegations set forth above.

206. The '382 Patent is titled "System for treating embolism and associated devices and methods." The '382 Patent discloses improved systems and methods for removing clot material

from a blood vessel of a human patient via a catheter intravascularly positioned within a blood vessel including by fluidly coupling the catheter to a pressure source via a valve or other fluid control device positioned outside the patient and applying a vacuum to the catheter via the pressure source to aspirate at least a portion of the clot material from the blood vessel. *See* Ex. D at 2:45-46, 4:17-34.

207. Inquis directly infringes—literally and/or under the doctrine of equivalents—one or more claims of the '382 Patent by making, using, selling, offering for sale, and/or importing into the United States the Accused Products. As evidenced below and in the exemplary claim chart attached as Exhibit H, use of the Accused Products together practices each limitation of at least claim 1 of the '382 Patent. In addition, as described above, Inquis worked in close association with at least one doctor who uses the Accused Products. On information and belief, Inquis employed doctors, or has directed or controlled the actions of doctors, or has acted as part of a joint enterprise with doctors, in the use of the Accused Products in an infringing way during development and/or testing of the Accused Products.

208. To the extent Inquis contends another entity (e.g., the doctors working with Inquis) perform one or more of the claimed method steps, Inquis infringes the '382 Patent jointly and/or vicariously. Inquis engages or participates in a joint enterprise and/or collective conduct of making, using, offering to sell, selling, and/or importing of the Accused Products with at least one or more subsidiaries and affiliates, customers, and/or other third parties. On information and belief, Inquis provides the direction and/or control of one or more different parties. The infringing acts of subsidiaries, affiliates, customers and other third parties are attributable to Inquis.

209. In addition, as evidenced below and in the exemplary claim chart attached as Exhibit H, Inquis has induced infringement of one or more of the claims of the '382 Patent by

encouraging direct infringement by its customers (e.g., hospitals and/or physicians). Specifically, operation of the Accused Products together directly infringes one or more method claims of the '382 Patent. By selling the Accused Products and, on information and belief, providing instructions regarding how to use those Accused Products, Inquis has induced its customers to directly infringe the '382 Patent. Inquis has done so with the knowledge that its actions have encouraged direct infringement by its customers. Inquis specifically intended and was aware that the ordinary and customary use of the Accused Products would infringe the '382 Patent.

210. Inquis has also engaged in contributory infringement by, on information and belief, offering to sell, selling, and/or importing into the United States the Accused Products (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of claims of the '382 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

211. Use of the Accused Products together practices each limitation of at least claim 1 of the '382 Patent.

212. Claim 1 of the '382 Patent recites:

> 1. A method of filtering clot material from blood, the method comprising:
>
> coupling a first syringe containing blood and clot material to a first connector of a filter device;
>
> coupling a second syringe to a second connector of the filter device;
>
> depressing a plunger of the first syringe to drive the blood and clot material into a chamber of the filter device; and
>
> withdrawing a plunger of the second syringe to draw the blood through a filter within the chamber of the filter device and into the second syringe, wherein the filter is sized to inhibit the clot material from passing therethrough.

213. The Aventus Thrombectomy System "is a catheter-based manual aspiration system designed for minimally invasive removal of emboli and thrombi from the peripheral vasculature[.]" K232730 510(k) Summary. "The Aventus Clot Management System is indicated for use with the Aventus Thrombectomy System for autologous blood transfusion." K240426 510(k) Summary. Thus, to the extent the preamble of claim 1 is construed to be limiting, use of the Accused Products together involves "[a] method of filtering clot material from blood[.]"

214. Use of the Accused Products practices "coupling a first syringe containing blood and clot material to a first connector of a filter device[.]" For example, the Accused Products include a "dual action manual syringe" that "directs aspirated blood and clot into the Clot Cannister." K240426 510(k) Summary. The Clot Cannister includes a "dual layer . . . polyester screen filter." K240426 510(k) Summary.

215. Use of the Accused Products further practices "coupling a second syringe to a second connector of the filter device." For example, in the Aventus Clot Management System, "blood passes through [the Accused Products'] Clot Cannister . . . filling a syringe pre-connected to the female luer lock that is positioned below the filter assembly." K240426 510(k) Summary.

216. Use of the Accused Products further practices "depressing a plunger of the first syringe to drive the blood and clot material into a chamber of the filter device." For example, "aspirant"—including blood and clot material—"is injected into the [Accused Products'] Clot Canister" via an "Aspiration Syringe." K240426 510(k) Summary.

217. Use of the Accused Products further practices "withdrawing a plunger of the second syringe to draw the blood through a filter within the chamber of the filter device and into the second syringe, wherein the filter is sized to inhibit the clot material from passing therethrough." For example, when using the Aventus Clot Management System, "blood passes through the Clot

Canister dual layer nominal 40µ/200µ polyester screen filter, filling a syringe pre-connected to the female luer lock that is positioned below the filter assembly." K240426 510(k) Summary. A person of ordinary skill in the art would understand that a 40µ/200µ polyester screen filter is sized to inhibit clot material from passing through. The syringe is filled "via negative pressure," *i.e.*, by withdrawing the syringe's plunger. *Id.* at 2.

218. Inquis has had knowledge of the '382 Patent and Inquis' infringement since receiving Inari's cease and desist letter and/or the filing of this Complaint. To the extent Inquis continues its infringing activities and inducing infringement after the filing of this Complaint, such post-filing inducement and infringement is intentional and with knowledge of the '382 Patent and infringement thereof.

219. With respect to 35 U.S.C. § 287, the '382 Patent includes only method claims, and thus imposes no marking requirement.

220. Inquis' infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

221. Inquis' infringement of the '382 Patent has been and continues to be willful and deliberate at least since receiving Inari's cease and desist letter and/or the filing of this Complaint, entitling Inari to an award of treble damages and attorneys' fees pursuant to 35 U.S.C. §§ 284-285.

PRAYER FOR RELIEF

WHEREFORE, Inari requests the following relief:

A. A preliminary and permanent injunction enjoining Inquis and Inquis' officers, agents, servants, employees, attorneys and any other persons who are in active concert or participation with such persons:

a. from making, selling, using, offering for sale or importing the Accused Products;

b. from possessing, disclosing, or using in any manner any Inari confidential or trade secret information;

c. to return to Inari or destroy all confidential or trade secret Inari information in their possession and certify such return or destruction;

B. Judgment in favor of Inari and against Inquis on all claims;

C. An award of damages, including double damages under 18 U.S.C. § 1836(b)(3)(d) and Cal. Civ. Code § 3426.3(c) and pre- and post-judgment interest;

D. An award of damages, including lost profits, and no less than a reasonable royalty under 35 U.S.C. § 284, arising from such infringement;

E. An award of damages increased up to three times under 35 U.S.C. § 284 as a result of Inquis' willful infringement;

F. For punitive damages as permitted by law;

G. For an award of attorneys' fees and costs pursuant to 18 U.S.C. § 1836(b)(3)(d), Cal. Civ. Code § 3426.4 and 35 U.S.C. §§ 284-285;

H. For such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all claims so triable.

/s/ Kelly E. Farnan

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