

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2025-01264
U.S. Patent No. 12,016,580

PATENT OWNER'S PRELIMINARY RESPONSE

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	Petitioner’s Exhibits
Exhibit	Description
EX1001	U.S. Patent No. 12,016,580 (“the ’580 patent”)
EX1002	’580 Patent Prosecution History
EX1003	Expert Declaration of Troy Thornton
EX1004	Resume of Troy Thornton
EX1005	WIPO Publication No. WO 2006/124307 A2 to Goff et al. (“Goff”)
EX1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
EX1007	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
EX1008	U.S. Patent Publication No. 2003/0116731 A1 to Hartley (“Hartley”)
EX1009	U.S. Patent Publication No. 2015/0352325 A1 to Quick (“Quick”)
EX1010	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
EX1011	U.S. Patent No. 8,734,374 B2 to Aklog et al. (“Aklog”)
EX1012	U.S. Patent Publication No. 2017/0043066 A1 to Laub (“Laub”)
EX1013	U.S. Patent No. 6,776,770 B2 to Trerotola (“Trerotola”)
EX1014	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
EX1015	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
EX1016	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
EX1017	U.S. Provisional Patent Application No. 62/554,931 (the “’931 application”)

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EX1018	U.S. Patent No. 6,481,439 B1 to Lewis et al.
EX1019	U.S. Patent No. 5,256,150 to Quiachon et al.
EX1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. ("Brady")
EX1021	U.S. Patent No. 12,109,384 B2 to Merritt et al.
EX1022	Expert Declaration of Dr. Aquilla S. Turk, III, DO
EX1023	Resume of Dr. Aquilla Turk, III, D.O.
EX1024	Shani, Jacob M.D., et al., Mechanical Manipulation of Thrombus: Coronary Thrombectomy, Intracoronary Clot Displacement, and Transcatheter Aspiration, 72 Am. J. Cardiol. 116G-118G (1993)
EX1025	Bose, A et al., The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism, 29 Am. J. Neuroradiol. 1409-1413 (Aug. 2008)
EX1026	Turk, Aquilla S. et al., Initial clinical experience with the ADAPT technique: A direct aspiration first pass technique for stroke thrombectomy, 6 J. NeuroIntervent. Surg. 231-237 (2014)
EX1027	Turk, Aquilla S. et al., ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy, 6 J. NeuroIntervent. Surg. 260-264 (2014)
EX1028	April 24, 2024 Letter from Inari to Imperative Care
EX1029	Turk, Aquilla S. et al., Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicentre, randomized, open label, blinded outcome, non-inferiority trial, 393 Lancet 998-1008 (March 2019)
EX1030	Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.stokeaha.org (2005).

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EX1031	Decision Granting Institution of IPR, IPR2024-01157, U.S. Patent No. 11,697,011 B2
EX1032	Decision Granting Institution of IPR, IPR2025-00156, U.S. Patent No. 11,697,012 B2
EX1033	Decision Granting Institution of IPR, IPR2025-00289, U.S. Patent No. 11,554,005 B2
EX1034	Merriam-Webster's Collegiate Dictionary – Previously Submitted by Patent Owner as Ex. 2002 in IPR2024-00289 – Definition of “Loosen”
EX1035	U.S. Patent No. 7,998,104 B2 to Chang
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EX1038	Case Management and Scheduling Order (Dkt. #54) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
EX1039	Imperative Care, Inc.'s Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
EX1040	Order Regarding Case Schedule and Motion to Stay in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
EX1041	Order Denying Motion for Preliminary Injunction (Dkt. #136) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued September 29, 2025)

	Patent Owner's Exhibits
Exhibit	Description
EX2001	Prosecution History Excerpt from U.S. Patent Application No. 17/865,307
EX2002	U.S. Patent No. 11,849,963 B2 to Quick ("Quick")
EX2003	Declaration of Brian Brown

I. INTRODUCTION

Petitioner has failed to demonstrate a reasonable likelihood that any of Claims 1-34 (“the Claims”) of the ’580 Patent are unpatentable. In some embodiments, the ’580 Patent discloses improved clot treatment systems and methods for removing clot material from a blood vessel of a human patient that utilize aspiration followed by mechanical engagement with an interventional device to remove remaining clot material, thereby treating the patient. EX1001, 3:46-49, 4:45-49, 21:41-52; EX2003, ¶37. Those systems and methods are particularly well-suited for treating venous thromboembolism (“VTE”), a disease caused by blood clot formation in the veins of the body that is, unfortunately, a leading cause of both death and disease worldwide. EX1001, 1:31-65; EX2003, ¶30. Pulmonary embolism (“PE”) and deep vein thrombosis (“DVT”) are common and particularly dangerous types of VTE that the methods and systems disclosed in the ’580 Patent are designed to treat. *Id.*

The sole independent claim, Claim 1, recites a method for the intravascular treatment of clot material within a blood vessel including steps of (i) “positioning a distal portion of an elongated shaft proximate to the clot material within the vessel,” (ii) aspirating by “pre-charging a vacuum in a pressure source” and then “fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft,” and then (iii) engaging with an interventional device by “advancing

an interventional device distally through the attachment member and the elongated shaft” and then “engaging the interventional device with a second portion of the clot material remaining within the blood vessel.” EX1001, cl.1.; EX2003, ¶37. That is, Claim 1 requires aspirating a first portion of clot material into an elongated shaft via application of a pre-charged vacuum, then advancing an interventional device through the elongated shaft and engaging the interventional device with a second portion of that *same clot material* “remaining within the blood vessel” after aspirating. EX2003, ¶49.

By pre-charging the vacuum, the method of Claim 1 can generate large suction forces (and corresponding fluid flow velocities) to effectively aspirate and remove the clot material from the patient. EX1001, 21:7-15; EX2003, ¶38. If any of that same clot material remains within the blood vessel after performing an aspiration pass (e.g., a strongly lodged or chronic portion of the clot material), Claim 1 further includes “unsealing an attachment member coupled to a proximal portion of the elongated shaft,” “advancing an interventional device distally through the attachment member and the elongated shaft,” and “engaging the interventional device with a second portion of the clot material remaining within the blood vessel.” EX1001, cl.1; EX2003, ¶39. In this manner, the interventional device treats a second portion of the same clot material “remaining within the blood vessel” after the aspiration step. EX2003, ¶39.

In each of grounds 1-4, Petitioner relies on Garrison alone for allegedly disclosing what Petitioner labels limitation [1f] of Claim 1: “*engaging the interventional device with a second portion of the clot material remaining within the blood vessel.*” Petition, pp.35-37. But Garrison does not disclose or render obvious that limitation alone or in combination with any of the other asserted references.

To allege anticipation (ground 1), Petitioner first relies on Garrison's disclosure in paragraph [0166] that “if a secondary more distal treatment site needs to be reached *after removal of a first occlusion*, a second, smaller diameter catheter may be inserted through the first catheter, and positioned at the distal treatment site.” EX1006, ¶[0166]; Petition, p.35 (emphasis in Petition). But that disclosure of Garrison expressly recites advancing and positioning a catheter to a “secondary more distal treatment site” with a second, different clot. EX2003, ¶52. Thus, paragraph [0166] of Garrison does not disclose using the second smaller diameter catheter or any interventional device to treat a remaining portion of the *same* clot after aspirating and thus does not disclose “engaging the interventional device with a second portion of the clot material remaining within the blood vessel” as recited in Claim 1. *Id.*

Similarly, Petitioner's reference to Garrison's disclosure that various devices can be inserted through its catheter 2030 (Petitioner's alleged “elongated shaft”) also does not demonstrate anticipation because those portions of Garrison do not disclose when those devices are inserted or that any of those devices engage a remaining

second portion of a clot. Petition, p.35; EX1006, ¶¶[0054], [0143]. That is, while that disclosure of Garrison discloses inserting “various devices,” it does not disclose the claimed method of “engaging [any of those various devices] with a second portion of the clot material remaining within the blood vessel” after a step of aspirating a first portion of that same clot material as recited in Claim 1. EX2003, ¶53.

Paragraphs [0125]-[0126] of Garrison also fail to disclose element 1[f] because the embodiments described therein are for a disruption device inserted into a catheter *before* aspiration and that continuously engages clot material as that clot material is aspirated into the catheter. EX1006, ¶¶[0125]-[0126]; Petition, p.36; EX2003, ¶¶55-56. Specifically, paragraphs [0125]-[0126] do not disclose “engaging [the thrombus disruption device] with a second portion of the clot material remaining within the blood vessel” as recited in Claim 1 because those paragraphs disclose that the disruption device disrupts a “first portion of the clot material” that is aspirated “into the elongated shaft” to prevent clogging. EX2003, ¶56. The disruption device is not engaged with “a second portion of the clot material remaining within the blood vessel” as required by Claim 1. EX2003, ¶56. Likewise, those embodiments also do not disclose “unsealing an attachment member,” “advancing the interventional device,” and “unsealing the interventional device” after aspirating as required by

Claim 1. Specifically, the thrombus disruption device is positioned within the catheter for the full duration of aspiration. *Id.* For those reasons, ground 1 fails.

Relying on Garrison alone to then allege obviousness of that same limitation [1f], Petitioner asserts that “a POSITA would have been motivated to engage the interventional device inserted through catheter 2030 with the second clot portion” citing paragraph [0165] of Garrison, which discloses that “[i]f the thrombus is too large or too strongly embedded into the vasculature such that it is not possible to remove the occlusion via aspiration alone, further steps are taken to remove the occlusion.” Petition, pp.36-37; EX1006, ¶[0165]. But Petitioner mischaracterizes paragraph [0165] of Garrison—omitting how Garrison discloses removing clots that are “not possible to remove ... via aspiration alone” in that paragraph. EX1006, ¶[0165]; EX2003, ¶62. Specifically, Petitioner’s selective quotation omits that Garrison discloses that when aspiration alone is insufficient a “thrombectomy device 15 may be deployed ***through the arterial access device*** to remove the clot.” *Id.* (emphasis added). That arterial access device through which the thrombectomy device 15 is deployed is not Petitioner’s alleged “elongated shaft,” catheter 2030. Instead, Garrison’s immediately preceding paragraph explains that the arterial access device is item 2010, not catheter 2030, and distinguishes the two as follows: “catheter 2030 is placed through the arterial access device 2010.” EX1006, ¶[0164]; *see also id.* at FIG.32 (illustrating the arrangement specified in paragraph [0165] in

which a thrombectomy device is inserted through the arterial access device); EX2003, ¶62.

Therefore, the sole paragraph [0165] of Garrison that Petitioner cites for motivation in its obviousness argument discloses inserting a thrombectomy device through a different part of Garrison's system—the arterial access device 2010—and not the catheter 2030 that Petitioner alleges is the “elongated shaft” recited in Claim 1. EX2003, ¶63. Petitioner and its expert fail to acknowledge that fundamental difference let alone provide any reason based on that disclosure why a POSA would have found it obvious to modify Garrison to insert a thrombectomy device through catheter 2030 instead of arterial access device 2010. For those reasons, the Petition has failed to demonstrate a reasonable likelihood that a POSA would have been motivated “to engage the interventional device inserted through catheter 2030 with the second clot portion” as Petitioner alleges. *Id.*; Petition, pp.36-37. Grounds 2-4 fail at least for those reasons.

Accordingly, grounds 1-4 do not anticipate Claim 1 or render obvious Claim 1. Grounds 5-14 pertain only to additional limitations of the dependent claims, and fail for the same reasons as grounds 1-4. Petitioner has therefore failed to demonstrate that any of the Claims are unpatentable under any of grounds 1-14.

II. BACKGROUND

A. Overview of the '580 Patent

The '580 Patent is directed to improved clot treatment systems and methods for removing clot material from a blood vessel of a human patient. EX1001, 1:21-23. In some embodiments, the systems and methods utilize aspiration followed by mechanical engagement with an interventional device to remove any clot material remaining after aspiration, thereby treating the patient. EX1001, 3:46-49, 4:45-49, 21:41-52; EX2003, ¶37. The disclosed systems and methods are particularly well-suited for treating venous thromboembolism ("VTE"), a disease caused by blood clot formation in the veins of the body that is, unfortunately, a leading cause of both death and disease worldwide. EX1001, 1:31-65; EX2003, ¶30. Pulmonary embolism ("PE") and deep vein thrombosis ("DVT") are common and particularly dangerous types of VTE. *Id.* DVT is a type of blood clot that typically forms in the deep veins of a limb, such as the leg, and can develop into PE if portions of the clot break off and migrate to the pulmonary system. EX1001, 1:44-46; EX2003, ¶33. PE is a life-threatening condition that occurs when a clot breaks free and becomes lodged in the arteries of the lungs, blocking the oxygenation of blood necessary to sustain the entire body. EX1001, 1:55-65; EX2003, ¶33.

PE has traditionally been treated with drugs (thrombolytic agents) or invasive surgeries. EX1001, 2:24-29; EX2003, ¶34. However, those approaches have

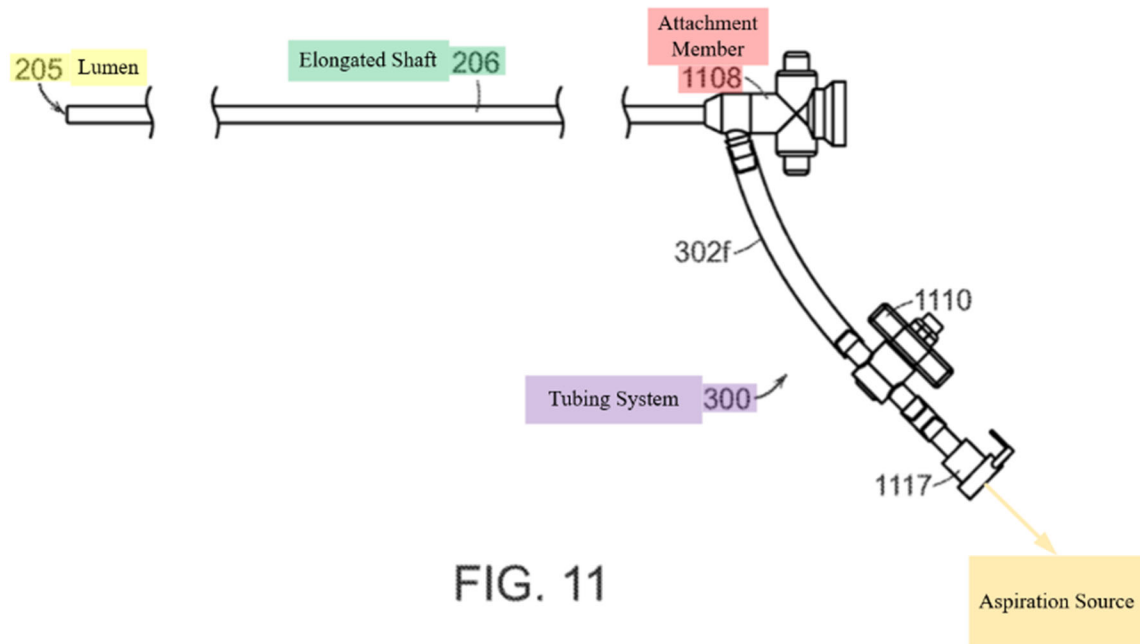
significant drawbacks. For example, thrombolytic agents do not always work, take hours or even days to be successful, can cause hemorrhage of the blood vessel, and cannot be used at all in many patients. EX1001, 2:26-29; EX2003, ¶¶35-36.

The sole independent claim—Claim 1—of the '580 Patent is directed to a method for the intravascular treatment of clot material with a blood vessel. EX1001, cl.1. The method includes steps of (i) “positioning a distal portion of an elongated shaft proximate to the clot material within the vessel,” (ii) aspirating by “pre-charging a vacuum in a pressure source” and then “fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft”, and then (iii) engaging using an interventional device by “advancing an interventional device distally through the attachment member and the elongated shaft” and then “engaging the interventional device with a second portion of the clot material remaining within the blood vessel.” *Id.*; EX2003, ¶37.

By pre-charging the vacuum, the method of Claim 1 can generate large suction forces (and corresponding fluid flow velocities) to effectively aspirate and remove all or a portion of the clot material from the patient. EX1001, 21:7-19; EX2003, ¶38. If any of that same clot material remains within the blood vessel after aspirating (e.g., a strongly lodged or chronic portion of the clot material or particularly large clots), Claim 1 recites steps for deploying the interventional device, including

“unsealing an attachment member coupled to a proximal portion of the elongated shaft,” “advancing an interventional device distally through the attachment member and the elongated shaft,” and then “engaging the interventional device with a second portion of the clot material remaining within the blood vessel.” EX1001, cl.1; EX2003, ¶39. The attachment member can be a user-actuatable hemostasis valve. EX1001, 17:46-18:67; EX2003, ¶39. In this manner, the interventional device treats a portion of the same clot that remains in the vessel after aspirating. EX2003, ¶39.

Figure 11 of the '580 Patent illustrates one example of a clot treatment system that can be used to carry out the method of Claim 1. EX2003, ¶40. The system includes a catheter 206 (e.g., an elongated shaft) having a distal portion configured to be positioned near clot material within a blood vessel and a proximal portion coupled to an attachment member 1108:



EX1001, 17:7-9; EX2003, ¶40. The attachment member 1108 can be a hemostasis valve that can be selectively opened and closed to provide access to a lumen 205 of the catheter 206. EX1001, 17:46-18:67, FIGS. 13A-13B; EX2003, ¶40. The system can further include a tubing system 300 having a tube 302f fluidly connected to the lumen 205 of the catheter, a connector 1117 that can be connected to an aspiration source (not shown in Figure 11 but annotated above), and a stopcock 1110 for controlling flow (e.g., blocking or allowing flow) from the catheter 206 to the aspiration source. EX1001, 17:12-27; EX2003, ¶40.

The '580 Patent explains that a “syringe or other pressure source can be fluidly coupled directly to the connector 1117 and used to aspirate the guide catheter 206.” EX1001, 20:58-61. Accordingly, “opening of the stopcock 1110 fluidly connects the

syringe to the lumen 205 of the guide catheter 206 and closing of the stopcock 1110 fluidly disconnects the syringe from the lumen 205 of the guide catheter 206.” *Id.* at 20:61-65. The “syringe or other pressure source can be pre-charged with a vacuum—such as by drawing a plunger of the syringe with the stopcock 1110 closed” and the “stopcock 1110 can then be opened to instantaneously or nearly instantaneously (e.g., immediately) apply the stored vacuum pressure to the tubing system 300 and to the lumen 205 of the guide catheter 206, thereby generating suction throughout the guide catheter 206.” *Id.* at 20:65-21:5.

If a portion of the clot material remains in the blood vessel after a step of aspirating the catheter 206, the '580 Patent discloses further steps for introducing a mechanical interventional device: unsealing the attachment member 1108 to provide access to the lumen 205 of the catheter 206 by, for example, depressing one or more buttons of the attachment member (e.g., a hemostasis valve). *Id.* at 18:41-48; EX2003, ¶42. Then, advancing an interventional device through the catheter 206 to engage the remaining clot material as shown in, for example, Figures 2A-2G of the '580 Patent:

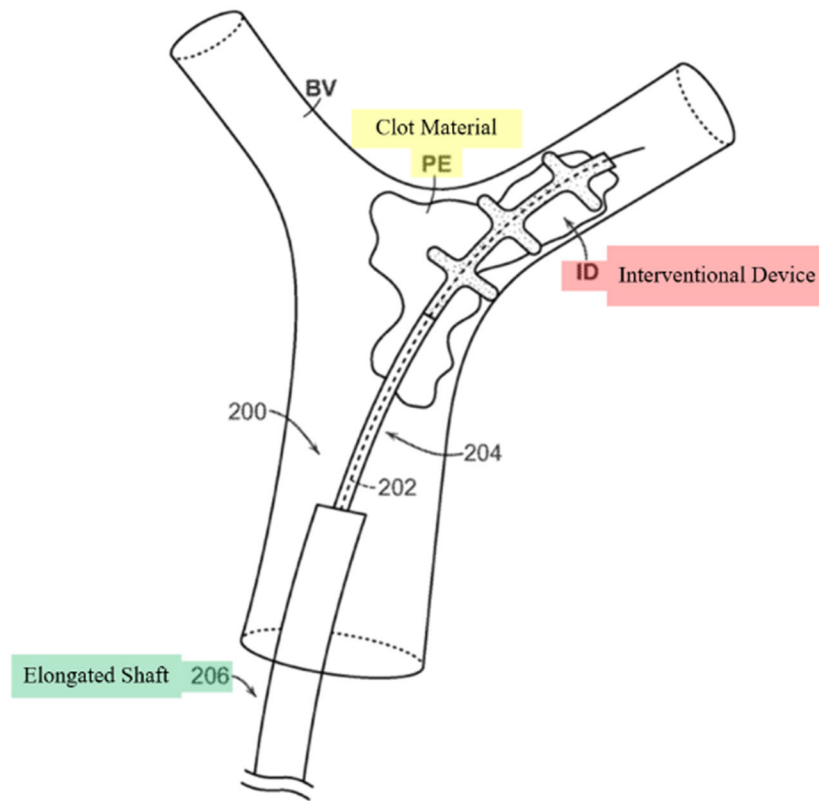


FIG. 2C

EX1001, 21:41-52; EX2003, ¶42. The interventional device can be retracted through the remaining portion of the clot material to physically engage and disrupt the clot material and/or pull all or a portion of it into the catheter 206:

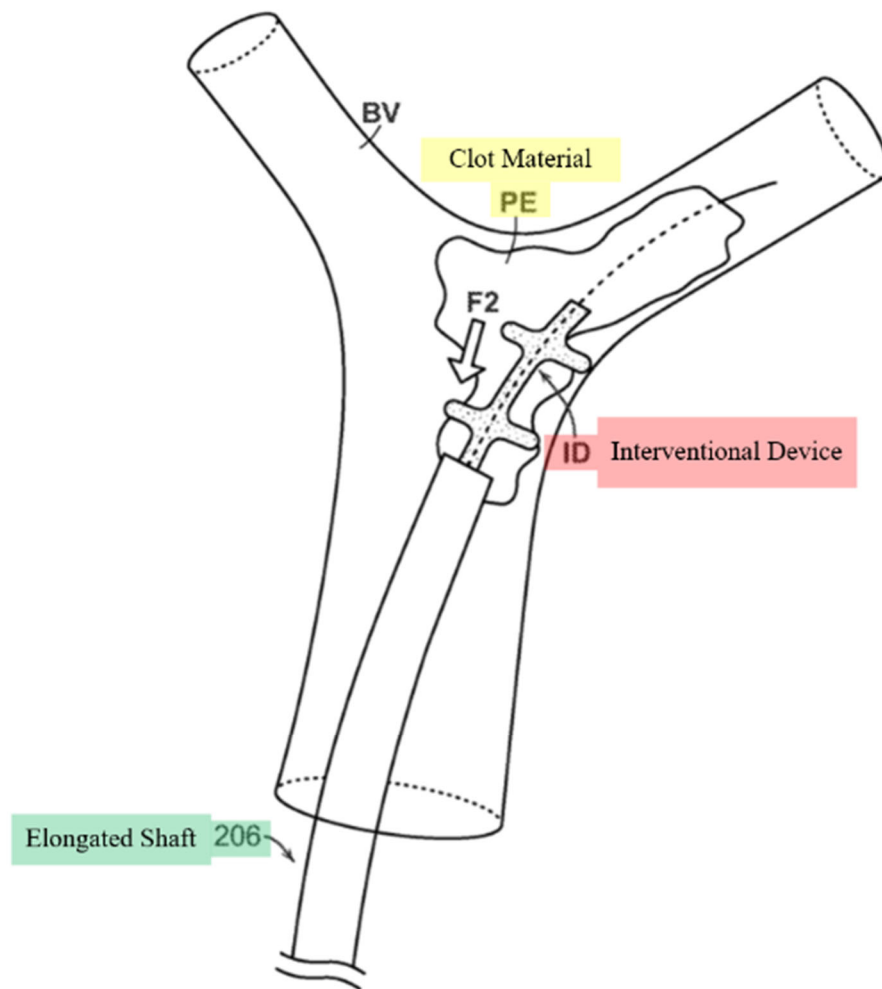


FIG. 2F

EX2003, ¶42. Accordingly, the methods claimed in the '580 Patent first utilize aspiration via pre-charged vacuum and then subsequent mechanical engagement with an interventional device to effectively remove and treat clot material such as PE and DVT. *Id.*

B. Prosecution History

In the sole Office action, the Examiner allowed independent claim 21 (which matured into Claim 1 of the '580 Patent), but rejected the other independent claim 32 as anticipated under 35 U.S.C. § 102(a)(1) over U.S. Patent Application No. 2015/0352325 (EX1009; "Quick"). EX1002, pp.1045-1047. The Examiner found independent claim 21 to be allowable over Quick because Quick did not disclose or suggest "the step of pre-charging the syringe then release valve 310 to apply vacuum to the clot material." *Id.* at p.1050.

In response to the Office action, Patent Owner canceled independent claim 32 and added new dependent claims 41-63 from allowable independent claim 21. *Id.* at pp.701-708. In the Notice of Allowance, the Examiner referred back to their statements of allowance in the Office action as grounds for allowing the claims. *Id.* at p.679.

Petitioner's primary reference for grounds 1-4 regarding Claim 1—Garrison—was extensively considered by the Office. Namely, Garrison was (and related Garrison applications were) disclosed to the Office in an Information Disclosure Statement and appears on the face of the '580 Patent. EX1001, p.6; EX1002, p.1120. Likewise, Hartley was also identified in an Information Disclosure Statement and appears on the face of the '580 Patent. EX1001, p.5, EX1002, p.1102.

Petitioner relies on Schaffer for only an attachment member, nothing more than what Petitioner also alleges is disclosed by Garrison and Hartley.

C. Person of Ordinary Skill in the Art

Petitioner asserts that a POSA has “an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of catheter design experience and, where necessary, would have consulted with a physician regarding the methods of treatment.” Petition, p.11. This is insufficient to qualify as a POSA. EX2003, ¶45. Nevertheless, Patent Owner applies Petitioner's definition herein as, even under this definition, Petitioner has failed to demonstrate a likelihood that any claim is invalid as anticipated or obvious.

D. Claim Construction

Petitioner proposes a claim construction for a single term, “filament,” recited in dependent Claims 15-17. Petition, p.11-13. This claim construction issue is not germane to Patent Owner's arguments here, and it is therefore not necessary at this time to analyze that claim term. Patent Owner reserves the right to construe “filament” or any other term according to its plain and ordinary meaning during the trial phase, if needed.

III. INDEPENDENT CLAIM 1 AND DEPENDENT CLAIMS 5, 9, 11-14, 18, 21-22, 24-28, 30, AND 33-34 ARE NOT ANTICIPATED BY GARRISON (GROUND 1)

Petitioner fails to demonstrate a reasonable likelihood that Claims 1, 5, 9, 11-14, 18, 21-22, 24-28, 30, and 33-34 of the '580 Patent are anticipated by Garrison. Anticipation requires that “each and every element of the claimed invention” must be disclosed either explicitly or inherently and that the “elements must be arranged or combined in the same way as in the claim” in a single reference. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

Here, Garrison fails to disclose the method of independent Claim 1 including “fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft” (Petitioner’s labeled limitation [1c]) and then “engaging the interventional device with a second portion of the clot material remaining within the blood vessel” (Petitioner’s labeled limitation [1f]). EX1001, cl.1; Petition, pp.22, 35. Claim 1 requires aspirating a first portion of a clot into an elongated shaft via application of a pre-charged vacuum, and then advancing an interventional device through the elongated shaft and engaging the interventional device with a second portion of that *same clot* that remains in the blood vessel after this aspiration. EX2003, ¶49.

Here, none of the various portions of Garrison relied on by Petitioner for allegedly disclosing limitation [1f] of Claim 1 disclose that limitation. Petition, pp.35-37. Put simply, Petitioner fails to demonstrate a reasonable likelihood that Garrison discloses the steps recited by Claim 1 including engaging an interventional device with a second portion of a clot remaining in a blood vessel after aspirating a first portion of that same clot. EX2003, ¶51.

Petitioner relies on Garrison's catheter 2030 for allegedly disclosing the "elongated shaft" required by Claim 1 and alleges that various additional devices inserted through that catheter 2030 disclose the "interventional device" recited in Claim 1. Petition, pp.18-19, 32-34. Then, Petitioner first alleges that Garrison discloses limitation [1f] based on its disclosure that "if a secondary more distal treatment site needs to be reached *after removal of a first occlusion*, a second, smaller diameter catheter may be inserted through the first catheter, and positioned at the distal treatment site." EX1006, ¶[0166]; Petition, p.35 (emphasis in Petition). But that disclosure of Garrison is for the treatment of a *different clot* at a different and more distal treatment site after removing a different first clot, as Petitioner itself emphasizes ("*after removal of a first occlusion*"). EX2003, ¶52; Petition, p.35 (emphasis in Petition). Paragraph [0166] of Garrison does not disclose using the second smaller diameter catheter to treat a remaining portion of the *same clot* after aspirating as required by Claim 1. *Id.* Put differently, paragraph [0166] of Garrison

discloses fully removing a first occlusion (clot) then treating a different more distal clot—not treating a remaining portion of the same clot at the same treatment site. *Id.*

Petitioner's conclusion in that same paragraph that "Garrison describes engaging an interventional device with a second portion of clot material" because "Garrison discloses many interventional devices including, for example, an expandable member deliverable through a microcatheter that can remove portions of a clot" is also incorrect. Petition, p.35. Namely, Garrison's disclosure of various thrombectomy devices that can be inserted through the catheter 2030 does not disclose the claimed method of aspirating a first portion of the clot material through an elongated shaft, advancing an interventional device through the elongated shaft, and then engaging that interventional device with a second portion of the clot material remaining in the blood vessel after aspirating as required by Claim 1. EX1006, ¶¶[0054], [0143]; EX2003, ¶53. That is, Petitioner's citations to paragraphs [0054] and [0143] of Garrison at best demonstrate that Garrison has some structural components similar to that of Claim 1, but do not demonstrate that Garrison discloses the methodology of Claim 1. EX2003, ¶53.

In fact, the embodiment of Garrison described in paragraph [0143] of Garrison is for a thrombectomy device 15 shown in Figure 39 and that is "configured to remove an occlusion *as a single piece by not breaking the occlusion into multiple pieces*" to "minimize or eliminate the creation of emboli distal to the location of the

clot.” EX1006, ¶[0143] (emphasis added). Removing the occlusion “as a single piece” is the opposite of the methodology recited in Claim 1 in which aspirating removes a first portion of the clot material, and then the interventional device engages a second portion of the clot material remaining in the blood vessel. EX2003, ¶53.

Petitioner's next allegation that “Garrison solves the very problem the '580 patent purportedly addresses - deploying separate devices to remove a clot” because Garrison incorporates “accessory devices, such as thrombectomy device 4100, into the system” is also insufficient to demonstrate a reasonable likelihood that Garrison anticipates Claim 1. Petition, p.35. Again, that Garrison discloses accessory devices and a catheter 2030 that can be aspirated does not disclose the methodology recited in Claim 1 including aspirating a first portion of clot material before engaging an interventional device with a second portion of the clot material that remains in the blood vessel after aspiration. EX2003, ¶54. Petitioner concludes that “Garrison discloses that the user can deploy these devices after aspirating a first clot portion” based on paragraph [0166] of Garrison. Petition, p.35. But, as explained above, the disclosure in that paragraph [0166] of Garrison is for treating a different clot at a different and more distal treatment site (at a different location) with a second smaller catheter rather than an interventional device and after removing a first clot at a first

treatment site—not treating a remaining portion of the same clot at the same treatment site as required by Claim 1. EX2003, ¶54.

Finally, paragraphs [0125]-[0126] of Garrison cited by Petitioner also do not disclose limitation [1f] because the embodiments disclosed therein include a thrombus disruption device that remains within a catheter during aspiration and that does not engage “clot material remaining within the blood vessel” after aspirating as required by Claim 1. Petition, p.36; EX2003, ¶¶55-56. Specifically, the embodiments in paragraphs [0125]-[0126] of Garrison disclose a catheter with a “structure for morcelating the thrombotic occlusion as it is being aspirated into the catheter” and that is “expanded proximal to the distal tip of the catheter” (i.e., within the catheter during aspiration). EX2003, ¶55. Figure 53 of Garrison shows such a thrombus disruption device 5105 expanded within a catheter 2830 that is “rotated throughout the aspiration step to ensure that the clot is never clogging the distal tip of the catheter”:

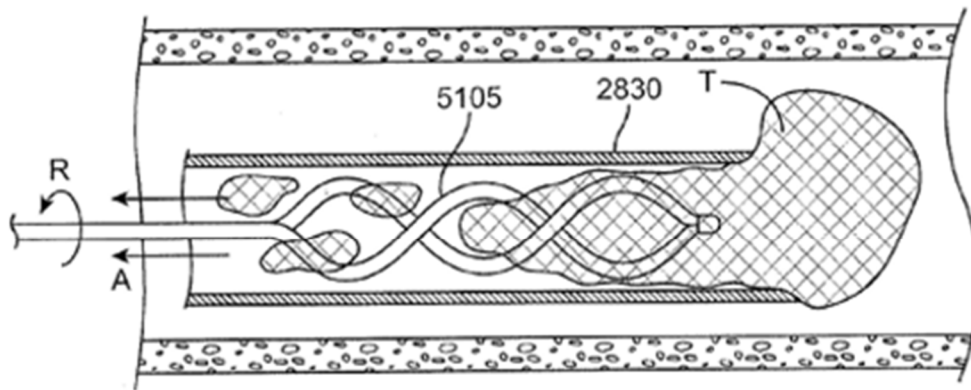


FIG. 53

EX1006, ¶[0126]; EX2003, ¶55. Garrison discloses that the thrombus disruption device is positioned within the catheter *before* aspiration and used during the aspiration treatment rather than advanced and engaged with remaining clot after aspiration: “a separate thrombus disruption device with an expandable distal segment is inserted into the catheter ... Aspiration is then initiated at the proximal end of the catheter.” EX1006, ¶[0125]; EX2003, ¶55. And, aspiration occurs continuously when the thrombus disruption device is expanded within the catheter: “Aspiration as indicated by the arrows A is maintained throughout this maneuver to ensure that the morecelated thrombus is removed via the catheter 2830 and not reinserted into the blood stream.” EX1006, ¶[0125]; EX2003, ¶55.

Accordingly, the embodiments in paragraphs [0125]-[0126] of Garrison do not disclose “engaging [a thrombus disruption device] with a second portion of the clot material remaining within the blood vessel” after aspiration as recited in Claim

1 because the thrombus disruption device engages the clot for the full duration the clot is aspirated and removed. Likewise, those embodiments also do not disclose “unsealing an attachment member,” “advancing the interventional device,” and “unsealing the interventional device” *after* aspirating as required by Claim 1. *Id.* Instead, the thrombus disruption device is positioned within the catheter for the full duration of aspiration. *Id.*

In sum, none of the portions of Garrison relied on by Petitioner to allege anticipation of Claim 1 disclose Petitioner's limitation [1f]: “*engaging the interventional device with a second portion of the clot material remaining within the blood vessel.*” EX2003, ¶57. The embodiment in paragraph [0166] of Garrison describes treating a first clot with a first catheter and then inserting a second catheter through the first to treat another different clot at a more distal treatment site—not a remaining portion of the same first clot. *Id.* And, Garrison's disclosure that the catheter 2030 (Petitioner's alleged “elongated shaft”) can receive other devices does not disclose the methodology of Claim 1 including aspirating a first portion of the clot material through an elongated shaft, advancing an interventional device through the elongated shaft, and then engaging that interventional device with a second portion of the clot material remaining in the blood vessel after aspirating. *Id.* Finally, the embodiments in paragraphs [0125]-[0126] advance a thrombus disruption device through a catheter before—rather than after—aspiration, and that thrombus

disruption device remains disrupting the clot during the entirety of aspiration rather than engaging with a second portion of the clot remaining afterward.

Therefore, Claim 1 is not anticipated by Garrison. Dependent Claims 5, 9, 11-14, 18, 21-22, 24-28, 30, and 33-34 depend from independent Claim 1. Therefore, those claims are also not anticipated by Garrison because they incorporate all the features of independent Claim 1.

IV. INDEPENDENT CLAIM 1 AND DEPENDENT CLAIMS 5-6, 9, 11-14, 18, 21-22, 24-28, 30, AND 33-34 ARE NOT RENDERED OBVIOUS BY GARRISON ALONE (GROUND 2) OR IN COMBINATION WITH SCHAFFER (GROUND 3) OR HARTLEY (GROUND 4)

A claim is not obvious if a limitation of the claim is missing in the cited art. *See Aug. Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011) (finding that asserted claims are not rendered obvious in view of the cited prior art because they do not supply the missing element for purposes of obviousness analysis). Moreover, to demonstrate obviousness, Petitioner must provide a reason why a POSA would have been motivated to modify/combine the prior art to achieve the claimed invention. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008); *see also Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023) (“When an obviousness challenge asserts a combination of identified prior art, the motivation-to-combine portion of the inquiry is ‘whether a ‘skilled artisan would

have been motivated to combine the teachings of the prior art references to achieve the claimed invention.”).

Here, Garrison alone or in combination with Schaffer or Hartley do not render obvious at least limitation [1f] of independent Claim 1 of the '580 Patent (“*engaging the interventional device with a second portion of the clot material remaining within the blood vessel*”). EX2003, ¶¶59-65. Petitioner relies only on Garrison, and on no portion of Schaffer or Hartley, for allegedly rendering obvious limitation [1f]. Petition, pp.35-37. Petitioner’s only alleged motivation to modify Garrison—that “a POSITA would have been motivated to engage the interventional device inserted through catheter 2030 with the second clot portion” based on paragraph [0165] of Garrison—is incorrect because that paragraph of Garrison does not disclose inserting any interventional device through the catheter 2030 (Petitioner’s alleged “elongated shaft”)—let alone to remove a second portion of clot remaining after aspirating a first portion of that clot. Petition, pp.36-37. More specifically, Petitioner’s only motivation to modify Garrison is as follows:

A POSITA would have been motivated to engage an interventional device with a second clot portion based on Garrison. (Ex. 1003, ¶116.) For example, Garrison explains that the clot may be “too large or too strongly embedded into the vasculature such that it is not possible to remove the occlusion via aspiration alone, [such that] further steps are taken to remove the occlusion.” (Ex. 1006, [0165].) Garrison expressly

discloses deploying a thrombectomy device to remove such clots. (*Id.*) Based on this disclosure, a POSITA would have been motivated to engage the interventional device inserted through catheter 2030 with the second clot portion.

Id. And Petitioner's expert parrots that same unsupported conclusion. EX1003, ¶116.

But Petitioner mischaracterizes paragraph [0165] of Garrison—omitting the specific steps disclosed by Garrison in that paragraph for removing clots that are “not possible to remove ... via aspiration alone.” EX1006, ¶[0165]; EX2003, ¶62. Namely, Garrison discloses that when aspiration alone is insufficient a “thrombectomy device 15 may be deployed *through the arterial access device* to remove the clot.” *Id.* (emphasis added). But the arterial access device through which the thrombectomy device 15 is deployed is not the catheter 2030 that Petitioner alleges is the “elongated shaft” of Claim 1. EX2003, ¶62. Instead, Garrison's immediately preceding paragraph distinguishes catheter 2030 from arterial access device 2010 as follows: “catheter 2030 is placed through the arterial access device 2010.” EX1006, ¶[0164]. And, Figure 32 of Garrison shows the arrangement specified in paragraph [0165] in which a thrombectomy device is inserted through the arterial access device:

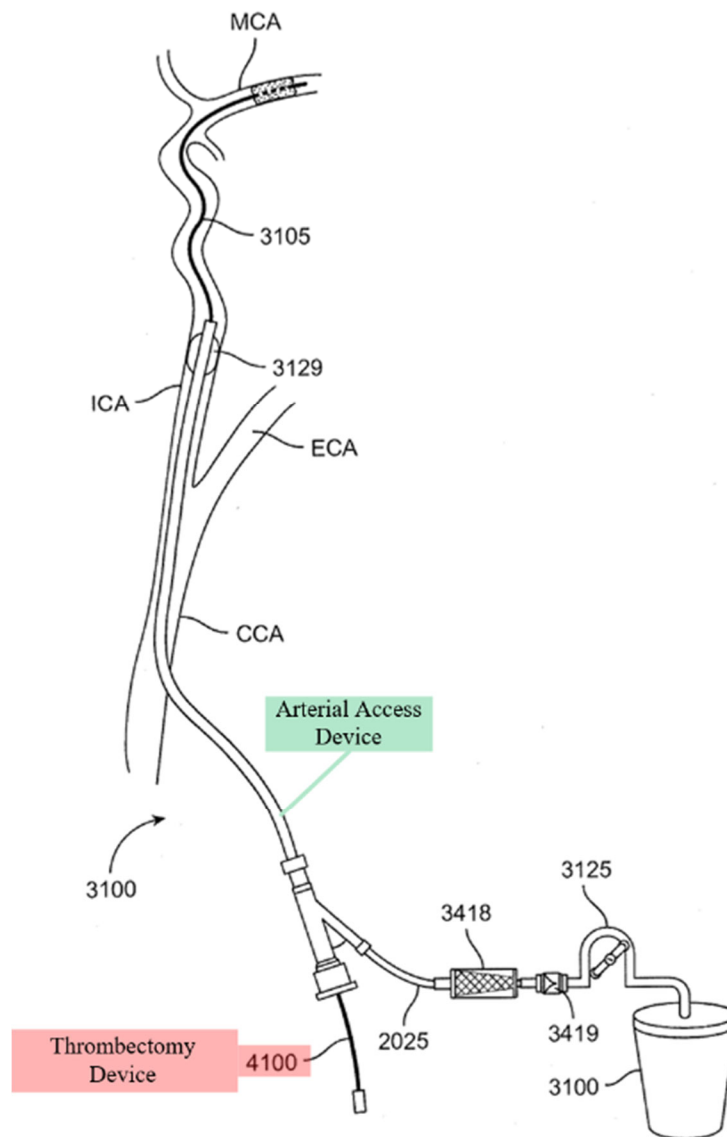


FIG. 32

EX2003, ¶62.

Therefore, the sole paragraph [0165] of Garrison that Petitioner cites for motivation in its obviousness argument discloses inserting a thrombectomy device through a different part of Garrison's system—the arterial access device 2010—and not the catheter 2030 that Petitioner alleges is the “elongated shaft” of Claim 1. *Id.*

at ¶63. Petitioner and its expert fail to acknowledge that fundamental difference and similarly provide no reasons why a POSA would have inserted a thrombectomy device through a different catheter (e.g., the catheter 2030) or why a POSA would have inserted that thrombectomy device through that different catheter after aspirating a first portion of clot material in the manner required by Claim 1, instead simply concluding that one would. For those reasons, Petitioner has failed to demonstrate that a POSA would have been motivated “to engage the interventional device inserted through catheter 2030 with the second clot portion” as Petitioner alleges. *Id.*; Petition, pp.36-37. Grounds 2-4 fail at least for those reasons.

Accordingly, as explained above and in §III, no portion of Garrison cited by Petitioner discloses the methodology of Claim 1 including “engaging [an] interventional device with a second portion of the clot material remaining within the blood vessel” after aspirating a first portion of the clot material. EX2003, ¶64. And, a POSA would not have been motivated to modify Garrison to advance an interventional device through the catheter 2030 based on paragraph [0165] of Garrison—the only portion of Garrison cited by Petitioner to support its obviousness assertions—because that paragraph discloses that if aspiration alone is insufficient to remove a clot a thrombectomy device can be inserted through the arterial access device 2010, not the catheter 2030. *Id.*

For those reasons, Garrison alone or in combination with Hartley and Schaffer fail to disclose or render obvious the method of Claim 1 including “engaging the interventional device with a second portion of the clot material remaining within the blood vessel.” Dependent Claims 5, 9, 11-18, 21-30, and 33-34 depend from independent Claim 1. Therefore, those claims are also not rendered obvious by Garrison alone or in combination with Hartley and Schaffer because they incorporate all the features of independent Claim 1.

V. DEPENDENT CLAIMS 10 AND 15-29 ARE NOT RENDERED OBVIOUS BY GARRISON IN COMBINATION WITH ANY OF SCHAFFER, HARTLEY, GOFF, LAUB, AND/OR AKLOG (GROUNDS 5-14)

As set forth in §§III-IV above, independent Claim 1 is not anticipated by Garrison, not rendered obvious by Garrison alone, and not rendered obvious by Garrison in combination with Schaffer or Hartley. Dependent Claims 10 and 15-29 depend from independent Claim 1. Petitioner does not allege that Schaffer and Hartley (ground 5; claims 15-17), Goff (ground 6; claims 18-22 and 24-28), Schaffer and Goff (ground 7; claims 18-29), Hartley and Goff (ground 8; claims 18-22 and 24-28), Laub (ground 9; claim 10), Aklog (ground 10; claim 10), Laub and Schaffer (ground 11; claim 10), Laub and Hartley (ground 12; claim 10), Aklog and Schaffer (ground 13; claim 10), or Aklog and Hartley (ground 14; claim 10) disclose any of the limitations of independent Claim 1 discussed above, including limitation [1f].

Therefore, those dependent Claims are also not rendered obvious by Garrison in combination with Schaffer, Hartley, Goff, Laub, and/or Aklog as explained above with respect to Claim 1 because they incorporate all the features of their independent Claim 1.

VI. CONCLUSION

For all the above reasons, Patent Owner respectfully requests that the Board deny institution.

Respectfully submitted,

Dated: October 17, 2025

By: / Joseph P. Hamilton /
Joseph Hamilton
Reg. No. 51,770
Lead Counsel for Patent Owner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph Hamilton, certify that **PATENT OWNER'S PRELIMINARY RESPONSE** contains 5,550 words, excluding those portions identified in 37 C.F.R. § 42.24(a), as measured by the word-processing system used to prepare this paper.

Dated: October 17, 2025

By: / Joseph P. Hamilton /
Joseph Hamilton
Reg. No. 51,770

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on October 17, 2025, a copy of
PATENT OWNER'S PRELIMINARY RESPONSE and Exhibit 2003 was
served upon the below-listed counsel by electronic mail:

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Dated: October 17, 2025

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