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12 13	UNITED STATES D NORTHERN DISTRIC	
14 15	MEMORY METAL HOLLAND BV and DON MICHAEL INTERNATIONAL, LLC,	Case No. 18-cv-2487
16	Plaintiffs,	COMPLAINT FOR PATENT INFRINGEMENT
17	VS.	DEMAND FOR JURY TRIAL
18	CLARET MEDICAL, INC.,	
19	Defendant.	
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Plaintiffs Memory Metal Holland BV ("Memory Metal") and Don Michael International, LLC ("DMI") (together, "Plaintiffs") bring this action against defendant Claret Medical, Inc. ("Claret") and hereby allege as follows:

THE PARTIES

- 1. Memory Metal Holland BV is a limited liability company organized and existing under the laws of the Netherlands having a principal place of business at Gronausestraat 1220, Enschede 7534 AT, Netherlands.
- 2. Memory Metal is in the business of developing and commercializing medical technology.
- 3. Don Michael International, LLC, is a limited liability company organized and existing under the laws of California having a principal place of business at 4109 Sill Place, Bakersfield, California 93306.
- 4. Claret Medical, Inc. is a corporation organized and existing under the laws of Delaware having a principal place of business at 1745 Copperhill Parkway, Suite 1, Santa Rosa, CA 95403.

JURISDICTION AND VENUE

- 5. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*. This Court accordingly has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2202.
- 6. This Court has jurisdiction over Claret because Claret does business in the State of California and this District, contracts to supply goods or services within the State of California and this District, has continuous and systematic business contacts within the State of California and this District, derives substantial revenue from interstate commerce from goods used or services rendered in the State of California and this District, and/or commits and has committed acts of patent infringement either within the State of California and this District, or outside the State of California and this District with a reasonable expectation that such acts would have consequences within the State of California and this District.
- 7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), 1400(b), and 1404(a).

FACTS

The Asserted Patents

- 8. On November 26, 2002, U.S. Patent No. 6,485,502 (the "'502 Patent''), entitled "Vascular Embolism Prevention Device Employing Filters," a copy of which is attached hereto as Exhibit A, was duly and legally issued by the United States Patent and Trademark Office ("USPTO") to T. Anthony Don Michael and Peter Besselink as inventors.
- 9. Plaintiffs are the owners of the '502 Patent by assignment, having received all right, title, and interest of the '502 Patent from the inventors.
- 10. On May 8, 2007, U.S. Patent No. 7,214,237 (the "'237 Patent," together with the '502 Patent, the "Asserted Patents"), entitled "Vascular Filter With Improved Strength and Flexibility," a copy of which is attached hereto as Exhibit B, was duly and legally issued by the USPTO to T. Anthony Don Michael and Peter Besselink as inventors.
- 11. Plaintiffs are the owners of the '237 Patent by assignment, having received all right, title, and interest of the '237 Patent from the inventors.
- 12. The Asserted Patents identify and sets out to prevent embolism in a vascular system, such as during angioplasty or stenting. ('502 Patent 1:12-24; '237 Patent at 1:14-20.) The claimed inventions of the Asserted Patents provide a system to prevent embolism by preventing the escape of debris from the treatment site in a blood vessel using filter elements. ('502 Patent 1:64-67; '237 Patent at 2:27-31.)

Claret's Infringing Systems and Services

- 13. Claret makes, uses, sells, and/or offers to sell various medical devices including, but not limited to, the Sentinel Cerebral Protection System (and any previous versions or alternate names, including but not limited to the CE Pro System and Montage) (the "Accused Product").
- 14. The Accused Product is a medical device that filters, captures, and removes embolic debris during vascular procedures.
- 15. The Accused Product accomplishes the removal of debris using two filters that deploy independently and collect debris released during the procedure, such as valve tissue,

calcification, thrombus, or other material, to prevent that material from traveling to the brain. When the procedure is complete, the filters and collected debris are removed.

- 16. Upon information and belief, Claret develops, designs, manufactures, and sells the Accused Product at its facility in Santa Rosa, California.
- 17. Claret markets, sells, and offers to sell the Accused Product to, without limitation, individual doctors, hospitals, and other medical and/or healthcare organizations.
- 18. Claret provides the Accused Product to at least fifty U.S. transcatheter aortic heart valve replacement ("TAVR") centers and TAVR providers throughout the world, including, for example, Pinnacle Health in Pennsylvania ("Customers").
- 19. Upon information and belief, Claret manufactures and/or combines all or at least a substantial portion of the components of the Accused Product in its Santa Rosa, California facility.
- 20. Upon information and belief, Claret supplies all or a substantial portion of the components of the Accused Product from its California facility to, without limitation, individual doctors, hospitals, and other medical and/or healthcare organizations around the world, including without limitation, Brazil, Canada (such as St. Paul's Hospital in Vancouver, Canada) and Europe (such as Erasmus Medical Center in Rotterdam, The Netherlands).
- 21. Claret instructs Customers regarding the combination of the components and the use of the Accused Product with knowledge that such combination and/or use would infringe the Asserted Patents. Claret provides at least the following instructions regarding use of the Accused Product: a guide of the procedure for using the Accused Product (http://www.claretmedical.com/physicians/technology/sentinel-cps-procedure/), "Instructions for Use" (http://claretmedical.com/ Sentinel-IFU.pdf?version=c), "Physician Resources" (http://www.claretmedical.com/ physicians/resources/healthcare-professionals/), and a YouTube channel.
- 22. The components of the Accused Product that Claret provides to Customers outside of the United States are especially made for, or especially adapted for, use in the Accused Product and have no other substantial non-infringing use and are not staple articles or commodities of commerce.

- 23. The Accused Product infringes at least claims 1-12 of the '502 Patent and at least claims 2-5 of the '237 Patent.
- 24. A general description of how the Accused Product infringes exemplary claims of the Asserted Patents is attached as Exhibit C, which is incorporated by reference herein in its entirety.

Claret's Knowledge of the Asserted Patents

- 25. Claret first learned of the Asserted Patents no later than April 20, 2010. On that date, Claret submitted an Information Disclosure Statement to the USPTO in association with Application Number 12/689,997, identifying the '502 and '237 Patents as relevant to its own application for a patent that eventually issued as U.S. Patent No. 8,372,108, entitled "Intravascular Blood Filter," which is listed as covering the Accused Product on certain Claret marketing documents, such as http://www.claretmedical.com/wordpress/wp-content/uploads/2018/03/US SentinelBroPL11066 02-RevRB.pdf.
- 26. Further, Claret identified both Asserted Patents in the following Information Disclosure Statements associated with its other patent applications: November 17, 2010 (Application Number 12/871,708) and March 26, 2012 (Application Numbers 13/338,966, 13/338,995, 13/338,916, and 13/338,957). At least some of these issued into patents which Claret also claims cover the Accused Product.
- 27. Additionally, on May 10, 2012, in association with a Patent Cooperation Treaty application, the International Searching Authority issued an International Search Report identifying EP 1253871 B1 to Don Michael et al. as relevant to claims Claret sought. This document detailed how EP 1253871 B1, which claims priority to the same provisional application (Provisional Application No. 60/188,179) to which the '502 Patent also claims priority, was relevant to Claret's claims, providing further notice to Claret of the Asserted Patents and their application to Claret's products.
- 28. On October 17, 2017, Plaintiffs, through their counsel, formally notified Claret CEO Dr. Azin Parhizgar, Ph.D., via letter that products made, used, sold, or offered for sale by Claret, including the Accused Product, infringed the Asserted Patents, including a chart detailing the

infringement of exemplary claims. Upon information and belief, Claret received the October 17, 2017 letter on or about October 18, 2017.

29. Since becoming aware of the Asserted Patents at least as early as April 20, 2010, and no later than on or about October 18, 2017, Claret continued to develop, make, use, sell, and offer to sell the Accused Product to customers, thereby willfully and knowingly infringing the Asserted Patents.

COUNT 1 – INFRINGEMENT OF THE '502 PATENT

- 30. Plaintiffs repeat the allegations contained in the preceding paragraphs 1 through 29 as though fully set forth herein.
- 31. Upon information and belief, Claret has in the past infringed and continues to infringe the '502 Patent, directly and/or by contributory infringement and/or by inducement of infringement, by making, using, selling and/or offering to sell, in this judicial district, throughout the United States, and elsewhere, the Accused Product, which embodies the patented inventions of the '502 Patent.
- 32. Pursuant to 35 U.S.C. § 271(a), Claret is liable for direct infringement of the '502 Patent by having made, used, offered to sell, or sold and continuing to make, use, sell and/or offer to sell the Accused Product in the United States. Claret's infringement includes, but is not limited to, the manufacture, use, sale, importation and/or offer for sale of Accused Product that embodies the patented invention of the '502 Patent. Claret has contracted to sell and has sold the Accused Product (in configurations generally similar to the allegations previously made herein) to, *inter alia*, Customers. Claret continues to make, use, sell, offer to sell, and/or import Accused Product despite having knowledge of the infringement of the '502 Patent as discussed *supra*.
- 33. Pursuant to 35 U.S.C. § 271(b), Claret is liable for inducement of infringement by having, and continuing to, knowingly cause (or intend to cause) the direct infringement of the '502 Patent by users of the Accused Product.
- 34. Pursuant to 35 U.S.C. § 271(c), Claret is liable for contributory infringement of the '502 Patent by having sold or offered to sell and continuing to sell or offer to sell the Accused Product, and the components thereof, that comprise a material component of the invention

embodied in the '502 Patent, that are especially made or adapted for use in infringing the '502 Patent, and that are not suitable for any substantial non-infringing use with knowledge that the '502 Patent was/is being directly infringed by users.

- 35. Pursuant to 35 U.S.C. § 271(f), Claret is liable for infringement of the '502 Patent by knowingly supplying customers outside of the United States with all or a substantial portion of the components of the Accused Product, the components having no other substantial non-infringing use and not being staple articles or commodities of commerce. Further, Claret knew that the combination of components supplied by Claret to foreign entities would infringe the '502 Patent if such combination occurred within the United States.
- 36. Upon information and belief, Claret's infringement of the '502 Patent is willful, deliberate, and intentional by continuing its acts of infringement with knowledge of the '502 Patent and thus acting in reckless disregard of Plaintiffs' patent rights.
- 37. As a result of Claret's acts of infringement of the '502 Patent, Plaintiffs have suffered injury to its business and property in an amount to be determined as damages, and will continue to suffer damages in the future.
- 38. Unless an injunction is issued enjoining Claret and their officers, agents, servants, employees and attorneys, and all those persons in active concert or participation with them from infringing the '502 Patent, Plaintiffs will suffer irreparable injury for which there is no adequate remedy at law.

<u>COUNT 2 – INFRINGEMENT OF THE '237 PATENT</u>

- 39. Plaintiffs repeat the allegations contained in the preceding paragraphs 1 through 39 as though fully set forth herein.
- 40. Upon information and belief, Claret has in the past infringed and continues to infringe the '237 Patent, directly and/or by contributory infringement and/or by inducement of infringement, by making, using, selling and/or offering to sell, in this judicial district, throughout the United States, and elsewhere, the Accused Product, which embodies the patented inventions of the '237 Patent.

- 41. Pursuant to 35 U.S.C. § 271(a), Claret is liable for direct infringement of the '237 Patent by having made, used, offered to sell, or sold and continuing to make, use, sell and/or offer to sell the Accused Product in the United States. Claret's infringement includes, but is not limited to, the manufacture, use, sale, importation and/or offer for sale of Accused Product that embodies the patented invention of the '237 Patent. Claret has contracted to sell and has sold the Accused Product (in configurations generally similar to the allegations previously made herein) to, *inter alia*, Customers. Claret continues to make, use, sell, offer to sell, and/or import Accused Product despite having knowledge of the infringement of the '237 Patent as discussed *supra*.
- 42. Pursuant to 35 U.S.C. § 271(b), Claret is liable for inducement of infringement by having, and continuing to, knowingly cause (or intend to cause) the direct infringement of the '237 Patent by users of the Accused Product.
- 43. Pursuant to 35 U.S.C. § 271(c), Claret is liable for contributory infringement of the '237 Patent by having sold or offered to sell and continuing to sell or offer to sell the Accused Product, and the components thereof, that comprise a material component of the invention embodied in the '237 Patent, that are especially made or adapted for use in infringing the '237 Patent, and that are not suitable for any substantial non-infringing use with knowledge that the '237 Patent was/is being directly infringed by users.
- 44. Pursuant to 35 U.S.C. § 271(f), Claret is liable for infringement of the '237 Patent by knowingly supplying customers outside of the United States with all or a substantial portion of the components of the Accused Product, the components having no other substantial non-infringing use and not being staple articles or commodities of commerce. Further, Claret knew that the combination of components supplied by Claret to foreign entities would infringe the '237 Patent if such combination occurred within the United States.
- 45. Upon information and belief, Claret's infringement of the '237 Patent is willful, deliberate, and intentional by continuing its acts of infringement with knowledge of the '237 Patent and thus acting in reckless disregard of Plaintiffs' patent rights.

- 46. As a result of Claret's acts of infringement of the '237 Patent, Plaintiffs have suffered injury to its business and property in an amount to be determined as damages, and will continue to suffer damages in the future.
- 47. Unless an injunction is issued enjoining Claret and their officers, agents, servants, employees and attorneys, and all those persons in active concert or participation with them from infringing the '237 Patent, Plaintiffs will suffer irreparable injury for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment and relief as follows:

- A. A declaration that Claret has infringed, is infringing, has induced and is inducing, has contributed and is contributing to the infringement of the '502 Patent;
- B. A declaration that Claret has infringed, is infringing, has induced and is inducing, has contributed and is contributing to the infringement of the '237 Patent;
- C. A permanent injunction enjoining Claret, its officers, agents, servants, employees, affiliates and attorneys, and all those in active concert or participation with them, from further infringing, inducing infringement, and contributing to the infringement of the '502 Patent;
- D. A permanent injunction enjoining Claret, its officers, agents, servants, employees, affiliates and attorneys, and all those in active concert or participation with them, from further infringing, inducing infringement, and contributing to the infringement of the '237 Patent;
- E. An award of damages adequate to compensate Plaintiffs for the infringement of the '502 Patent by Claret and its Customers;
- F. An award of damages adequate to compensate Plaintiffs for the infringement of the '237 Patent by Claret and its Customers;
- G. A declaration that Claret's continuing infringement of the '502 Patent was and is willful, justifying a trebling of the award of damages under 35 U.S.C. § 284, or such other enhancement of the award of damages that the Court deems appropriate;

1	H. A declaration that Claret's continuing infringement of the '237 Patent was and is willful,	
2	justifying a trebling of the award of damages under 35 U.S.C. § 284, or such other	
3	enhancement of the award of damages that the Court deems appropriate;	
4	I. An award of pre-judgment and post-judgment interest on the damages caused by reason or	
5	Claret's infringement of the Asserted Patents;	
6	J. A declaration that this an exceptional case and that Plaintiffs be granted its reasonable	
7	attorneys' fees and expenses in accordance with 35 U.S.C. § 285;	
8	K. An award of costs and expenses to Plaintiffs; and	
9	L. A grant to Plaintiffs of such other and further relief as the Court may deem just and proper	
10	JURY DEMAND	
11	Memory Metal Holland BV and Don Michael International, LLC, demand trial by jury or	
12	all claims and issues so triable.	
13		
14	Dated: April 26, 2018	
15	By: <u>/s/ Sarah A. Pfeiffer</u>	
16	Sarah A. Pfeiffer	
17	Mark B. Chassman (CA Bar No. 119619)	
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