PERKINSCOIE

1201 Third Avenue
Suite 4900
Seattle, WA 98101-3099

+1.206.359.8000
+1.206.359.9000
PerkinsCoie.com

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Ramsey M. Al-Salam
RAlsalam@perkinscoie.com
D. +1.206.359.6385
F. +1.206.359.7385

VIA EMAIL

Gerard von Hoffmann
Vice President, Intellectual Property
Imperative Care
210 E. Hacienda
Campbell, CA 95008
gvhoffmann@imperativecare.com

Re: Imperative Care's Infringement of Inari Medical's Patents

Dear Gerard:

Thank you for your letter of January 15, 2024. In your letter, you indicate that Imperative Care will not provide us with a sample of its Symphony product and refer to prior art that you contend invalidates certain claims of Inari's patents. Notably, other than a single noninfringement argument for claim 1 of U.S. Patent No. 11,559,382 ("the '382 patent"), you do not deny that all of the other patent claims identified in my September letter "read on" the Symphony product, which is an implicit admission that Imperative Care's use and sale of the product are acts of infringement.

As to validity, as you know, there is a presumption that patent claims are valid. In litigation this presumption can only be overcome by clear and convincing evidence. The presumption of validity is particularly strong where the Patent and Trademark Office considered the relevant prior art in examining the application.[1] Even beyond these points, however, we do not agree that the prior art that you have cited renders the claims of the Inari patents invalid.

More specifically, Imperative Care relies heavily on U.S. Patent Publication No. 2015/0173782 to Garrison ("Garrison I"), asserting that Garrison I renders invalid the relevant claims of the '382 and '691 patents. We disagree. Garrison I relates to neurovascular procedures, whereas both Inari's products and the Symphony product are designed to treat deep vein thrombosis (DVT) and/or pulmonary embolisms (PE). As you know, DVT and PE treatments are significantly different

[1] As your letter acknowledges, almost all of the prior art that you cite was before the Patent and Trademark Office during prosecution of the relevant patents. The Garrison I patent was before the Patent Office during prosecution of the '382 patent and U.S. Patent No. 11,744,691 ("the '691 patent"), for instance. And the Examiner considered Hartley during prosecution of U.S. Patent No. 11,697,012, and the combination of U.S. Patent Publication No. 2016/0220741 (Garrison III) and Hartley during prosecution of U.S. Patent No. 11,554,005.

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US Patent 12,016,580
Imperative Care Ex. 1028

from treatments for neurovascular clots. For one thing, neurovascular thrombosis treatments require much smaller catheters, and the vasculature and the nature of the clots are different than for DVT or PE. For at least these reasons, the Patent and Trademark Office has allowed Inari patent claims over Garrison I. For example, we have enclosed correspondence from the Patent and Trademark Office demonstrating that the disclosure of Garrison I was considered by the Examiner before allowance of U.S. Patent Application No. 18/329,450 (Pub. No. US 2023/0310138 A1, which is scheduled to issue as U.S. Patent No. 11,969,333.[2] Likewise, we have enclosed Office Actions where the Patent Office allowed claims over Garrison I in U.S. Patent Application No. 18/342,553 (Pub. No. US 2023/0338131 A1). The claims of these applications, including but not necessarily limited to claims 23, 42, and 44 of the '333 patent and claims 1 and 3 of the '553 application, are about to issue and will read on Imperative Care's Symphony product once issued. If you disagree that the claims will read on the Symphony product, please tell us the basis for your disagreement.

Similarly, the '382 and '691 patents have dependent claims that are directed to DVT and/or PE applications that use larger catheter sizes and are distinguishable from Garrison I. For example, claim 24 of the '382 patent recites a telescoping system with at least 16 French and 24 French catheters, far larger than disclosed in Garrison I and which could not have been used in the neurovascular procedures taught by Garrison I. Similarly, claims 7, 8, 21, 22, and 31 of the '691 patents recite use in DVT or PE applications.

We have also now had an opportunity to inspect the hemostasis valve in the Symphony product, despite Imperative Care's misleading claim that the product, which is being sold to doctors and hospitals, is "confidential." Inari has at least four issued patents — U.S. Patents 11,697,011, 11,697,012, 11,844,921, and 11,865,291 — that have claims that read on Symphony's hemostasis valve structure. For example, at least claims 1, 2, 4, 5-7 and 9 of the '011 patent and claims 1-4 and 7-14 of the '291 patent read directly on the hemostasis valve for the Symphony product. Similarly, at least claims 1 and 10 of the '921 patent read directly on Symphony's hemostasis valve. And at least claims 1-4 and 7-9 of the '012 patent read directly on the Symphony product with an aspiration catheter and a hemostasis valve on the proximal end of the aspiration catheter. Again, if Imperative Care disagrees that these claims read on the valve strucutre, please tell us the basis for your disagreement.

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[2] Such correspondence indicates, for example, that U.S. Patent Application Publication No. 2017/0274180 A1 ("Garrison '180") was brought to the Examiner's attention and discussed with the Examiner during prosecution of U.S. Patent Application No. 18/329,450. Garrison '180 corresponds to U.S. Patent Application No. 15/425,460, which is a continuation of Garrison I (U.S. Patent Application No. 14/576,953). Specifically, Garrison '180 has the same specification and figures as Garrison I.

Further, the combination of prior art in your letter does not render these claims invalid. To begin, it would not be obvious to substitute the spring mechanism taught by Schaffer in the rotary actuator system taught by Hartley because, at least in part, such a modification would require a complete redesign of Hartley that would negate the stated purpose of at least Hartley's ball and recess structure. For example, to provide the complete and immediate closure of the tubular diaphragm as taught by Schaffer, any springs somehow substituted into Hartley's design would need to be strong enough to override Hartley's ball/recess structure. This would eliminate Hartley's ability to retain the position of Hartley's rotary actuator in anything other than a closed position, which would negate Hartley's stated purpose to provide a tactile indication of the position of the rotary actuator and to allow the rotary actuator to be retained at multiple different positions other than a closed position.

We also disagree that Hartley's flexible string is a predictable substitute for the U-shaped actuation members of Schaffer's system. It would not be obvious to substitute Hartley's flexible string for Schaffer's U-shaped actuation member at least because Hartley's flexible string would operate completely differently than Schaffer's U-shaped actuation members. For example, Hartley's flexible string would not have enough strength or rigidity to "forcibly disengage" the tubular member as taught by Schaffer. Instead, upon depressing Schaffer's actuation buttons, the end portions of a flexible string would merely collapse while continuing to engage the containment structure, which is a completely different mechanism of action than providing forcible disengagement as taught by Shaffer. For at least these reasons, it would not be obvious to a person having ordinary skill in the art to substitute Harley's flexible string for Shaffer's U-shaped actuation members.

Further, claim 10 of the '921 patent and its dependents recite the use of two filaments, which corresponds to the Symphony system, but distinguishes both Schaffer and Hartley. Similarly, claims 1 and 3 of the '011 patent recite a filament or other engagement member having different ends coupled to two different actuators, and a filament that circumferentially constricts and/or loops completely around the tubular member, again corresponding to the Symphony product but missing in Hartley and Schaffer.

In light of the above, it seems clear that Imperative Care's sale of the Symphony product infringes Inari's patents. For that reason, we again ask that Imperative Care respect Inari's patent rights and cease any launch of the infringing Symphony product. If you would like to discuss any of this, please tell me. Otherwise, we look forward to your prompt response.

Sincerely,

Ramsey M. Al-Salam

Enclosures

1. 2024-03-13 Notice of Allowance
2. 2023-11-06 Non-Final Office Action Prioritized Examination
3. 2024-01-31 Applicant-Initiated Interview Summary
4. 2024-03-01 Notice of Allowance
5. 2024-01-30 Response to NFOA 2023-10-30
6. '333 Issue Notification