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11
12 **IN THE UNITED STATES DISTRICT COURT**
13 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**
14 **SAN JOSE DIVISION**

15
16 INARI MEDICAL, INC.,
17
18 Plaintiff,
19 v.
20 IMPERATIVE CARE, INC.,
21 Defendant.

Civil Action No. 5:24-cv-03117-EKL-
(SVKx)

**IMPERATIVE CARE, INC.’S
PRELIMINARY INVALIDITY
CONTENTIONS AND
DOCUMENT PRODUCTION
REGARDING U.S. PATENT NOS.
12,109,384 AND 12,156,669
PURSUANT TO PATENT LOCAL
RULES 3-3 AND 3-4**

1 Pursuant to Patent Local Rules (“PLR”) 3-3 and 3-4, the Court’s Case
2 Management & Scheduling Order (Dkt. #54), and the Court’s Order Granting
3 Joint Stipulation Setting Deadline (Dkt. #74), Defendant Imperative Care, Inc.
4 (“Imperative Care”) provides these Supplemental Preliminary Invalidity
5 Contentions as to the asserted claims of U.S. Patent Nos. 12,109,384 (“the ’384
6 Patent”) and 12,159,669 (“the ’669 Patent) (collectively with the patents
7 addressed in Imperative Care’s first set of Preliminary Invalidity Contentions,
8 “the Asserted Patents”).

9 I. GENERAL STATEMENTS

10 These preliminary contentions are based on information reasonably
11 available to Imperative Care at this time, are necessarily preliminary, and may
12 require subsequent amendment, alteration and/or supplementation. Accordingly,
13 Imperative Care reserves the right to amend, alter and/or supplement these
14 contentions based on further investigation, fact or expert discovery, evaluation
15 of the scope and content of the prior art, any claim construction from the Court,
16 or as a result of Stryker/Inari’s contentions. These contentions may be in the
17 alternative and do not constitute any concession by Imperative Care for
18 purposes of claim construction or non-infringement. *See* Fed. R. Civ. P. 8(d).

19 Furthermore, these preliminary contentions are provided without
20 prejudice to Imperative Care’s right to introduce at trial any subsequently
21 discovered evidence or expert opinions relating to currently known facts and to
22 produce and introduce at trial all evidence, whenever discovered, relating to the
23 proof of subsequently discovered facts. Moreover, facts, documents, and things
24 now known may be imperfectly understood and, accordingly, such facts,
25 documents, and things may not be included in the following contentions.
26 Imperative Care reserves the right to refer to, conduct discovery with reference
27 to, or offer into evidence at the time of trial, any and all facts, expert opinion
28 testimony, documents and things notwithstanding the written statements herein.

1 Imperative Care further reserves its right to refer to, conduct discovery with
2 reference to, or offer into evidence at the time of trial, any and all facts,
3 documents and things that are not currently recalled but might be recalled at
4 some time in the future.

5 The information set forth below is provided without waiving Imperative
6 Care's right to (1) object to the use of any statement for any purpose, in this
7 action or any other action, on the grounds of privilege, relevance, materiality or
8 any other appropriate grounds; (2) object to any request involving or relating to
9 the subject matter of the statements herein; or (3) revise, correct, supplement or
10 clarify any of the statements provided below at any time.

11 **A. Stryker/Inari's Identification of Asserted Claims**

12 In its Preliminary Disclosure of Asserted Claims and Infringement
13 Contentions, Stryker/Inari identified the following asserted claims: (1) claims 1-
14 7, and 9-15 of U.S. Patent Nos. 11,554,005 ("the '005 Patent"); (2) claims 1-7,
15 and 9 of U.S. Patent No. 11,697,011 ("the '011 Patent"); (3) claims 1-7, and 9
16 of U.S. Patent No. 11,697,012 ("the '012 Patent"); (4) claims 14-22 of U.S.
17 Patent No. 11,744,691 ("the '691 Patent"); (5) claims 1-3, 5-7, 9, and 10 of U.S.
18 Patent No. 11,844,921 ("the '921 Patent"); (6) claims 1-8, 12-17, and 19 of U.S.
19 Patent No. 11,865,291 ("the '291 Patent"); (7) claims 1-4, 6-12, 14-23, 25-31,
20 and 33-38 of U.S. Patent No. 11,969,333 ("the '333 Patent"); (8) claims 1-8, 11-
21 15, and 18-20 of U.S. Patent No. 11,974,910 ("the '910 Patent"); and (9) claims
22 1, 5, 6, 9-30, and 33-34 of U.S. Patent No. 12,016,580 ("the '580 Patent").

23 On February 7, 2025, Stryker/Inari filed a First Amended Complaint,
24 which withdrew the '011 Patent from the lawsuit and added two new asserted
25 patents, U.S. Patent Nos. 12,109,384 ("the '384 Patent") and 12,156,669 ("the
26 '669 Patent"). *See* Dkt. 68. Also on February 7, 2025, Stryker/Inari served
27 Imperative Care with a Supplemental Preliminary Disclosure of Asserted
28 Claims and Infringement Contentions. Stryker/Inari identified the following

1 asserted claims: (1) claims 1-4, 6-18, 20-30 of the '384 Patent; and (2) claims 1-
2 5, 8, 10-12, 14-19, 22, 24-28, and 30 of the '669 Patent. On February 27, 2025,
3 Imperative Care served Stryker/Inari with its Preliminary Invalidity
4 Contentions. Accordingly, these Preliminary Invalidity Contentions did not
5 address the '011 Patent. Imperative Care now serves its Supplemental
6 Preliminary Invalidity Contentions to address the asserted claims of the '384
7 Patent and the '669 Patent). *See* Dkt. 74 (granting leave to file Invalidity
8 Contentions on March 24, 2025).

9 **B. Claim Construction**

10 The Court has not yet construed the Asserted Claims. Nor have the
11 parties proposed any constructions of the Asserted Claims that may be in
12 dispute. Imperative Care's position on the invalidity of particular claims will
13 depend on how those claims are construed by the Court. Imperative Care
14 therefore reserves the right to identify additional prior art and/or to supplement
15 its disclosures or contentions in light of the Court's construction of the Asserted
16 Claims. These Preliminary Invalidity Contentions are based, at least in part, on
17 Imperative Care's present understanding of the Asserted Claims.

18 To the extent that these Preliminary Invalidity Contentions reflect
19 constructions of claim terms that may be consistent with or implicit in
20 Stryker/Inari's Preliminary Infringement Contentions, no inference is intended,
21 nor should any inference be drawn, that Imperative Care agrees with such claim
22 constructions. Imperative Care takes no position on any matter of claim
23 construction in these Preliminary Invalidity Contentions other than to allege that
24 certain claim terms are invalid as anticipated under 35 U.S.C. § 102, obvious
25 under 35 U.S.C. § 103, and/or are indefinite, not enabling and/or lacking written
26 description support under 35 U.S.C. § 112, as set forth below. Any statement
27 herein describing or tending to describe any claim element is provided solely for
28 the purpose of understanding the relevant prior art or other basis for invalidity.

1 Imperative Care expressly reserves the right to propose any claim construction it
2 considers appropriate and/or contest any claim construction it considers
3 inappropriate.

4 In part because claim construction has not been resolved, these
5 Preliminary Invalidity Contentions may be made in the alternative and are not
6 necessarily intended to be consistent with each other, and should be viewed
7 accordingly. Furthermore, Imperative Care's inclusion of prior art that would
8 render a claim anticipated or obvious based on a particular scope or construction
9 of the claim, including that apparently applied by Stryker/Inari in its Preliminary
10 Infringement Contentions, is not, and should in no way be seen as, an adoption
11 or admission as to the accuracy of such scope or construction. Imperative Care
12 reserves all rights to further supplement and/or modify the positions and
13 information in these Preliminary Invalidity Contentions, including without
14 limitation, the prior art and grounds of invalidity set forth herein, after the Court
15 has construed the Asserted Claims.

16 **C. Ongoing Discovery and Disclosures**

17 Discovery in this case is in its early stages and Imperative Care's
18 investigation, including Imperative Care's search for prior art, is ongoing. For
19 example, Imperative Care has served document subpoenas on several third
20 parties relating to prior art and those third parties have not yet produced
21 responsive documents. Imperative Care therefore reserves the right to further
22 supplement and/or alter the positions taken and information disclosed in these
23 Preliminary Invalidity Contentions including, without limitation, the prior art
24 and grounds of invalidity set forth herein, to take into account information or
25 defenses that may come to light as a result of these continuing efforts.

26 Moreover, because expert discovery has not started, Imperative Care
27 reserves the right to amend these Preliminary Invalidity Contentions as a result
28 of new information disclosed through the parties' experts. Therefore, Imperative

1 Care reserves all rights to further supplement and/or amend these Preliminary
2 Invalidity Contentions if and when further information becomes available.
3 Imperative Care also incorporates any invalidity expert reports that it serves in
4 the future, and any *inter partes* review filings related to the Asserted Claims.

5 **II. IDENTIFICATION OF PRIOR ART (PLR 3-3(A))**

6 Below, and in Appendices I-J, Imperative Care identifies the items of
7 prior art that anticipate one or more of the claims of the Asserted Patents under
8 35 U.S.C. § 102, and separately or in combination, render obvious one or more
9 of the claims of the Asserted Patents under 35 U.S.C. § 103. Imperative Care
10 further incorporates by reference, in full, all references cited in the following
11 prior art references and their prosecution histories, where applicable. The
12 citations provided below and in Appendices I-J are representative of the
13 references and are not exhaustive. To the extent that similar claim limitations
14 occur in one or more claims of the Asserted Patents, the disclosures below and
15 in Appendices I-J should be read to apply to all similar claim limitations.

16 Imperative Care intends to rely upon the prior art identified below and in
17 Appendices I-J to establish the scope and content of the prior art, a motivation
18 to combine or modify the prior art, that a person of ordinary skill in the art
19 would have had a reasonable expectation of success in combining the art, or
20 knowledge and level of skill of those of ordinary skill in the art. Imperative Care
21 also may rely on (1) non-prior art patents, patent applications or publications, or
22 other evidence (for example, the prosecution history files of U.S. and foreign
23 patent applications) that may not qualify as prior art under 35 U.S.C. § 102, and
24 (2) admissions made by Stryker/Inari and its employees or agents, for example
25 in the Asserted Patents or during prosecution of the Asserted Patents, to
26 establish these findings.

27 If and to the extent that they are prior art, Imperative Care reserves the
28 right to rely upon: (1) foreign counterparts of the U.S. Patents identified below;

1 (2) U.S. counterparts of foreign patents and foreign patent applications
2 identified below; (3) U.S. and foreign patents and patent applications
3 corresponding to articles and publications identified below; and (4) U.S. and
4 foreign patents and patent applications, articles, and publications corresponding
5 to items of prior art identified below. Imperative Case also reserves the right to
6 rely on any prior art cited or discussed in the prosecution histories of the
7 Asserted Patents or their related applications, as well as any patents and
8 applications, and any prior art produced by Stryker/Inari or a third party in this
9 action, or identified in any other action(s) involving one or more of the Asserted
10 Patents as a basis for contending that the claims are invalid.

11 Many of the references discussed herein are representative of additional
12 prior art references in the relevant field. Persons of ordinary skill in the art at
13 the time of the filing of the Asserted Patents would have reviewed the references
14 as a whole and in view of other publications, literature, and/or general
15 knowledge in the relevant field. Imperative Care may rely on all such
16 information, including other portions of the prior art references listed herein and
17 other publications and/or expert testimony to provide context to and to aid in
18 understanding and interpreting the listed references, and/or to establish that it
19 would have been obvious for a person of ordinary skill in the art to modify or
20 combine any of the cited references.

21 **A. Identification of Prior Art Patents and Printed Publications**

Number	Country of Origin	Date of Issue/Publication	Reference Name
2003/0225379	United States	Dec. 4, 2003	Schaffer
2003/0116731	United States	June 26, 2003	Hartley
9980813	United States	May 29, 2018	Eller
5429616	United States	July 4, 1995	Schaffer '616

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Number	Country of Origin	Date of Issue/Publication	Reference Name
2011/0144592	United States	June 16, 2011	Wong
2015/0173782	United States	June 25, 2015	Garrison
8734374	United States	May 27, 2014	Aklog
WO 2006/124307	United States	Nov. 23, 2006	Goff
6776770	United States	Aug. 17, 2004	Trerotola
2010/0042118	United States	Feb. 18, 2010	Garrison '118
8535283	United States	Sept. 17, 2013	Heaton
2005/0004534	United States	Jan. 6, 2005	Lockwood
2015/0352325	United States	Dec. 12, 2015	Quick
5938645	United States	Aug. 17, 1999	Gordon
2014/0296868	United States	Oct. 2, 2014	Garrison '868
7998104	United States	Aug. 16, 2011	Chang
8157760	United States	Apr. 17, 2012	Criado
6481439	United States	Nov. 19, 2002	Lewis
8075510	United States	Dec. 13, 2011	Aklog '510
WO 2018/019829	PCT	Feb. 1, 2018	Brady '829
2019/0239910	United States	Aug. 8, 2019	Brady '910
9216277	United States	Dec. 22, 2015	Myers
4723550	United States	Feb. 9, 1988	Bales
5895376	United States	Apr. 20, 1999	Schwartz
2016/0220741	United States	Aug. 4, 2016	Garrison '741
2017/0043066	United States	Feb. 16, 2017	Laub
11096712	United States	Aug. 24, 2021	Teigen

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Number	Country of Origin	Date of Issue/Publication	Reference Name
WO2014151209	PCT	Sept. 25, 2014	Grey
6719717	United States	Apr. 13, 2004	Johnson
7775501	United States	Aug. 17, 2010	Kees
20180338770	United States	Nov. 29, 2018	Mogi
11432835	United States	Sept. 6, 2022	Shaffer
8038704	United States	Oct. 18, 2011	Sherburne
6767353	United States	July 27, 2004	Shiber
20090287190	United States	Nov. 19, 2009	Shippert
11589880	United States	Feb. 28, 2023	Aklog '880
10383983	United States	Aug. 20, 2019	Aklog '983
10517617	United States	Dec. 31, 2019	Aklog '617
D744,639	United States	Dec. 1, 2015	Aklog '639
DE202006008306	Germany	July 27, 2006	DE '306

Publication Title	Date of Publication	Author/Publisher	Reference Name
The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism	Aug. 2008	Bose, A et al., 29 Am. J. Neuroradiol. 1409-1413	Bose
System of surgery v.2, 1895	1895	Dennis, F et al., Lea Brothers & Co.	Dennis

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Publication Title	Date of Publication	Author/Publisher	Reference Name
Thrombectomy Using Suction Filtration and Venovenous Bypass: Single Center Experience with a Novel Device	2015	Donaldson, C et al., Catheterization and Cardiovascular Interventions, 86:E81-E87	Donaldson
Utility of Thrombectomy in Primary Percutaneous Coronary Intervention	2013	Dragstedt, C et al., Intervent Cardiol Clin 2 (2013) 361-374	Dragstedt
Acute DVT: Are We Overtreating or Undertreating?	July 2018	Silver, M et al., Endovascular Today (Vol. 17, No. 7; pp. 84-87)	Silver
Use of a Modified Cardiopulmonary Bypass Circuit for Suction Embolectomy with the AngioVac Device	2017	Michelson, C et al., J Extra Coror Technol. 2017;49:299-303	Michelson
AngioVac Procedure: Treatment for Deep Venous Thrombosis	Feb. 2017	Zayed, M., Broadcast Med	Zayed
Successful management of acute massive pulmonary embolism using the Angiovac suction catheter technique in a hemodynamically unstable patient	2014	Pasha, A.K. et al., Cardiovascular Revascularization Medicine 15 (2014), 240-243	Pasha

Publication Title	Date of Publication	Author/Publisher	Reference Name
Catheter directed interventions for acute deep vein thrombosis	2016	Kohi, M et al., Cardiovasc Diagn. Ther., 2016;6(6):599-611	Kohi
Under Pressure: Comparison of Aspiration Techniques for Endovascular Mechanical Thrombectomy	May 2018	Nikoubashmanm O et al., AHNR Am J Neuroradiol 2017, 39:905-909	Nikoubashmanm

B. Physical Prior Art

The following summary of physical prior art is not meant to be comprehensive, and any quotations or citations provided herein are representative of the available printed materials associated with the physicals and are not exhaustive. Imperative Care has served third party subpoenas in this litigation to request additional information and samples relating to some of the physical prior art identified below. The third parties have not yet produced materials in response to those subpoenas. Imperative Care has done its best to identify the relevant information below based on information currently available to it but anticipates that it will update the information as discovery progresses. When the third parties produce the responsive information, Imperative Care will update these contentions as necessary.

Imperative Care reserves the right to rely on drawings or schematics of the listed physical products, other commercial versions of the listed products, any testing of the listed products, other similar products not specifically listed herein, and any combination of the listed products with any of the above-listed prior art patents or publications that a skilled artisan would have been motivated

1 to make as of the earliest priority date of the Asserted Patents.

Item Offered for Sale or Publicly Used or Known	Date the Offer or Use Took Place or the Information Became Known	Identity of the Person or Entity Which Made the Use or Which Made and Received the Offer	Person or Entity Which Made the Information Known or to Whom it was Made Known
Penumbra INDIGO System (+ Pump MAX; Canister)	July 22, 2015	Penumbra, Inc.	Penumbra Inc.; FDA 510(k) Clearance (K142870; K122756)
Penumbra INDIGO System (+ Aspiration Pump (ENGINE); Canister; CATRX	May 24, 2017	Penumbra, Inc.	Penumbra Inc.; FDA 510(k) Clearance (K163618; K180412)
AngioVac Cannula and Circuit	December 11, 2014	AngioDynamics, Inc.	AngioDynamics, Inc.; FDA 510(k) Clearance (AngioVac Brochure; AngioDynamics Patent Marking Page; K142607)
Gore DrySeal Flex introducer sheath	Aug. 31, 2016	Gore & Associates, Inc.	Gore & Associates, Inc. (Gore DrySeal Sheath – Vascular News)

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Item Offered for Sale or Publicly Used or Known	Date the Offer or Use Took Place or the Information Became Known	Identity of the Person or Entity Which Made the Use or Which Made and Received the Offer	Person or Entity Which Made the Information Known or to Whom it was Made Known
Merit VacLok (+VacLok AT)	July 27, 2017	Merit Medical Systems, Inc.	Merit Medical Systems, Inc.; FDA 510(k) Clearance (VacLok Negative Pressure Syringe Brochure; K163597)
Medtronic Export Catheter (AP; Advance; XT)	August 16, 2006	Medtronic, Inc.	Medtronic, Inc.; FDA 510(k) Clearance (Medtronic Export Aspiration Catheter IFU; Dragstedt; K100569)
Medtronic Affinity Pump	June 22, 2010	Medtronic, Inc.	Medtronic, Inc.; FDA 510(k) Clearance (K100631)
Enpath Medical Deflectable Catheter	May 19, 2005	Enpath Medical, Inc.	Enpath Medical, Inc.; FDA 510(k) Clearance (K043489)

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Item Offered for Sale or Publicly Used or Known	Date the Offer or Use Took Place or the Information Became Known	Identity of the Person or Entity Which Made the Use or Which Made and Received the Offer	Person or Entity Which Made the Information Known or to Whom it was Made Known
Enpath Medical Steerable Sheath	May 18, 2006	Enpath Medical, Inc.	Enpath Medical, Inc.; FDA 510(k) Clearance (K061119)
ENROUTE Transcarotid Neuroprotection System	Feb. 9, 2015	Silk Road Medical	Silk Road Medical; FDA 510(k) Clearance (ENROUTE Transcarotid NPS IFU 11858.E)
ANGIOJET ULTRA Thrombectomy System (Power Pulse Delivery)	Sept. 2015	Boston Scientific, Corporation	Boston Scientific Corporation (AngioJet Ultra Brochure PI-335503-AA)
Merit ASAP Aspiration Catheter (+ASAPLP; Kit)	Nov. 7, 2013	Merit Medical Systems, Inc.	Merit Medical Systems, Inc.; FDA 510(k) Clearance (K132155; K100569)
AXS Universal Aspiration Set (+ Dominant Flex Surgical Suction Pump)	June 2017	Stryker Corporation	Stryker Corporation (AXS Universal Aspiration Set Brochure)

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Item Offered for Sale or Publicly Used or Known	Date the Offer or Use Took Place or the Information Became Known	Identity of the Person or Entity Which Made the Use or Which Made and Received the Offer	Person or Entity Which Made the Information Known or to Whom it was Made Known
Inari ClotTrievers	Fe. 16, 2017	Inari Medical, Inc.	Inari Medical, Inc.; FDA 510(k) Clearance (K163549, K180329)
Inari Retraction Aspirator (+ FlowTrievers Retrieval/Aspiration System)	Aug. 25, 2015	Inari Medical, Inc.	Inari Medical, Inc.; FDA 510(k) Clearance (K152097; Triever20 IFU)
INVATEC Diver C.E. Max	2013	Carl A. Dragstedt, DO; Anthony A. Bavry, MD, MPH	Elsevier; Carl A. Dragstedt, DO; Anthony A. Bavry, MD, MPH (INVATEC Diver C.E. Max Brochure; Dragstedt)
Pronto V3 Extraction Catheter	Dec. 14, 2006	Vascular Solutions, Inc.	Vascular Solutions, Inc.; FDA 510(k) Clearance (K063371; Dragstedt)

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Item Offered for Sale or Publicly Used or Known	Date the Offer or Use Took Place or the Information Became Known	Identity of the Person or Entity Which Made the Use or Which Made and Received the Offer	Person or Entity Which Made the Information Known or to Whom it was Made Known
Fairmont Medical Disposable Orthopaedic Suction Set	February 5, 2016	Fairmont Medical Products	Fairmont Medical Products (IFU)

1 **III. INVALIDITY BASED ON 35 U.S.C. §§ 102-103 (PLR 3-3(B))**

2 Imperative Care contends the Asserted Claims are invalid under at least
3 35 U.S.C. §§ 102 and 103. Exemplary prior-art citations and statements
4 explaining the invalidity of the Asserted Claims under 35 U.S.C. §§ 102 & 103
5 are specified in the following contentions and corresponding claim charts
6 (Appendices I-J). Imperative Care may rely on cited or uncited portions of the
7 prior art, other documents, and expert testimony to establish (1) the state of the
8 relevant art, (2) the general knowledge of one of skill in the art, and (3) that a
9 person of ordinary skill in the art would have been motivated to combine the
10 prior art so as to render the claim invalid as obvious.

11 Below, Imperative Case provides exemplary combinations of prior art
12 references and the motivation to combine such references for purposes of its
13 obviousness contentions. Such combinations are exemplary and not exhaustive.
14 Thus, the combinations below should not be construed to suggest that any
15 reference or sub-combination of references would not alone have rendered the
16 Asserted Claims obvious. Imperative Care reserves the right to rely on any
17 combination or combinations of the prior art references cited or otherwise
18 discussed in these contentions, including Appendices I-J. Furthermore, to the
19 extent that similar claim limitations occur in one or more claims, the contentions
20 below applied to a given claim should be read to apply to all similar claim
21 limitations, as should the corresponding prior art disclosures.

22 **C. Anticipation Under 35 U.S.C. § 102**

23 A claimed invention is not novel, and thus invalid as anticipated, if:

24 (1) the claimed invention was patented, described in a printed
25 publication, or in public use, on sale, or otherwise available to the
26 public before the effective filing date of the claimed invention; or

27 (2) the claimed invention was described in a patent issued under
28 section 151, or in an application for patent published or deemed
published under section 122(b), in which the patent or application,

1 as the case may be, names another inventor and was effectively
2 filed before the effective filing date of the claimed invention.

3 35 U.S.C. § 102(a). “Under 35 U.S.C. § 102 a claim is anticipated ‘if each and
4 every limitation is found either expressly or inherently in a single prior art
5 reference.’” *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1274 (Fed. Cir.
6 2010) (quoting *Celeritas Techs. Ltd. v. Rockwell Int’l Corp.*, 150 F.3d 1354,
7 1361 (Fed. Cir. 1998)).

8 **D. Obviousness Under 35 U.S.C. § 103**

9 35 U.S.C. § 103 states:

10 A patent for a claimed invention may not be obtained,
11 notwithstanding that the claimed invention is not identically
12 disclosed as set forth in section 102, if the differences between the
13 claimed invention and the prior art are such that the claimed
14 invention as a whole would have been obvious before the effective
15 filing date of the claimed invention to a person having ordinary
16 skill in the art to which the claimed invention pertains.
17 Patentability shall not be negated by the manner in which the
18 invention was made.

19 35 U.S.C. § 103.

20 Invalidity under 35 U.S.C. § 103 is a legal conclusion based on the
21 following factual inquiries: (1) the scope and content of the prior art; (2) the
22 differences between the prior art and the claims at issue; (3) the level of
23 ordinary skill in the art at the time when the invention was made; and (4) any
24 other evidence of obviousness or nonobviousness. *Graham v. John Deere Co. of*
25 *Kansas City*, 383 U.S. 1, 17–18 (1966); *see also TQ Delta*, 929 F.3d at 1360
26 (“Obviousness is a question of law based on underlying findings of fact.”)
27 (internal citation and quotations removed).

28 To determine the level or ordinary skill in the art, the relevant field of art
must be identified. Courts accomplish this by looking to “the nature of the
problem confronting the inventor.” *Verizon Servs. Corp. v. Cox Fibernet*

1 *Virginia, Inc.*, 602 F.3d 1325, 1338 (Fed. Cir. 2010) (quoting *Bancorp Servs.*,
2 *L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1375 (Fed. Cir. 2004)); *see also*
3 *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 666 (Fed. Cir. 2000) (“The
4 determination of the level of ordinary skill in the art is an integral part of the
5 Graham analysis.”). A person of ordinary skill in the identified art is presumed
6 to have knowledge of all pertinent prior art. *Custom Accessories, Inc. v. Jeffrey-*
7 *Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986). “A reference qualifies as
8 prior art for an obviousness determination under § 103 only when it is
9 analogous to the claimed invention.” *In re Klein*, 647 F.3d 1343, 1348 (Fed. Cir.
10 2011); *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986) (quoting *In re Wood*,
11 599 F.2d 1032, 1036 (C.C.P.A. 1979)); *see also In re Clay*, 966 F.2d 656, 659
12 (Fed. Cir. 1992) (“A reference is reasonably pertinent if, even though it may be
13 in a different field from that of the inventor’s endeavor, it is one which, because
14 of the matter with which it deals, logically would have commended itself to an
15 inventor’s attention in considering his problem.”).

16 As the United States Supreme Court held in *KSR Int’l Co. v. Teleflex Inc.*,
17 “[t]he combination of familiar elements according to known methods is likely to
18 be obvious when it does no more than yield predictable results.” 127 S. Ct.
19 1727, 1739 (2007). The Supreme Court further held that “[w]hen a work is
20 available in one field of endeavor, design incentives and other market forces can
21 prompt variations of it, either in the same field or a different one. If a person of
22 ordinary skill can implement a predictable variation, § 103 likely bars its
23 patentability. For the same reason, if a technique has been used to improve one
24 device, and a person of ordinary skill in the art would recognize that it would
25 improve similar devices in the same way, using the technique is obvious unless
26 its actual application is beyond his or her skill.” *Id.* at 1740.

27 Following the initial factual determinations, the legal test for obviousness
28 is a flexible inquiry focused on the objective reach of the claims. *See KSR Int’l*

1 *Co. v. Teleflex Inc.*, 550 U.S. 398, 415-16, 419 (2007) (“The combination of
2 familiar elements according to known methods is likely to be obvious when it
3 does no more than yield predictable results.”); *see also Indivior Inc. v. Dr.*
4 *Reddy’s Labs., S.A.*, 930 F.3d 1325, 1352 (Fed. Cir. 2019) (“obviousness
5 demands a more expansive and flexible approach”) (internal quotations and
6 citation removed). Importantly, obviousness must be evaluated as of the time of
7 invention so as not to improperly inject hindsight bias into the inquiry. *See*
8 *Graham*, 383 U.S. at 36 (instructing courts to “resist the temptation to read into
9 the prior art the teachings of the invention in issue” and “guard against slipping
10 into use of hindsight”) (quoting *Monroe Auto Equip. Co. v. Heckethorn Mfg. &*
11 *Supply Co.*, 332 F.2d 406, 412 (6th Cir. 1964)); *Para-Ordnance Mfg., Inc. v.*
12 *SGS Imps. Int’l, Inc.*, 73 F.3d 1085, 1087 (Fed. Cir. 1995) (“Obviousness may
13 not be established using hindsight . . .”).

14 A patent may be proved obvious under the “teaching, suggestion, or
15 motivation” (“TSM”) test “if some motivation or suggestion to combine the
16 prior art teachings can be found in the prior art, the nature of the problem, or the
17 knowledge of a person having ordinary skill in the art.” *KSR*, 550 U.S. at 407
18 (internal citation and quotation marks omitted). Conversely, “when the prior art
19 teaches away from combining certain known elements, discovery of a successful
20 means of combining them is more likely to be nonobvious.” *Id.* at 416 (citing
21 *United States v. Adams*, 383 U.S. 39, 51–52 (1966)).

22 An obviousness determination, however, does not require application of
23 the TSM test. Rather, the inquiry must also “take account of the inferences and
24 creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550
25 U.S. at 418–19. Moreover, a patent may be found obvious when the
26 combination of elements was obvious to try. *Id.* at 420.

27 When there is a design need or market pressure to solve a problem
28 and there are a finite number of identified, predictable solutions, a

1 person of ordinary skill has good reason to pursue the known
2 options within his or her technical grasp. If this leads to the
3 anticipated success, it is likely the product not of innovation but of
4 ordinary skill and common sense. In that instance the fact that a
5 combination was obvious to try might show that it was obvious
6 under § 103.

7 *Id.* at 421. Conversely, the obvious to try standard is not met when “the inventor
8 would have had to try all possibilities in a field unreduced by direction of the
9 prior art.” *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341, 1347
10 (Fed. Cir. 2009); *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)
11 (foreclosing an obvious to try analysis when the patentee simply “var[ies] all
12 parameters or tr[ies] each of numerous possible choices until [arriving] at a
13 successful result, where the prior art gave either no indication of which
14 parameters were critical or no direction as to which of many possible choices is
15 likely to be successful”); *see also Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952,
16 972–73.

17 A claimed invention can be obvious even if there is no teaching,
18 suggestion, or motivation for combining the prior art to produce that invention.
19 127 S. Ct. 1727, 1741 (2007). In view of the *KSR* decision, the U.S. Patent and
20 Trademark Office incorporated Examination Guidelines in the Manual of Patent
21 Examination Procedure (“MPEP”). Those Guidelines identify various rationales
22 for finding a claim obvious, including those based on other precedents. Those
23 rationales include:

- 24 • Combining prior art elements according to known methods to yield
25 predictable results;
- 26 • Simply substituting one known element for another to obtain predictable
27 results;
- 28 • Using a known technique to improve similar devices (methods or
products) in the same way;

- 1 • Applying a known technique to a known device (method or product)
2 ready for improvement to yield predictable results;
- 3 • Choosing from a finite number of identified, predictable solutions, with a
4 reasonable expectation of success;
- 5 • Using known work in one field of endeavor to prompt variations of such
6 work for use in either the same field or a different field based on design
7 incentives or other market forces if the variations would have been
8 predictable to one of ordinary skill in the art;
- 9 • Finding some teaching, suggestion, or motivation in the prior art that
10 would have led one of ordinary skill to modify the prior art reference or to
11 combine prior art reference teachings to arrive at the claimed invention.

12 MPEP § 2141.

13 Importantly, courts must consider all objective evidence of
14 nonobviousness (also called secondary factors or considerations)—such as
15 unexpected results, commercial success, long-felt need, licensing by
16 competitors, and failure of others—before making an obviousness
17 determination. *In re Cyclobenzaprine*, 676 F.3d 1063, 1075-76 (“[A] fact finder
18 . . . may not defer examination of the objective considerations until after the fact
19 finder makes an obviousness finding.”); *see also Tokai Corp. v. Easton Enters.,*
20 *Inc.*, 632 F.3d 1358, 1369–70 (Fed. Cir. 2011) (citing *Graham*, 383 U.S. at
21 17–18). Still, the burden of production is shifted to require the patentee to
22 produce evidence of nonobviousness, which may include objective evidence of
23 nonobviousness, “after the challenger has successfully made his prima facie
24 case demonstrating that the patent might be obvious.” *Novo Nordisk A/S v.*
25 *Caraco Pharm. Labs., Ltd.*, 719 F.3d at 1353. To this point, the Federal Circuit
26 has acknowledged that in some cases, evidence of secondary considerations
27 “simply cannot overcome a strong prima facie case of obviousness.” *Wyers v.*
28 *Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010).

1 **E. Exemplary Invalidity Grounds**

2 Below, Imperative Care identifies (1) prior art that anticipates one or
3 more of the Asserted Claims and (2) exemplary combinations of prior art that
4 render the Asserted Claims obvious. The prior art combinations identified below
5 are not exhaustive; rather, they are illustrative examples of prior art
6 combinations using the prior art identified above. To the extent Stryker/Inari
7 contends any of the cited prior art fails to disclose one or more limitations of the
8 Asserted Claims, Imperative Care reserves the right to identify other prior art
9 references that, when combined with the other above prior art, would render the
10 claims obvious despite the allegedly missing limitation.

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Patent	Asserted Claim(s)	Basis of Invalidity	Applicable Prior Art
12 12,109,384	1, 3, 7, 9-10, 23-25	35 U.S.C. § 102	Schaffer
13	1-4, 6-18, 20-30	35 U.S.C. § 103	Schaffer alone or in 14 combination with Hartley and/or Eller
15 12,156,669	1-5, 8, 10-12, 14- 16 19, 22, 24-28, 30	35 U.S.C. § 103	Garrison in 17 combination with Aklog, Laub, Goff, 18 Schaffer, Hartley, and/or Eller

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20 **F. Level of Ordinary Skill in the Art**

21 The analyses presented herein are provided from the perspective of a
22 person having ordinary skill in the relevant art during the relevant time period.
23 The Asserted Patents generally claim two types of devices: a valve or an
24 aspiration system.

25 For the valve patents, a person of ordinary skill in the art would have had
26 an undergraduate degree in mechanical engineering or a related discipline and 2-
27 4 years of product design or engineering experience. For the aspiration system
28 patents, a person of ordinary skill in the art would have had an undergraduate

1 degree in mechanical engineering or a related engineering discipline and 2-4
2 years of catheter design experience.

3 Imperative Care reserves its right to evaluate Stryker/Inari's proposed
4 level of ordinary skill, if and when it is provided in this case, and to respond
5 accordingly. Likewise, Imperative Care reserves its right to modify these
6 contentions in view of Stryker/Inari's proposed level of ordinary skill, if and
7 when it is provided in this case.

8 **G. General Motivations to Combine Prior Art References**

9 The prior art references cited herein were within the field of the
10 patentee's endeavor or are at least reasonably pertinent to the field with which
11 the patentee was concerned, that is, valves for use during intravascular
12 procedures and devices for aspirating unwanted material from a patient.
13 Because the Asserted Patents simply arrange well-known elements found in the
14 prior art, with each performing the same function it had been known to perform
15 and yield no more than what one would expect from such an arrangement, the
16 combinations of prior art were obvious. *KSR*, 127 S. Ct. at 1742.

17 Further, in the prior art, there were well-recognized design needs and
18 market pressures to develop improved valves for use during intravascular
19 procedures and devices for aspirating unwanted material from a patient. Such
20 design needs and market pressures provide ample reason to combine prior art
21 elements in the manner combined. *KSR*, 127 S. Ct. at 1742. Moreover, because
22 there were a finite number of predictable solutions for the elements recited in
23 the Asserted Claims, a person of ordinary skill in the art had good reason to
24 pursue the known options. *Id.* Indeed, a person skilled in the art would have
25 been familiar with all the claim elements that the patentee used to distinguish
26 the prior art during prosecution. The above-identified prior art references merely
27 use those familiar elements for their primary or well-known purposes in a
28 manner well within the ordinary level of skill in the art. Accordingly, common

1 sense and the knowledge of the prior art render the claims invalid under either
2 35 U.S.C. § 102 or § 103.

3 Moreover, a person of ordinary skill would have perceived a reason to
4 combine the above prior art based on the nature of the problem to be solved, the
5 teachings of the prior art, and the knowledge of persons of ordinary skill in the
6 art. The identified prior art addresses the same or similar technical issues and
7 suggests the same or similar solutions to those issues. *See In re Inland Steel Co.*,
8 265 F.3d 1354, 1362 (Fed. Cir. 2001). Some of the prior art refers to or
9 discusses other prior art, illustrating the close technical relationship among the
10 prior art.

11 Therefore, for every prior art reference identified herein, it would have
12 been obvious to combine that prior art reference with any other prior art
13 reference identified above. It would also be obvious to combine that prior art
14 reference with any combination of the prior art references identified herein.
15 Exemplary combinations that Imperative Care relies upon are discussed in more
16 detail below.

17 **IV. INVALIDITY OF THE '384 PATENT**

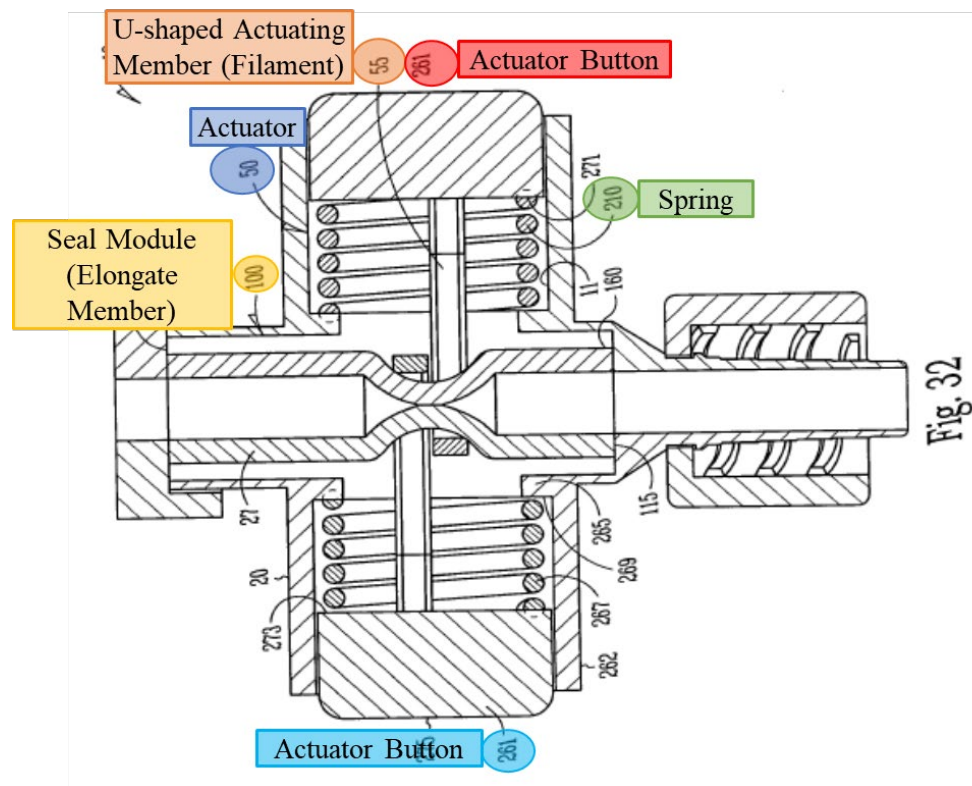
18 As set forth below, claims 1-4, 6-18, 20-30 of the '384 Patent are invalid
19 at least because they are anticipated under 35 U.S.C. § 102 by Schaffer, or
20 rendered obvious under 35 U.S.C. § 103 at least by Schaffer, alone or in
21 combination with Hartley and/or Eller. In addition to the invalidity arguments
22 described below, an exemplary claim chart is also attached hereto as Appendix
23 I, which identifies additional prior art references and disclosures that, when
24 combined with other prior art references identified therein, renders the Asserted
25 Claims of the '384 Patent obvious.

26 Imperative Care may rely on cited or uncited portions of the prior art,
27 other documents, and expert testimony to establish (1) the state of the relevant
28 art and (2) the general knowledge of one of skill in the art. Furthermore, to the

1 extent similar claim limitations occur in one or more claims, the disclosures
2 below applied to a given claim should be read to apply to all similar claim
3 limitations, as should the prior art descriptions above.

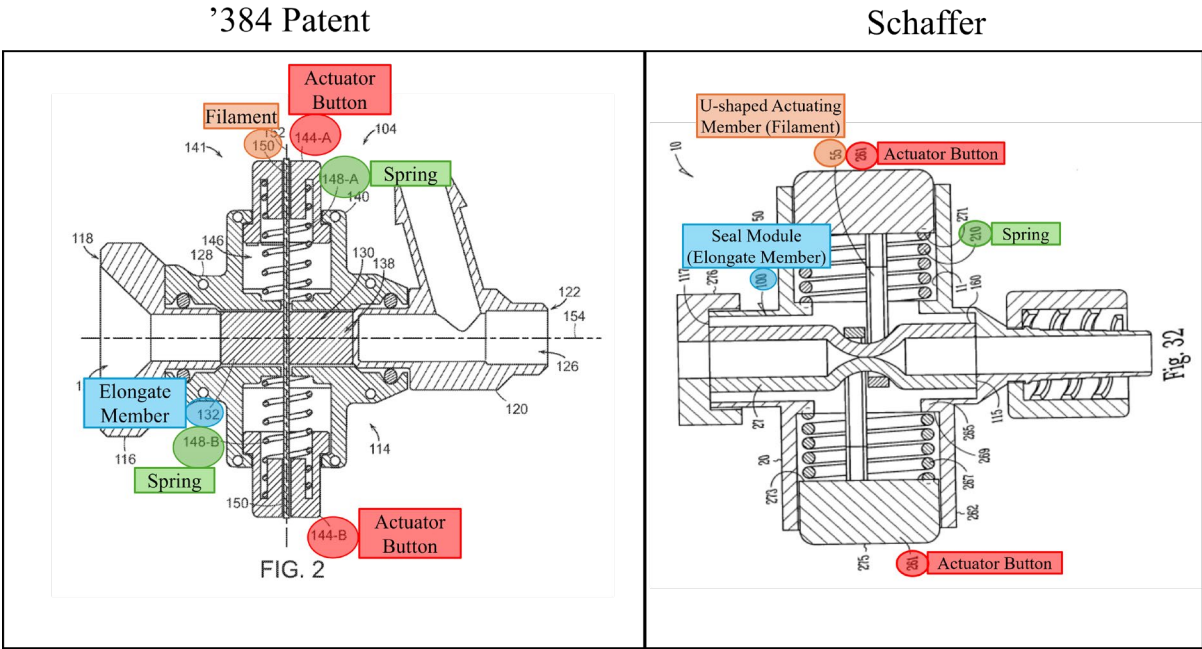
4 **A. Claims 1, 3, 7, 9-10, and 23-25 of the '384 Patent are Anticipated by**
5 **Schaffer**

6 Schaffer discloses a hemostasis valve for use during minimally invasive
7 intravascular procedures. Like the claimed valves, Schaffer's valve includes a
8 tubular member having a lumen, actuators (e.g., buttons) coupled to filaments,
9 and a biasing system (e.g., springs):



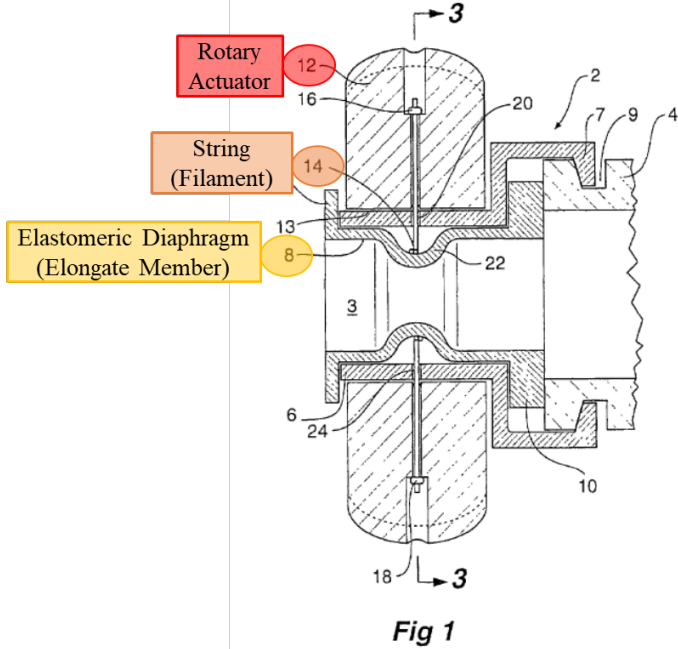
23 (Schaffer, Fig. 32.) As illustrated below, Schaffer's valve has the same
24 components, in the same arrangement, as the valve claimed in the '384 patent.
25 Thus, Schaffer anticipates or renders obvious the challenged claims.
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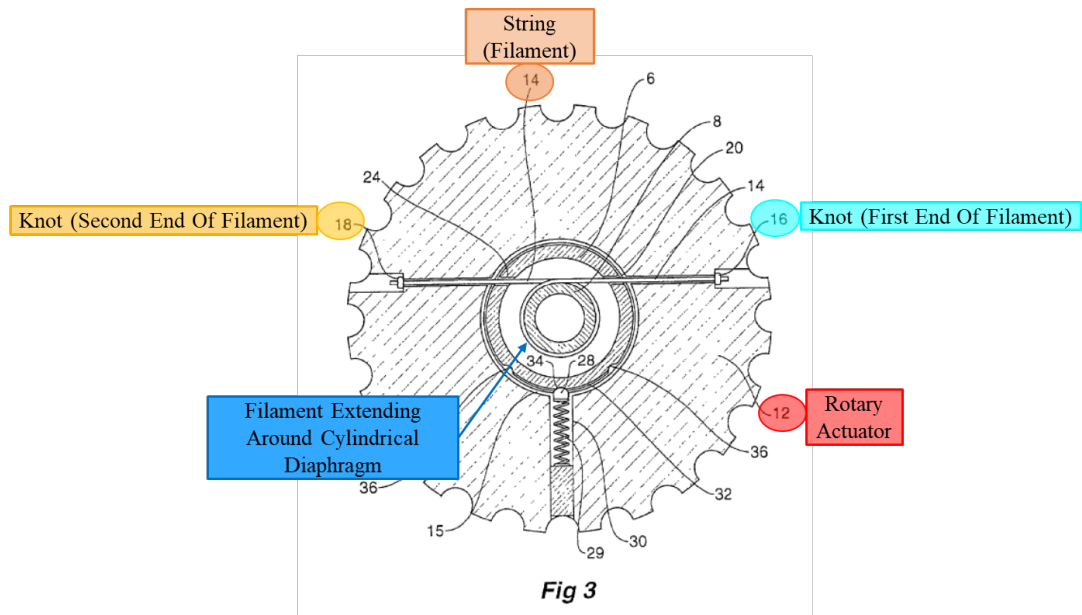
B. Claims 1-4, 6-18, and 20-30 of the '384 Patent are Obvious over Schaffer, alone or in combination with Hartley and/or Eller

Schaffer also renders claims 1-4, 6-18, and 20-30 of the '384 Patent obvious in combination with the "filaments" described in Hartley or Eller. Hartley discloses a hemostasis valve having a filament that constricts the lumen of an elongate member:



1 (Hartley, [0031], Fig. 3.) Hartley’s valve also includes a “string 14 ... mounted
2 into the rotary actuator.” (*Id.*) Hartley’s string 14 is a “filament” because the
3 string is made of at least one or more threads, lines, or cords.

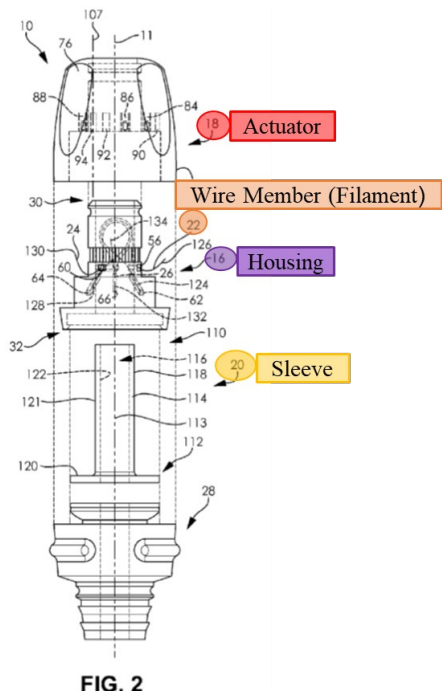
4 Hartley’s filament is attached to a rotary actuator that applies tension to
5 the filament. Rotation of the actuator in one direction constricts the lumen
6 while rotation in the opposition direction opens the lumen.



17 (Hartley, [0031], Fig. 3). Hartley discloses that “[r]otation of the rotary actuator
18 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled
19 in both directions at once and hence the cylindrical diaphragm 8 to be
20 constricted.” (*Id.*, [0031], [0034], Fig. 4.) Hartley further discloses that its valve
21 “will close over a range of diameters of devices passed through the valve or can
22 close completely down to be self sealing.” (*Id.*, [0037].)

23 Eller discloses a rotatable hemostasis valve like the valve disclosed in
24 Hartley. Eller’s hemostasis valve includes a filament that constricts an elongate
25 member to seal the valve:

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(Eller, 5:1-12, Fig. 2.)

To the extent Schaffer’s actuating members do not comprise “filaments,” a POSITA would have found it obvious to replace Schaffer’s actuating members with the filaments in Hartley or Eller. A POSITA would have found it obvious to substitute Hartley’s or Eller’s filaments for Schaffer’s actuating members. For example, the combination of Hartley’s string and Schaffer’s valve, or Eller’s wire member and Schaffer’s valve, would have merely entailed substitution of one known element (Hartley’s string or Eller’s wire member) for another (Schaffer’s actuating members) to yield the predictable result of constricting Schaffer’s valve to form a seal. *KSR*, 550 U.S. at 416.

Hartley’s disclosure that its string can “close over a range of diameters of devices passed through the valve or can close completely down to be self-sealing” would have further motivated POSITAs to substitute Hartley’s string for Shaffer’s actuating members. (Hartley, [0037].) POSITAs would have recognized that Hartley’s string may seal more effectively across a wider range of diameters and shapes for the inserted devices than Schaffer’s U-shaped

1 actuating members. Likewise, Eller's disclosure that the wire member can form
2 a seal around one or more medical devices passed through the valve would have
3 further motivated POSITAs to substitute Eller's wire member for Schaffer's
4 actuating members. (Eller, 15:21-40, 17:38-43, 18:3-8.)

5 POSITAs also had a finite number of materials to select from to constrict
6 a tubular member in a hemostasis valve in 2017. Hartley and Schaffer disclose
7 two such materials: Hartley's string and Schaffer's actuating members formed
8 from metal or plastic. Eller discloses a third option: one or more wire members.
9 A POSITA would have found it obvious to select from these finite, predictable
10 options and, as discussed below, would have had a reasonable expectation of
11 success in implementing them. *KSR*, 550 U.S. at 421

12 POSITAs would have had a reasonable expectation of success in
13 substituting Hartley's string for Schaffer's U-shaped actuating members.
14 Hartley teaches a simple method of attaching the string to the rotary actuator – a
15 knot at each end of the string. (Hartley, [0031].) POSITAs would have
16 reasonably expected that similar knots could be used to secure the ends of
17 Hartley's string to Schaffer's actuator buttons. For example, small holes could
18 be made in each of Schaffer's actuator buttons, and each end of the string could
19 be threaded through the hole and knotted on the other side. This simple
20 modification would have been within a POSITA's skills. In this arrangement,
21 the first end of the string would be secured to the first actuator button, the string
22 would loop at least once around Schaffer's seal module, and the second end of
23 the string would be secured to the second actuator button.

24 Also, POSITAs would have recognized that Hartley's string and
25 Schaffer's U-shaped actuating members function in similar ways and, therefore,
26 no other modifications to Schaffer's valve would be necessary. Hartley
27 collapses the valve lumen by pulling the ends of the string in opposite
28 directions. (Hartley, [0031].) Schaffer also collapses the valve lumen by

1 pulling the U-shaped actuating members in opposite directions. (Schaffer,
2 [0077].) Thus, if Hartley's string were incorporated into Schaffer's valve, a
3 POSITA would have reasonably expected Schaffer's springs to pull the ends of
4 the string in opposite directions in the first position, thereby causing the string to
5 constrict Schaffer's seal module. (*Id.*; Hartley, [0031].)

6 Further, Hartley discloses that looping the string around the central lumen
7 forms an effective seal. (Hartley, [0031], [0037].) Thus, when replacing
8 Schaffer's actuating members with Hartley's string, POSITAs would have been
9 motivated to loop Hartley's string around Schaffer's seal module. POSITAs
10 would have reasonably expected success in using this configuration because
11 Hartley discloses the configuration forms an effective seal.

12 A POSITA would have also reasonably expected that pressing Schaffer's
13 buttons inwardly (i.e., second position) would release the tension on the string,
14 causing the string to loosen around the seal module and allowing the lumen to at
15 least partially open. (*See* Schaffer, [0077]; Hartley, [0034].) Schaffer's seal
16 module is formed from a "highly deformable, non-compressible material 166
17 (e.g., plastic)" and is "configured to maintain an open lumen 193 when no
18 compressive force 67 is applied." (Schaffer, [0054].) A POSITA would have
19 reasonably expected Schaffer's seal module to have the resilience to return to its
20 open configuration when the tension on the string is released such that no
21 compressive force is applied to the seal. Moreover, if the resiliency of
22 Schaffer's lumen required adjustment to function with Hartley's string, a
23 POSITA would have possessed the skills and knowledge to select an
24 appropriate material with the proper resiliency. For example, Schaffer discloses
25 various materials for the seal module, including "modified vinyl, silicone,
26 polyurethane or a combination thereof." (Schaffer, [0081].) Similarly, Eller
27 discloses various materials for its sleeves, including "NuSil MED-4755, NuSil
28 MED-4765, and NuSil MED-4014." (Eller, 36:27-60.)

1 A POSITA also would have had a reasonable expectation of success in
2 substituting Eller's wire member for Schaffer's actuating members for several
3 reasons. First, Eller discloses that the "[a]ttachment between a wire member
4 and a housing and/or actuator can be accomplished using any suitable method or
5 technique." (Eller, 14:37-43.) Eller further identifies several means for
6 securing its wire member to an actuator, including "using adhesives, welding,
7 fusing, providing a friction fit between the wire member and the ... actuator."
8 (*Id.*, 14:43-49.) POSITAs would have reasonably expected success in securing
9 Eller's wire member to Schaffer's actuator buttons using one or more of these
10 simple methods. For example, the first end of the wire member would be
11 adhered or welded to the first actuator button, looped at least once around
12 Schaffer's seal module, and the second end of the wire member would be
13 adhered or welded to the second actuator button.

14 Second, Eller discloses that its wire member may be used with "any
15 suitable actuator capable of moving the selective fluid barrier valve device
16 between a first configuration and a second configuration" and that "[s]killed
17 artisans will be able to select a suitable actuator to include on a selective fluid
18 barrier valve device according to a particular embodiment based on various
19 considerations, including the number of wire members included in the selective
20 fluid barrier valve device and/or the structural arrangement of the housing."
21 (Eller, 8:27-39.) Eller discloses that suitable actuators include "rotatable
22 actuators, linear actuators, slidable actuators, pivotable actuators, levers, and
23 any other actuator considered suitable for a particular embodiment." (*Id.*, 8:39-
24 44 (emphasis added).) Given this disclosure, POSITAs would have reasonably
25 expected Eller's wire member to work with Schaffer's buttons, which are linear
26 and/or slidable actuators.

27 Third, Eller's wire member and Schaffer's U-shaped actuating members
28 function similarly to close the valves. Both Schaffer and Eller create a seal by

1 moving an actuator from a first position to a second position to constrict the seal
2 module/sleeve. (Schaffer, [0077]; Eller, 15:21-40, 17:47-18:3.) In both
3 devices, the actuators pull the wire/actuating members in opposite directions to
4 constrict/compress the valve's central lumen. (Schaffer, [0077], Eller, 15:21-40,
5 17:47-18:3.)

6 POSITAs would have recognized that Eller's wire member would
7 function like Schaffer's U-shaped actuating members. In the first position, the
8 springs coupled to Schaffer's actuator buttons would pull the ends of the wire
9 member in opposite directions, thereby causing the wire member to constrict the
10 lumen of Schaffer's seal module. (*See* Schaffer, [0077]; Eller, 15:21-40, 17:47-
11 18:3.) When Schaffer's actuator buttons are pressed inwardly, the tension on
12 the wire member would be relaxed, causing the wire member to loosen around
13 the seal module allowing the lumen to at least partially open. (*See* Schaffer,
14 [0077]; Eller, 15:21-40, 17:47-18:3.) Schaffer discloses that the seal module is
15 formed from a "highly deformable, non-compressible material 166 (e.g.,
16 plastic)" and is "configured to maintain an open lumen 193 when no
17 compressive force 67 is applied." (Schaffer, [0054].) Therefore, a POSITA
18 would have expected Schaffer's seal module to have the resilience to return to
19 its open configuration when "no compressive force [] is applied" to the lumen."
20 (*Id.*)

21 During prosecution of the '384 patent, the Examiner did not issue any
22 office actions or make any prior-art based rejections. However, in the Notice of
23 Allowance, the Examiner found that Hartley taught each limitation of the '384
24 Patent's independent claims except the "actuators is as a pair of actuators; a
25 second filament." (July 26, 2024, Notice of Allowance, 8.) The Examiner
26 never addressed whether a POSITA would have found it obvious to add a
27 second actuator and filament to Hartley. Yet, valves comprising multiple
28 actuators and filaments, such as that disclosed in Schaffer, were well-known by

1 September 2017.

2 Eller combines a torsion spring with a rotational actuator to bias the valve
3 toward the closed position. (Eller, 19:22-30.) A POSITA would have found it
4 obvious to combine Eller's torsion spring with Hartley's rotatable hemostasis
5 valve. In the Notice of Allowance, the Examiner found that Eller taught each
6 limitation of the '384 Patent's independent claims except "the actuator is as a
7 pair of the actuator". (July 26, 2024, Notice of Allowance, 9.) The Examiner
8 never addressed whether a POSITA would have add a second actuator to Eller.
9 Yet, valves comprising multiple actuators, such as that disclosed in Schaffer,
10 were well-known by September 2017.

11 Thus, for at least the reasons discussed above, claims 1-4, 6-18, 20-30 of
12 the '384 Patent are obvious over Schaffer, alone or in combination with Hartley
13 and/or Eller.

14 **V. INVALIDITY OF THE '669 PATENT**

15 As set forth below, claims 1-5, 8, 10-12, 14-19, 22, 24-28, and 30 of the
16 '669 Patent are invalid at least because they are rendered obvious under 35
17 U.S.C. § 103 at least by Garrison in combination with Aklog, Goff, Laub,
18 Schaffer, Hartley, and/or Eller. In addition to the invalidity arguments
19 described below, an exemplary claim chart is also attached hereto as Appendix
20 J, which identifies additional prior art references and disclosures that, when
21 combined with other prior art references identified therein, renders the Asserted
22 Claims of the '669 Patent obvious.

23 Imperative Care may rely on cited or uncited portions of the prior art,
24 other documents, and expert testimony to establish (1) the state of the relevant
25 art and (2) the general knowledge of one of skill in the art. Furthermore, to the
26 extent similar claim limitations occur in one or more claims, the disclosures
27 below applied to a given claim should be read to apply to all similar claim
28 limitations, as should the prior art descriptions above.

1 A. **Claims 1-5, 8, 10-12, 14-19, 22, 24-28, and 30 of the '669 Patent are**
2 **Obvious over Garrison in combination with Aklog, Goff, Laub,**
3 **Schaffer, Hartley, and/or Eller**

4 Claims 1-5, 8, 10-12, 14-19, 22, 24-28, and 30 of the '669 Patent are
5 directed to systems for the intravascular treatment of clot material within a
6 blood vessel. The claimed systems recite, *inter alia*, fluidly coupling along
7 fluid paths “a vacuum source”, “a catheter”, “a filter chamber”, “a flow
8 controller”, and “a hemostasis valve” that allows insertion of a catheter and
9 interventional device. ('669 Patent, Claims 1, 15). The asserted dependent
10 claims further identify limitations regarding: the fluid paths (e.g. claims 4, 11,
11 14, 25, 30), the flow controller (e.g. claims 2-3, 16-17), the filter chamber (e.g.
12 claims 8, 10, 18, 22, 24), the hemostasis valve (e.g. claims 12, 26-28), and the
13 interventional device (e.g. claims 5, 19).

14 Garrison, in combination with Aklog, Goff, Laub, Schaffer, Hartley,
15 and/or Eller render claims 1-5, 8, 10-12, 14-19, 22, 24-28, and 30 of the '669
16 Patent obvious. Garrison discloses an aspiration system for removing unwanted
17 material from a patient's vasculature. As illustrated below, Garrison's
18 aspiration system includes the same components required to practice the
19 methods recited in claim 1 (and corresponding dependent claims) of the '669
20 patent: a pressure source (e.g., pump or syringe) [red], an elongate member (e.g.
21 an aspiration catheter) [orange], a filter chamber [blue], hemostasis valves
22 [yellow], and a fluid control device (e.g. a valve) [purple].

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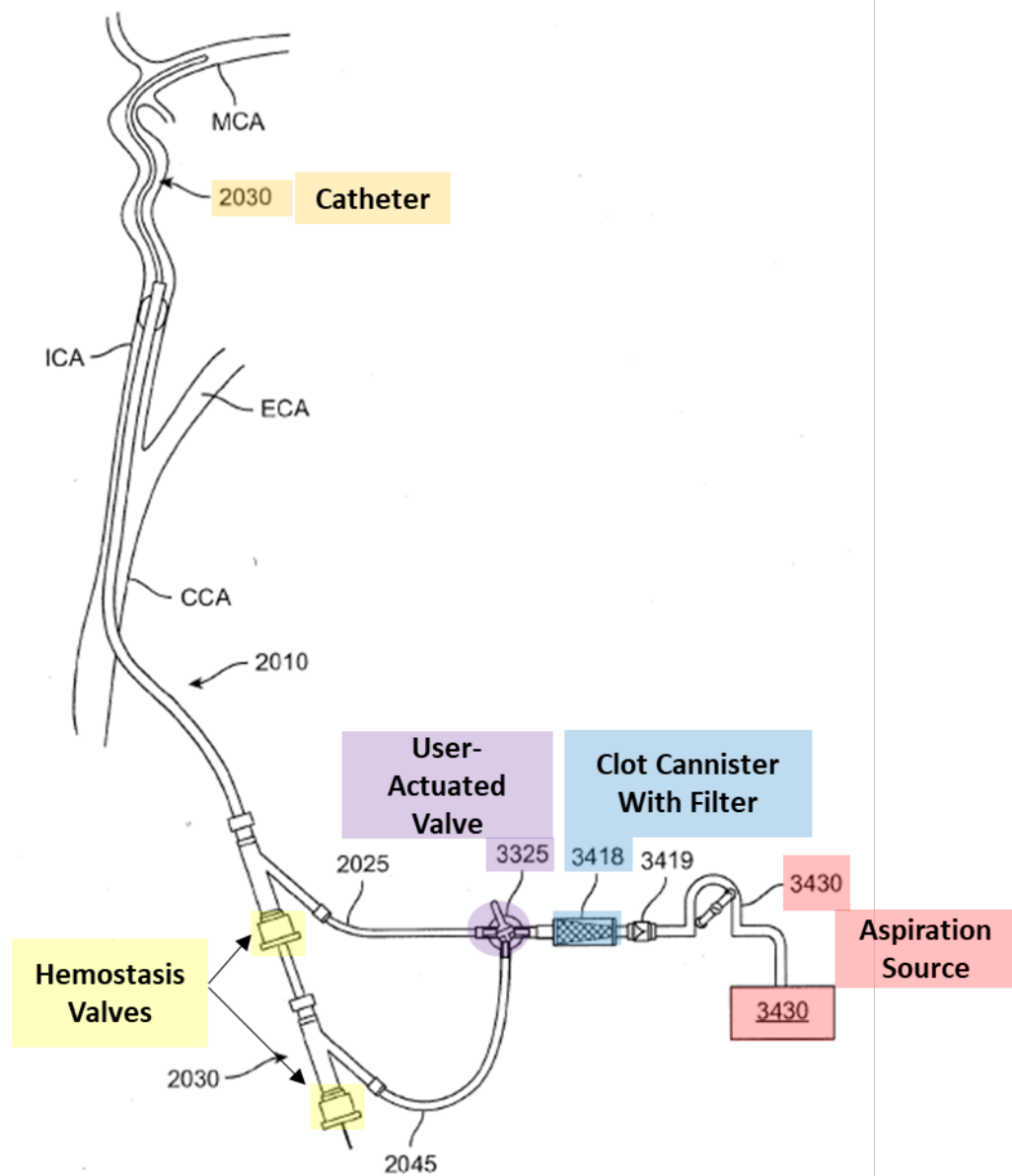


FIG. 34

(Garrison, Fig. 34.)

Aklog discloses an aspiration system for removing undesirable materials. (Aklog, 2:7-32.) Aklog's system has similar components to Garrison's system, including an aspiration source (e.g., pump or syringe) [red], an aspiration catheter [orange], a filter chamber [blue], and a hemostasis valve (described, but not illustrated below).

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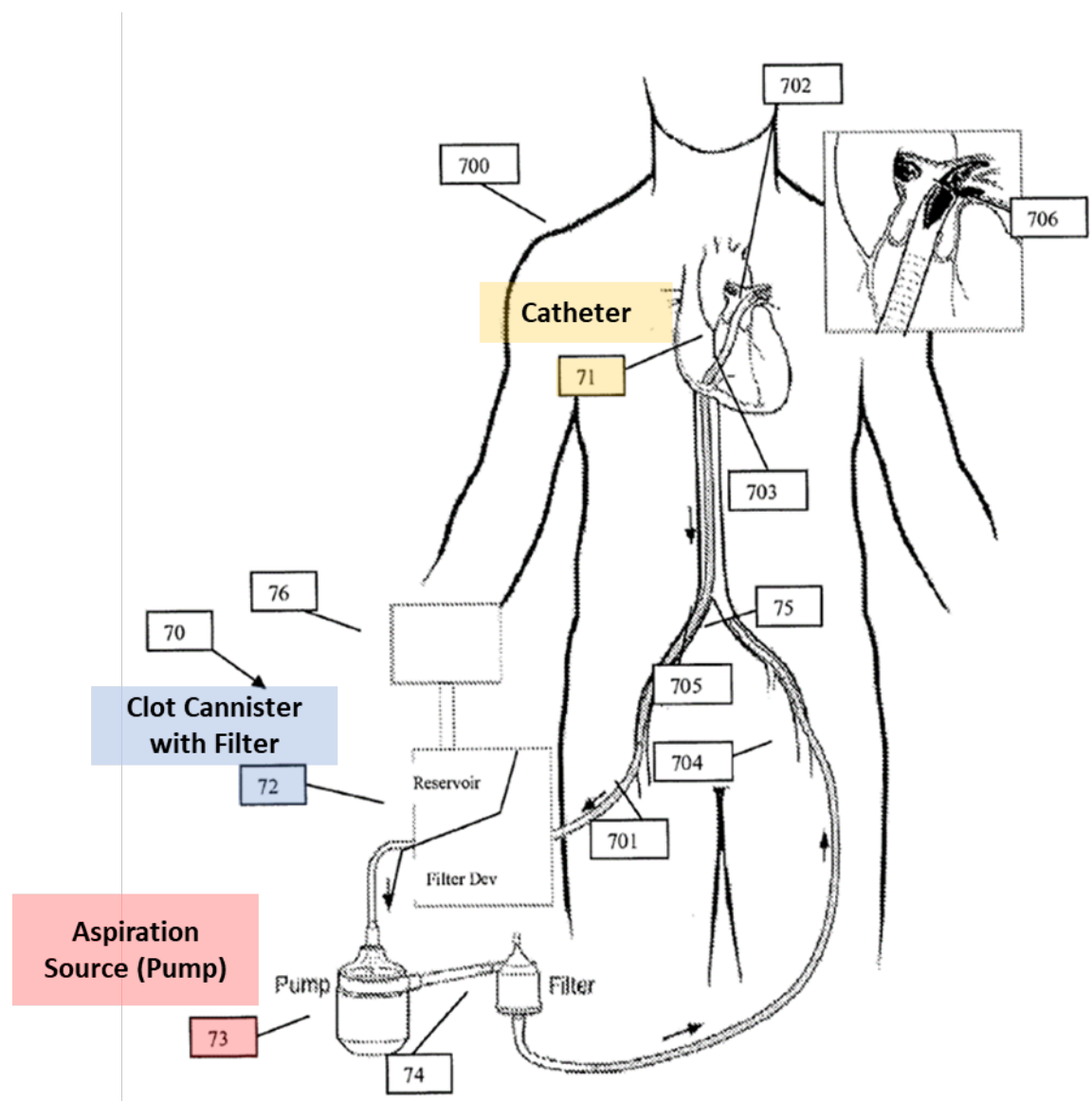


Fig. 7

(*Id.*, Fig. 7.)

Similarly, Laub discloses an aspiration system for removing “unwanted material such as emboli, thrombi, tumors, or debris” from a patient’s vasculature. (Laub, [0002].) Like Garrison, Laub’s clot treatment system includes an aspiration catheter connected to a pump (i.e., pressure source), working port (i.e., hemostasis valve), and a filter (i.e., filter chamber):

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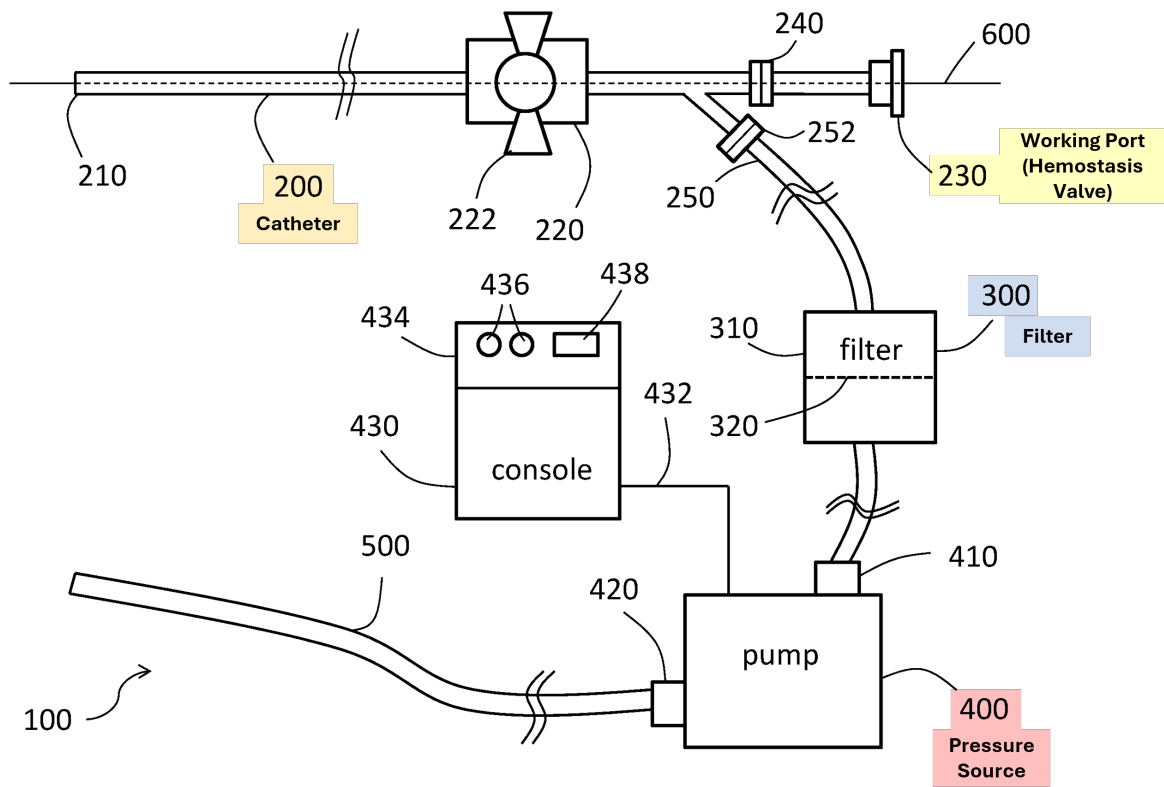
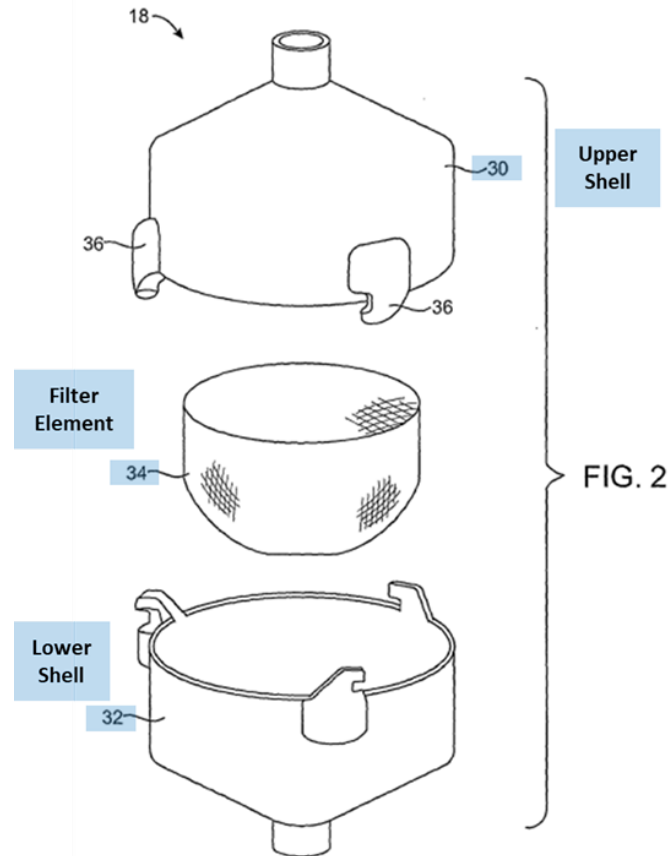


FIG. 1A

(*Id.* at ¶ [0024], Fig. 1A.)

The claims of the '669 Patent that recite the use of a “filter chamber” are also obvious over the prior art. For example, Garrison and Aklog both disclose clot cannisters that contain a filter. Laub discloses a filter “configured to trap solid material received through aspiration catheter”. (Laub, [0040].) Although these references do not expressly disclose removable filters (as recited in some of the dependent claims), aspiration systems having removable filters were well known by August 2018 simply because the clot may plug the filter or exceed the capacity of the filter chamber. Such clogging would bring an abrupt halt to this time sensitive procedure if the chamber could not be opened to empty the captured clot. Moreover, Goff discloses an aspiration system having a filter housing 18 to “remove solid materials from the aspirate.” (Goff, [0011].) The

1 “filter housing has an upper shell and a lower shell which may be taken apart to
2 permit introduction, *removal*, and replacement of the filter element in the
3 interior of the housing.” (*Id.*, [0015] (emphasis added).)

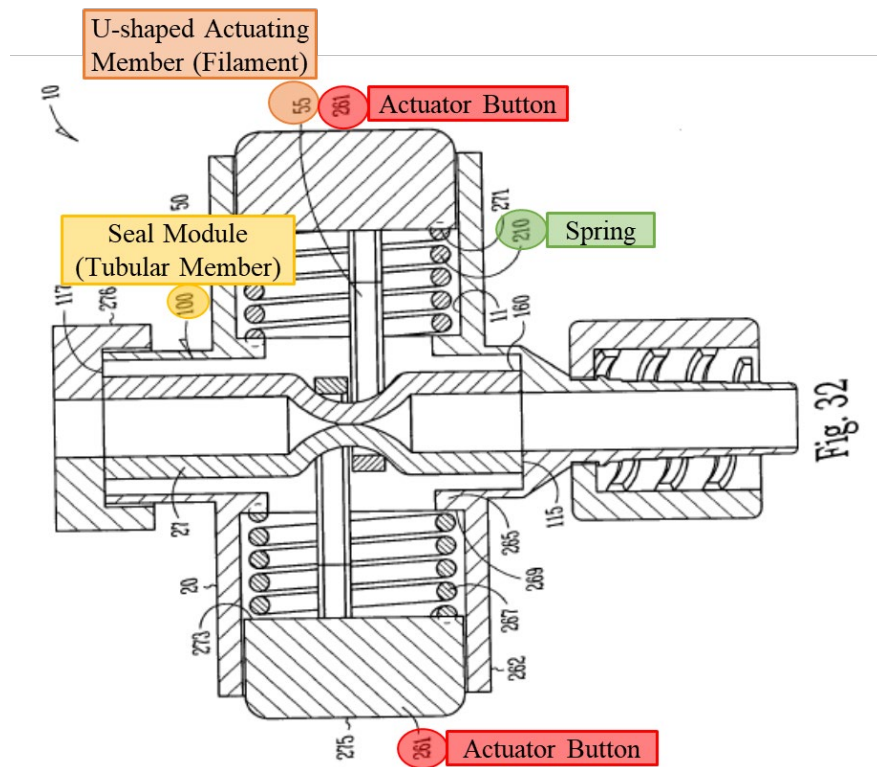


18 Goff further discloses that the “housing will further have conventional
19 connectors to permit connection at an upper end to the aspiration catheter and at
20 a lower end to the aspirate receptacle.” (*Id.*) The use of conventional
21 connectors, such as Luer-type connectors, means that the housing is removable.
22 As shown herein, a POSITA would have found it obvious to incorporate Goff’s
23 filter device into Garrison’s system or modify Garrison’s existing filter to make
24 the filter and housing removable as taught in Goff.

25 The dependent claims of the ’669 Patent that recite the use of a
26 hemostasis valve are also obvious over Garrison in combination with other prior
27 art. Garrison discloses several different hemostasis valves that can be
28 interchangeably used with its aspiration system including, for example, an

1 “adjustable-opening valve” or a “rotating hemostasis valve.” Garrison presumes
2 a person of ordinary skill in the art would have been familiar with the available
3 hemostasis valves and, therefore, does not describe their structures. However,
4 other prior art references do.

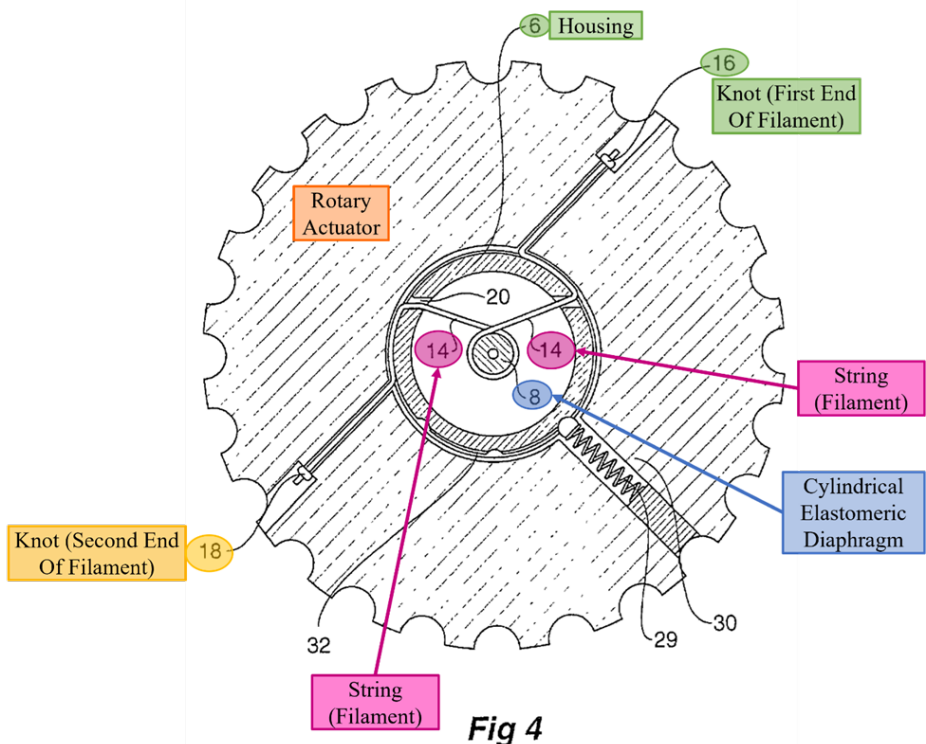
5 For example, Schaffer discloses an adjustable-opening hemostasis valve
6 for use during minimally invasive intravascular procedures. (Schaffer, [0002],
7 [0008].) Schaffer’s valve includes a tubular member that can slidably receive a
8 second catheter, a constricting mechanism including a filament, an actuator
9 coupled to the filament, and a biasing system (e.g., spring):



23 (*Id.*, Fig. 32.)

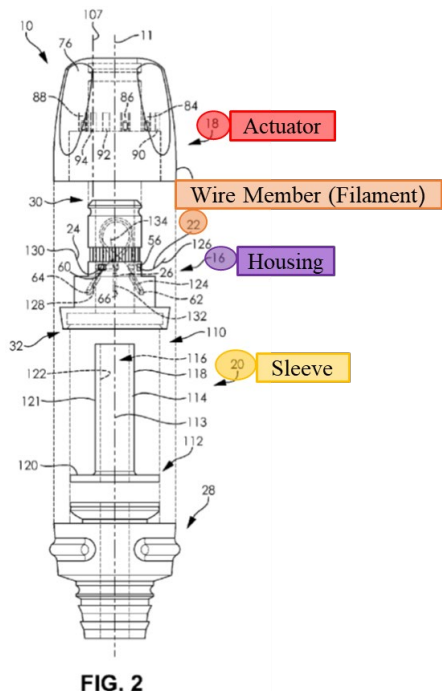
24 Hartley discloses the structure for a rotating hemostasis valve that
25 includes a filament extending around a tubular member to restrict the member
26 and close the valve:

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(Hartley, Fig. 4.)

Eller discloses a rotatable hemostasis valve like the valve disclosed in Hartley. Eller's hemostasis valve includes a filament that constricts an elongate member to seal the valve:



1 (Eller, 5:1-12, Fig. 2.) To the extent Schaffer’s actuating members do not
2 comprise “filaments,” a POSITA would have found it obvious to replace
3 Schaffer’s actuating members with the filaments in Hartley or Eller for the same
4 reasons discussed in connection with the ’384 Patent, above. Likewise, a
5 POSITA would have found it obvious to include a hemostasis valve, such as
6 that disclosed in Schaffer, Hartley, and/or Eller for the same reasons discussed
7 in connection with the ’005 Patent in Imperative Care’s Invalidation Contentions
8 served on February 27th, 2025.

9 The dependent claims of the ’669 Patent that recite an interventional
10 device are also obvious over Garrison, in combination with other prior art. For
11 example, Garrison discloses the use of a hemostasis valve “to allow introduction
12 of devices such as a microcatheter, guide wire, or thrombectomy device while
13 preventing or minimizing blood loss during the procedure.” (Garrison, [0098].)
14 Similarly, Laub discloses embodiments wherein a “working port” (i.e. a
15 hemostasis valve) “allows insertion of instruments into and/or through the
16 lumen of aspiration catheter” (Laub, [0035].)

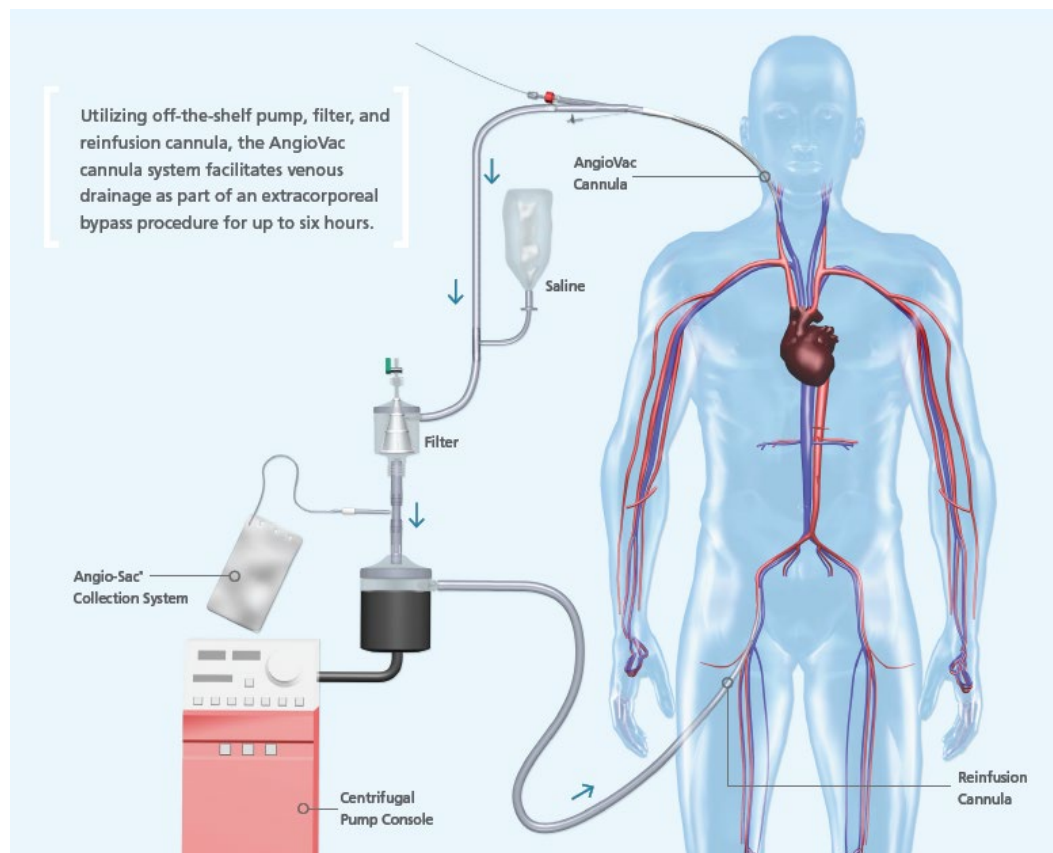
17 Thus, for at least the reasons discussed above, claims 1-5, 8, 10-12, 14-
18 19, 22, 24-28, and 30 of the ’669 Patent are obvious over Garrison, in
19 combination with Aklog, Goff, Laub, Schaffer, Hartley, and/or Eller.

20 **B. Alternative Obviousness Combinations that Render Claims 1-5, 8, 10-**
21 **12, 14-19, 22, 24-28, and 30 of the ’669 Patent Obvious**

22 The exemplary obviousness combination discussed above relies on
23 Garrison’s disclosure of an aspiration system, comprising fluidly connecting a
24 “vacuum source”, “catheter”, “filter chamber”, “flow controller”, and
25 “hemostasis valve” that allows insertion of a catheter and interventional device.
26 as recited in claims 1 and 15 of the ’669 Patent. However, the prior art is replete
27 with examples of clot treatment systems with similar components and methods.
28 Thus, to the extent Stryker/Inari contends Garrison does not disclose one or

1 more of these steps or elements, it would have been obvious to a person of
2 ordinary skill in the art to combine other prior art aspiration systems with
3 Garrison to achieve the claimed invention.

4 For example, Aklog discloses “systems and methods for removing
5 substantially en bloc clots, thrombi, and emboli, among others, from within
6 heart chambers, as well as medium to large vessels.” (Aklog, 1:17-24.) The
7 Aklog system, commercially released as the AngioVac system, shown below:



22 (AngioVac Brochure.)

23 Likewise, Laub discloses “a system for removing thrombi and other
24 unwanted material from the body of a patient, particularly from the patient’s
25 vasculature.” (Laub, [0005].) An embodiment of Laub is shown in the figure
26 below:

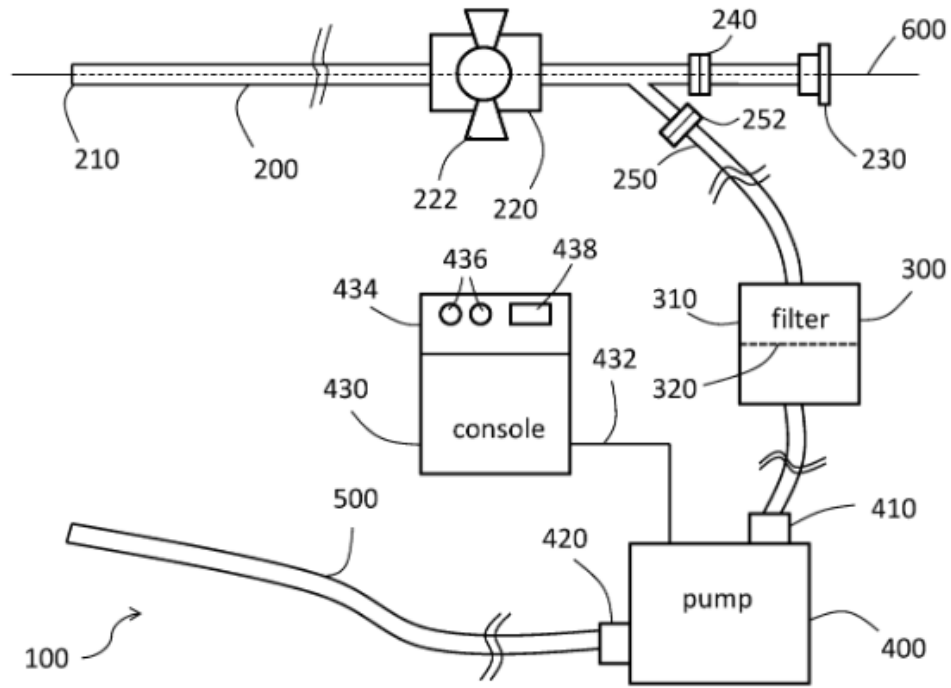
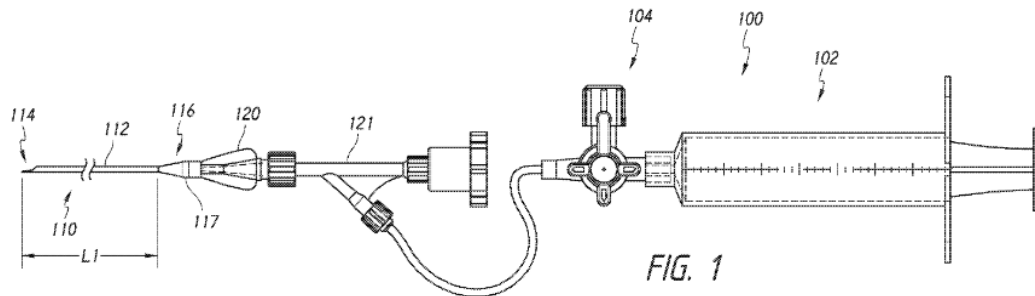


FIG. 1A

(Laub, Fig. 1A.) “In some embodiments ... fluid path 250 may optionally connect with aspiration catheter 200 via a separate connector (e.g., connector 252) which may allow detachment of fluid path 250 from aspiration catheter 200.” (Laub, [0039].)

In addition, Mogi discloses “an embodiment of an assistive jet aspiration catheter system 100 having a suction source 102 (which can be a Vaclok 30 cc syringe, a pump system such as a Penumbra™ pump, or otherwise), a stopcock or valve 104 to control the suction and flow of fluid through the system 100, and an assistive jet aspiration catheter 110 (also referred to herein as a assistive jet catheter and just an aspiration catheter).” (Mogi, [0154].) This embodiment is shown in the figure below:



(Mogi, Fig. 1.)

Moreover, several aspiration systems with similar components and employing similar methods, including the use of interventional devices in connection with aspiration-based thrombectomy procedures, were being sold well before the priority date of the '669 Patent, including AngioDynamic's AngioVac system (discussed above), Penumbra's Indigo Aspiration System, Medtronic's Export Aspiration Catheter, and even Stryker/Inari's own FlowTrievers and ClotTrievers systems.

In addition to Garrison, other references disclose the claimed "fluid control device" that can be closed to pre-charge a vacuum and opened to release the vacuum and aspirate the clot. For example, Mogi discloses "stopcock or valve 104 to control the suction and flow of fluid through the system 100." (Mogi, [0154].) Teigen discloses the use of valves to create a "pressure differential between the vacuum source and the catheter," which "results in a pressure pulse." (Teigen, 18:34-37.) Michelson discloses: "The AngioVac suction is initiated by the perfusionist removing the clamp from the inflow and venous line and opening the clamp to the bubble trap. This clamp placement provides a closed circuit allowing the centrifugal pump to provide the necessary suction for thrombus removal without the use of additional vacuum." (Michelson, 300.)

In addition to Garrison, other prior art references disclose the use of valves, such as hemostasis valves, to facilitate the insertion of treatment devices

1 into the system while minimizing blood loss. For example, Laub discloses
2 “working port 230 is configured to provide a fluid tight seal around stylet 700 or
3 other device inserted through working port 230, for example, so as to prevent
4 leakage of blood out of working port 230 during use.” (Laub, [0036].) For the
5 same reasons discussed above in connection with Garrison, in view of these
6 disclosures, a person of ordinary skill in the art would have been motivated to
7 combine the above-referenced aspiration systems with the hemostasis valves of
8 Schaffer, Hartley, and/or Eller to achieve the claimed invention.

9 In addition to Garrison, other prior art references disclose the use of filter
10 chambers positioned along a flow path to facilitate the filtering of blood. For
11 example, Trerotola discloses “Assembly 10 includes a device 20 for filtering
12 and salvaging the removed blood.” (Trerotola, 4:29-33.) “The device includes a
13 housing having a first end defining a fluid port and an opposite end defining a
14 suction port.” (Trerotola, 2:27-30.) Teigen discloses “A filter plate 86, shown
15 as a perforated screen but which could also be a woven screen or other
16 separating member is held in the mid-section of the interior of the main body 78
17 of the canister 44. (Teigen 9:63-66.)

18 In view of this additional prior art, and the other prior art references
19 identified in Appendix J, the asserted claims of the ’669 Patent would have been
20 obvious to a person of ordinary skill in the art.

21 **VI. INVALIDITY BASED ON OTHER GROUNDS (PLR 3-3(D))**

22 Many of the Asserted Claims are invalid under 35 U.S.C. § 112 for failure
23 to particularly point out and distinctly claim the subject matter of the inventions
24 and for failure to provide an adequate written description. Other Asserted
25 Claims are invalid for obviousness-type double patenting. Those grounds are
26 discussed below.

27 **A. Indefiniteness Under 35 U.S.C. 112(b)**

28 As set forth in 35 U.S.C. § 112, the “specification must conclude with one

1 or more claims particularly pointing out and distinctly claiming the subject
2 matter which the inventor or a joint inventor regards as the invention.” To
3 satisfy the definiteness requirement, the “claims, when read in light of the
4 specification and the prosecution history, must provide objective boundaries for
5 those of skill in the art.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364,
6 1371 (Fed. Cir. 2014) (citing *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.
7 Ct. 2120, 2130 (2014)). Claims are invalid as indefinite where they fail this test.
8 *See id.*; *Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1349 (Fed. Cir.
9 2002) (concluding that the term “perpendicular” is indefinite when it should be
10 read to mean “parallel”), cited with approval by *Trs. of Columbia Univ. v.*
11 *Symantec Corp.*, 811 F.3d 1359, 1366 (Fed. Cir. 2016).

12 The following Asserted Claims are indefinite for failing to provide
13 objective boundaries for those of skill in the art:

- 14 • ’384 Patent – Claims 1, 17, 27 - "wherein the first/second filament is
15 flexible” – The ’384 Patent does not use or define the term “flexible”
16 with relation to the filament. Nor does the specification describe a
17 structure that a person of ordinary skill in the art would understand to
18 fall within this claim term. Further, neither the specification nor the
19 claims provide objective boundaries for those skilled in the art
20 regarding what would constitute “wherein the first/second filament is
21 flexible.” Consequently, the claims fail to inform with reasonable
22 certainty those skilled in the art about the scope of the invention and
23 do not afford clear notice of what is claimed. Thus, the claims are
24 indefinite and invalid.
- 25 • ’384 Patent – Claim 1 - "first/second portion operably acted upon by
26 the first/second one of the actuators” – The ’384 Patent does not use or
27 define the term “operably acted upon”. Nor does the specification
28 describe a structure that a person of ordinary skill in the art would

1 understand to fall within this claim term. Further, neither the
2 specification nor the claims provide objective boundaries for those
3 skilled in the art regarding what would constitute a “first/second
4 portion operably acted upon by the first/second one of the actuators”.
5 Consequently, the claims fail to inform with reasonable certainty those
6 skilled in the art about the scope of the invention and do not afford
7 clear notice of what is claimed. Thus, the claims are indefinite and
8 invalid.

9 • '384 Patent – Claim 25 - "first/second portion operably coupled to the
10 first/second one of the actuators" – The '384 Patent does not use or
11 define the term “operably coupled to”. Nor does the specification
12 describe a structure that a person of ordinary skill in the art would
13 understand to fall within this claim term. Further, neither the
14 specification nor the claims provide objective boundaries for those
15 skilled in the art regarding what would constitute a “first/second
16 portion operably coupled to the first/second one of the actuators”.
17 Consequently, the claims fail to inform with reasonable certainty those
18 skilled in the art about the scope of the invention and do not afford
19 clear notice of what is claimed. Thus, the claims are indefinite and
20 invalid.

21 • '384 Patent – Claim 4, 18, 26 - "first/second filament is directly
22 attached to the first/second one of the actuators" – The '384 Patent
23 does not use or define the term “directly attached to”. Nor does the
24 specification describe a structure that a person of ordinary skill in the
25 art would understand to fall within this claim term. Further, neither
26 the specification nor the claims provide objective boundaries for those
27 skilled in the art regarding what would constitute the “first/second
28 filament directly attached to the first/second one of the actuators”.

1 Consequently, the claims fail to inform with reasonable certainty those
2 skilled in the art about the scope of the invention and do not afford
3 clear notice of what is claimed. Thus, the claims are indefinite and
4 invalid.

- 5 • '384 Patent – Claim 11 - "wherein, in the second position, the tubular
6 member has a diameter of at least 14 French" – The '384 Patent does
7 not use or define the term "14 French". Nor does the specification
8 describe a structure that a person of ordinary skill in the art would
9 understand to fall within this claim term. Further, neither the
10 specification nor the claims provide objective boundaries for those
11 skilled in the art regarding what would constitute "wherein, in the
12 second position, the tubular member has a diameter of at least 14
13 French". Consequently, the claims fail to inform with reasonable
14 certainty those skilled in the art about the scope of the invention and
15 do not afford clear notice of what is claimed. Thus, the claims are
16 indefinite and invalid.

- 17 • '384 Patent – Claims 12, 20, 28 - "wherein, in the second position, the
18 tubular member has a diameter of at least 16 French" – The '384
19 Patent does not use or define the term "16 French". Nor does the
20 specification describe a structure that a person of ordinary skill in the
21 art would understand to fall within this claim term. Further, neither
22 the specification nor the claims provide objective boundaries for those
23 skilled in the art regarding what would constitute "wherein, in the
24 second position, the tubular member has a diameter of at least 16
25 French". Consequently, the claims fail to inform with reasonable
26 certainty those skilled in the art about the scope of the invention and
27 do not afford clear notice of what is claimed. Thus, the claims are
28 indefinite and invalid.

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- '384 Patent – Claims 13, 21, 29 - "wherein, in the second position, the tubular member has a diameter of at least 20 French" – The '384 Patent does not use or define the term "20 French". Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute "wherein, in the second position, the tubular member has a diameter of at least 20 French". Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.
- '384 Patent – Claims 14, 22, 30 - "wherein, in the second position, the tubular member has a diameter of at least 24 French" – The '384 Patent does not use or define the term "24 French". Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute "wherein, in the second position, the tubular member has a diameter of at least 24 French". Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.
- '669 Patent – Claims 14, 30 – "wherein the vacuum source comprises a vacuum chamber" – The '669 Patent does not use or define the term "vacuum chamber". Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within

1 this claim term. Further, neither the specification nor the claims
2 provide objective boundaries for those skilled in the art regarding what
3 would constitute the “vacuum chamber”. Consequently, the claims
4 fail to inform with reasonable certainty those skilled in the art about
5 the scope of the invention and do not afford clear notice of what is
6 claimed. Thus, the claims are indefinite and invalid.

- 7 • ’669 Patent – Claims 14, 30 – “wherein the connection tubing/catheter
8 is fluidically coupled to [the] vacuum chamber” – The ’669 Patent
9 does not use or define the term “vacuum chamber”. Nor does the
10 specification describe a structure that a person of ordinary skill in the
11 art would understand to fall within this claim term. Further, neither
12 the specification nor the claims provide objective boundaries for those
13 skilled in the art regarding what would constitute the “vacuum
14 chamber”. Consequently, the claims fail to inform with reasonable
15 certainty those skilled in the art about the scope of the invention and
16 do not afford clear notice of what is claimed. Thus, the claims are
17 indefinite and invalid.

18 To the extent Imperative Care asserts, in the alternative, invalidity
19 arguments based upon a construction of the above-identified claim terms, it does
20 so without waiver of its position that these terms are indefinite. Imperative Care
21 reserves the right to identify additional claim limitations as indefinite as the case
22 proceeds and as Stryker/Inari clarifies its Infringement Contentions.

23 **B. Lack of Written Description Under 35 U.S.C. § 112(a)**

24 35 U.S.C. §112(a) states:

25 The specification shall contain a written description of the
26 invention, and of the manner and process of making and using it, in
27 such full, clear, concise, and exact terms as to enable any person
28 skilled in the art to which it pertains, or with which it is most
nearly connected, to make and use the same, and shall set forth the

1 best mode contemplated by the inventor or joint inventor of
2 carrying out the invention.

3 35 U.S.C. §112(a). Written description and enablement are separate and distinct
4 requirements.

5 To satisfy the written description requirement of 35 U.S.C. § 112, the
6 specification of a patent must describe the full scope of the claimed invention in
7 sufficient detail so “that one skilled in the art can clearly conclude that the
8 inventor invented the claimed invention as of the filing date sought.” *Lockwood*
9 *v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *see also*
10 *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1344–45
11 (Fed. Cir. 2005); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479
12 (Fed. Cir. 1998); *Eiselstein v. Frank*, 52 F.3d 1035, 1039 (Fed. Cir. 1995).
13 “Such description need not recite the claimed invention in haec verba but must
14 do more than merely disclose that which would render the claimed invention
15 obvious.” *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1377 (Fed.
16 Cir. 2009).

17 Notably, Stryker/Inari has admitted that it has not developed a product
18 that is covered by many of the Asserted Claims. Stryker/Inari’s failure to
19 develop such a device is evidence that Stryker/Inari did not possess the claimed
20 aspiration systems and/or valves as of the earliest claimed priority date of the
21 Asserted Patents.

22 The test for enablement is whether, upon reading the specification and in
23 view of information known in the art, a person of ordinary skill in the art could
24 make or use the invention without undue experimentation. *See Callicrate v.*
25 *Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1374 (Fed. Cir. 2005); *see also In re*
26 *Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (providing non-exhaustive list of
27 factors to be considered in the enablement analysis).

28 The following Asserted Claims fail the written description requirement

1 for at least the following reasons:

- 2 • '384 Patent – Claims 1, 17, 27 - "wherein the first/second filament is
3 flexible" – The '384 Patent does not use or define the term "flexible" with
4 relation to the filament. Nor does the specification describe a structure
5 that a person of ordinary skill in the art would understand to fall within
6 this claim term. Consequently, the specification does not reasonably
7 convey to those skilled in the art that the inventor had possession of a
8 valve wherein "the first/second filament is flexible" as of the earliest
9 claimed priority date. Thus, the claims lack written description and are
10 invalid.
- 11 • '384 Patent – Claim 1 - "first/second portion operably acted upon by the
12 first/second one of the actuators" – The '384 Patent does not use or define
13 the term "operably acted upon". Nor does the specification describe a
14 structure that a person of ordinary skill in the art would understand to fall
15 within this claim term. Consequently, the specification does not
16 reasonably convey to those skilled in the art that the inventor had
17 possession of a valve with the "first/second portion operably acted upon
18 by a first/second one of the actuators" as of the earliest claimed priority
19 date. Thus, the claims lack written description and are invalid.
- 20 • '384 Patent – Claim 25 - "first/second portion operably coupled to the
21 first/second one of the actuators" – The '384 Patent does not use or define
22 the term "operably coupled to". Nor does the specification describe a
23 structure that a person of ordinary skill in the art would understand to fall
24 within this claim term. Consequently, the specification does not
25 reasonably convey to those skilled in the art that the inventor had
26 possession of a valve with the "first/second portion operably coupled to
27 the first/second one of the actuators" as of the earliest claimed priority
28 date. Thus, the claims lack written description and are invalid.

- 1 • '384 Patent – Claim 4, 18, 26 - "first/second filament is directly attached
2 to the first/second one of the actuators" – The '384 Patent does not use or
3 define the term "directly attached to". Nor does the specification describe
4 a structure that a person of ordinary skill in the art would understand to
5 fall within this claim term. Consequently, the specification does not
6 reasonably convey to those skilled in the art that the inventor had
7 possession of a valve wherein the "first/second filament is directly
8 attached to the first/second one of the actuators" as of the earliest claimed
9 priority date. Thus, the claims lack written description and are invalid.
- 10 • '384 Patent – Claim 11 – "wherein, in the second position, the tubular
11 member has a diameter of at least 14 French." – The '384 Patent does not
12 define the term "14 French". Nor does the specification describe a
13 structure that a person of ordinary skill in the art would understand to fall
14 within this claim term. Consequently, the specification does not
15 reasonably convey to those skilled in the art that the inventor had
16 possession of a valve wherein, in the second position, the tubular member
17 has a diameter of at least "14 French" as of the earliest claimed priority
18 date. Thus, the claims lack written description and are invalid.
- 19 • '384 Patent – Claims 12, 20, 28 – "wherein, in the second position, the
20 tubular member has a diameter of at least 16 French." – The '384 Patent
21 does not define the term "16 French". Nor does the specification describe
22 a structure that a person of ordinary skill in the art would understand to
23 fall within this claim term. Consequently, the specification does not
24 reasonably convey to those skilled in the art that the inventor had
25 possession of a valve wherein, in the second position, the tubular member
26 has a diameter of at least "16 French" as of the earliest claimed priority
27 date. Thus, the claims lack written description and are invalid.
- 28 • '384 Patent – Claims 13, 21, 29 – "wherein, in the second position, the

1 tubular member has a diameter of at least 20 French.” – The ‘384 Patent
2 does not define the term “20 French”. Nor does the specification describe
3 a structure that a person of ordinary skill in the art would understand to
4 fall within this claim term. Consequently, the specification does not
5 reasonably convey to those skilled in the art that the inventor had
6 possession of a valve wherein, in the second position, the tubular member
7 has a diameter of at least “20 French” as of the earliest claimed priority
8 date. Thus, the claims lack written description and are invalid.

9 • ’384 Patent – Claims 14, 22, 30 – “wherein, in the second position, the
10 tubular member has a diameter of at least 24 French.” – The ‘384 Patent
11 does not define the term “24 French”. Nor does the specification describe
12 a structure that a person of ordinary skill in the art would understand to
13 fall within this claim term. Consequently, the specification does not
14 reasonably convey to those skilled in the art that the inventor had
15 possession of a valve wherein, in the second position, the tubular member
16 has a diameter of at least “24 French” as of the earliest claimed priority
17 date. Thus, the claims lack written description and are invalid.

18 • ’669 Patent – Claims 14, 30 – “wherein the vacuum source comprises a
19 vacuum chamber” – The ’669 Patent does not use or define the term
20 “vacuum chamber”. Nor does the specification describe a structure that a
21 person of ordinary skill in the art would understand to fall within this
22 claim term. Consequently, the specification does not reasonably convey
23 to those skilled in the art that the inventor had possession of a valve
24 wherein the vacuum source comprises a “vacuum chamber” as of the
25 earliest claimed priority date. Thus, the claims lack written description
26 and are invalid.

27 • ’669 Patent – Claims 14, 30 – “wherein the connection tubing/catheter is
28 fluidically coupled to [the] vacuum chamber” – The ’669 Patent does not

1 use or define the term “vacuum chamber”. Nor does the specification
2 describe a structure that a person of ordinary skill in the art would
3 understand to fall within this claim term. Consequently, the specification
4 does not reasonably convey to those skilled in the art that the inventor had
5 possession of a valve wherein the connection tubing/catheter is fluidically
6 coupled to [the] “vacuum chamber” as of the earliest claimed priority
7 date. Thus, the claims lack written description and are invalid.

8 **C. Improper Dependent Claim Under 35 U.S.C. § 112(d)**

9 35 U.S.C. § 112(d) requires:

10 Subject to subsection (e), a claim in dependent form shall contain a
11 reference to a claim previously set forth and then specify a further
12 limitation of the subject matter claimed. A claim in dependent form shall
13 be construed to incorporate by reference all the limitations of the claim to
14 which it refers.

14 “A dependent claim that contradicts, rather than narrows, the claim from which
15 it depends is invalid.” *Multilayer Stretch Cling Film Holdings, Inc. v. Berry*
16 *Plastics Corp.*, 831 F.3d 1350, 1362, (Fed. Cir. 2016).

17 The following Asserted Claims are improper dependent claims for at least
18 the following reasons:

- 19 • ’384 Patent – Claim 7 – “wherein the tubular member is elastically
20 deformable” – This claim does not specify a further limitation of the
21 claim from which it depends. Thus, the dependent claim is improper and
22 invalid.
- 23 • ’384 Patent Claim 8 – “wherein the tubular member is configured to
24 resiliently expand” – This claim does not specify a further limitation of
25 the claim from which it depends. Thus, the dependent claim is improper
26 and invalid.

27 **D. Improper Double Patenting by Stryker/Inari**

28 Many of Stryker/Inari’s Asserted Claims are invalid for obviousness-type

1 double patenting (“ODP”). The below table identifies the Asserted Claims that
2 are invalid for double patenting and the reference(s) that render those claims
3 invalid.

ODP Reference	Asserted Patent	Asserted Claims
11,554,005	12,156,669	1-5, 8, 10-12, 14-19, 22, 24-28, 30
11,744,691	12,156,669	1-5, 8, 10-12, 14-19, 22, 24-28, 30

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VII. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Objective indicia of non-obviousness, also known as secondary considerations of non-obviousness, may be considered in an obviousness analysis, but do not control the ultimate conclusion of obviousness. *See Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Where a strong showing of *prima facie* obviousness has been made, as is the case here (*see supra*, Sections V-XI), the Federal Circuit has repeatedly held that even relevant objective indicia supported by substantial evidence are insufficient to overcome obviousness. *See, e.g., Leapfrog*, 485 F.3d at 1162.

Secondary considerations of non-obviousness must be attributable to the claimed invention, and must be apart from what is unclaimed or in the prior art. *See In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011); *see also, e.g., Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006). Additionally, secondary considerations are relevant only where the patentee can establish a “nexus” between the secondary consideration and the claimed invention. *See, e.g., In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). Moreover, “[e]vidence of secondary considerations must be reasonably commensurate with the scope of the claims.” *Huai-Hung Kao*, 639 F.3d at 1068.

Discovery in this case is in its early stages. Imperative Care reserves the right to amend, supplement, and/or modify these Preliminary Invalidity Contentions—or to proffer expert reports—to respond to Stryker/Inari’s purported evidence of objective indicia of non-obviousness as fact and expert discovery proceeds in this case.

A. No Nexus

Imperative Care is not aware of any alleged secondary consideration with a nexus to any of the Asserted Claims, that could support a finding of non-obviousness. Imperative Care reserves the right to respond to any contention by Stryker/Inari of any such nexus.

1 **B. No Unexpected Results**

2 Imperative Care is not aware of any evidence of unexpected results that
3 could support a finding of non-obviousness. Imperative Care reserves the right
4 to respond to any contention by Stryker/Inari of any such unexpected results.

5 **C. No Commercial Success**

6 Imperative Care is not aware of any evidence of commercial success that
7 could support a finding of non-obviousness. Imperative Care reserves the right
8 to respond to any contention by Stryker/Inari of any such commercial success.

9 **D. No Long-Felt but Unmet Need**

10 Imperative Care is not aware of any evidence of long-felt but unmet need
11 that could support a finding of non-obviousness. Imperative Care reserves the
12 right to respond to any contention by Stryker/Inari of any such long-felt but
13 unmet need.

14 **E. No Industry Praise or Skepticism**

15 Imperative Care is not aware of any evidence of industry praise or
16 skepticism that could support a finding of non-obviousness. Imperative Care
17 reserves the right to respond to any contention by Stryker/Inari of any such
18 industry praise or skepticism.

19 **F. No Copying**

20 Imperative Care is not aware of any evidence of copying that could
21 support a finding of non-obviousness. Imperative Care reserves the right to
22 respond to any contention by Stryker/Inari of any such copying.

23 **G. No Failure by Others**

24 Imperative Care is not aware of any evidence of failure of others that
25 could support a finding of non-obviousness. Imperative Care reserves the right
26 to respond to any contention by Stryker/Inari of any such failure of others.

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1 **VIII. IMPERATIVE’S DOCUMENT PRODUCTION ACCOMPANYING**
2 **ITS INVALIDITY CONTENTIONS (PLR 3-4)**

3 **A. PLR 3-4(a): “Source code, specifications, schematics, flow charts,**
4 **artwork, formulas, or other documentation sufficient to show the operation**
5 **of any aspects or elements of an Accused Instrumentality identified by the**
6 **patent claimant in its Patent L.R. 3-1(c) chart.”**

7 Documents providing the information required by Patent Local Rule 3-
8 4(a) can be found at IC_00000001-IC_00004727. However, in identifying this
9 bates range, Imperative Care does not mean to represent, and does not represent,
10 that each document in the range is responsive to this Patent Local Rule.

11 **B. PLR 3-4(b): “A copy or sample of the prior art identified pursuant to**
12 **Patent L.R. 3-3(a) which does not appear in the file history of the patent(s)**
13 **at issue. To the extent any such item is not in English, an English**
14 **translation of the portion(s) relied upon shall be produced.”**

15 Documents providing the information required by Patent Local Rule 3-
16 4(b) can be found at IC_00005028-IC_00006768; IC_00011312-IC_00011469.
17 However, in identifying this bates range, Imperative Care does not mean to
18 represent, and does not represent, that each document in the range is responsive
19 to this Patent Local Rule.

20 **C. PLR 3-4(c): “All agreements that may be related to the accused**
21 **instrumentality or may be comparable to a license that would result from a**
22 **hypothetical reasonable royalty negotiation.”**

23 Documents providing the information required by Patent Local Rule 3-
24 4(c) can be found at IC_00004728-IC_00005027. However, in identifying this
25 bates range, Imperative Care does not mean to represent, and does not represent,
26 that each document in the range is responsive to this Patent Local Rule.

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1 **D. PLR 3-4(d): “Documents sufficient to show the sales, revenue, cost,**
2 **and profits for accused instrumentalities identified pursuant to Patent L.R.**
3 **3-1(b) for any period of alleged infringement.”**

4 Documents providing the information required by Patent Local Rule 3-
5 4(d) can be found at IC_00006769.

6 **E. PLR 3-4(e): “All agreements that may be used to support the party**
7 **denying infringement’s damages case.”**

8 Documents providing the information required by Patent Local Rule 3-
9 4(e) can be found at IC_00004728-IC_00005027. However, in identifying this
10 bates range, Imperative Care does not mean to represent, and does not represent,
11 that each document in the range is responsive to this Patent Local Rule.

12
13 KNOBBE, MARTENS, OLSON & BEAR, LLP

14
15 Dated: March 24, 2025

16 By: /s/ Joshua J. Stowell

17 Joseph R. Re
18 Joshua J. Stowell
19 Nicholas A. Belair

20 *Attorneys for Defendant*
21 Imperative Care, Inc.
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CERTIFICATE OF SERVICE

I am a citizen of the United States of America and I am employed in Irvine, California. I am over the age of 18 and not a party to the within action. My business address is 2040 Main Street, Fourteenth Floor, Irvine, California.

On March 24, 2025, I served the foregoing: **IMPERATIVE CARE, INC.’S PRELIMINARY INVALIDITY CONTENTIONS AND DOCUMENT PRODUCTION REGARDING U.S. PATENT NOS. 12,109,384 AND 12,156,669 PURSUANT TO PATENT LOCAL RULES 3-3 AND 3-4** on the parties or their counsel shown below, by transmitting it electronically to the addresses as follows:

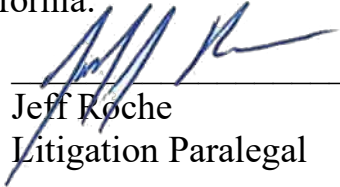
VIA ELECTRONIC MAIL:

<p style="text-align: center;">Amanda Tessar Perkins Coie Llp 1900 Sixteenth Street Suite 1400 Denver, CO 80202 303-291-2357 Email: atessar@perkinscoie.com</p>	<p style="text-align: center;">Ramsey M. Al-Salam Perkins Coie LLP 1201 Third Avenue Suite 4000 Seattle, WA 98101-3099 206-359-8000 Email: ralsalam@perkinscoie.com</p>
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	<p style="text-align: center;">Inari-Imperative@perkinscoie.com</p>

I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

1 Executed on March 24, 2025, at Irvine, California.

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Jeff Roche
Litigation Paralegal