IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AERIN MEDICAL INC. and THE FOUNDRY, LLC, Plaintiffs, v. NEURENT MEDICAL INC. and NEURENT MEDICAL LTD., Defendants.	Civil Action No. **DEMAND FOR JURY TRIAL**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Aerin Medical Inc. ("Aerin") and The Foundry, LLC ("Foundry"), by way of this Complaint for Patent Infringement under 35 U.S.C. § 271 against Defendants Neurent Medical Inc. and Neurent Medical Ltd. (collectively "Defendants" or "Neurent"), state on information and belief as follows:

NATURE OF THE ACTION

1. Aerin and Foundry bring this action for patent infringement after Neurent released in the United States the NEUROMARK® System ("Neuromark" or "Neuromark system") for treating rhinitis using Aerin's and Foundry's patented technology. In particular, this is an action for infringement of U.S. Patent Nos. 9,072,597 ("the '597 patent), 9,415,194 ("the '194 patent"), 10,610,675 ("the '675 patent"), 10,894,011 ("the '011 patent"), 11,033,318 ("the '318 patent"), 11,241,271 ("the '271 patent"), and 11,679,077 ("the '077 patent") (collectively, "patents-in-suit"), which are attached as Exhibits A-G. Aerin and Foundry seek damages resulting from Neurent's infringement and a permanent injunction against further infringement.

THE PARTIES

2. Plaintiff Aerin Medical Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 2526 Leghorn Street, Mountain View, California 94043.

3. Aerin is in the business of developing, manufacturing, and marketing innovative solutions for chronic rhinitis and nasal airway obstruction. In January 2018, Aerin announced FDA clearance for, and the launch of, the VivAer® Stylus, providing innovative treatment for patients having trouble breathing through their nose, including due to nasal congestion. And in March 2020, Aerin announced FDA clearance for, and the launch of, the RhinAer® Stylus, providing an innovative system and procedure for treating chronic rhinitis. Aerin's RhinAer has been recognized as breakthrough technology for treating chronic rhinitis. MedTech Breakthrough named Aerin Medical the winner in the 2021 MedTech Breakthrough Awards program, awarding the "Best New Therapeutic Solution" to Aerin for the RhinAer and its innovative treatment for chronic rhinitis.

4. Plaintiff The Foundry, LLC is a California limited liability company, with a principal place of business at 4040 Campbell Ave. Suite 110, Menlo Park, California 94025.

5. Foundry innovates in the field of medical devices, including developing devices and treatments for chronic rhinitis.

6. On information and belief, Defendant Neurent Medical Ltd. is a foreign corporation organized and existing under the laws of Ireland, with a principal place of business at No. 1 Oran Point, Main Street, Oran More, Galway, Co. Galway, Ireland.

7. On information and belief, Defendant Neurent Medical Inc. is a company organized and existing under the laws of the State of Delaware, with a principal place of business

at 150 Grossman Dr., Suite 203, Braintree, Massachusetts 02184. On information and belief, Neurent Medical Inc. is a wholly owned and controlled subsidiary company of Neurent Medical Ltd.

8. On information and belief, Neurent is in the business of making, using, selling, offering for sale, and/or importing the Neuromark system, which includes the Neuromark Device and Neuromark Generator, in and throughout the United States.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq*, including 35 U.S.C. § 271. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1332, and 1338(a).

10. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

11. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b) as to Neurent Medical Inc. at least because Neurent Medical Inc. is incorporated in and resides in Delaware and in this District.

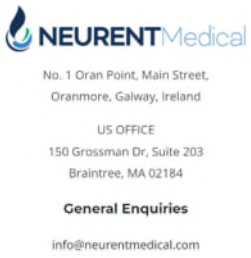
12. Venue is proper under 28 U.S.C. § 1391(c)(3) as to Neurent Medical Ltd. at least because Neurent Medical Ltd. is not a resident of the United States and, therefore, venue is proper in any judicial district.

13. Each Defendant is subject to this Court's specific and general jurisdiction consistent with the principles of due process and/or the Delaware Long Arm Statute.

14. This Court has personal jurisdiction over Neurent Medical Inc. at least because, on information belief, Neurent Medical Inc. is incorporated in Delaware and resides in this District. The Court also has personal jurisdiction over Neurent Medical Inc. at least because this lawsuit arises out of Neurent Medical Inc.'s infringing activity, including, without limitation,

distributing, selling, offering to sell, and/or importing infringing products in Delaware and/or inducing and contributing to infringement in Delaware. In addition, this Court has personal jurisdiction over Neurent Medical Inc. at least because, on information and belief, Neurent Medical Inc. has made, used, sold, offered for sale, and/or imported infringing products and placed such infringing products in the stream of interstate commerce with the expectation that such infringing products would be used, distributed, sold, and/or offered for sale in Delaware.

15. This Court has jurisdiction over Neurent Medical Ltd. at least because, on information and belief, Neurent Medical Inc. is an agent of Neurent Medical Ltd. for making, using, selling, distributing, offering to sell, and importing infringing products throughout the United States, including in Delaware. On information and belief, Neurent Medical Ltd. set up Neurent Medical Inc. and incorporated it in Delaware for the purpose of commercializing and selling the Neuromark system in the United States, including in Delaware. Neurent Medical Ltd. refers to the principal place of business of Neurent Medical Inc. as its "US Office," including on its website at neurentmedical.com:



16. This Court has jurisdiction over Neurent Medical Ltd. under 10 Del. C. § 3104(c) because, on information and belief, at least one provision of the Delaware long-arm statute is satisfied. On information and belief, Neurent Medical Ltd. and/or its agent Neurent Medical Inc. satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or

service in the State"), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), and/or § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State").

17. This Court also has personal jurisdiction over Neurent Medical Ltd. at least because, on information and belief, Neurent Medical Ltd. has made, used, sold, offered for sale, and/or imported infringing products and placed such infringing products in the stream of interstate commerce with the expectation that such infringing products would be used, distributed, sold, and/or offered for sale in Delaware.

18. This Court also has jurisdiction over Neurent Medical Ltd. at least because this lawsuit arises out of Neurent Medical Inc.'s infringing activity, including actively encouraging and inducing Neurent Medical Inc.'s importing, manufacturing, using, distributing, selling, and/or offering to sell infringing products in Delaware and actively encouraging and inducing physicians to infringe the patents-in-suit in Delaware. On information and belief, Neurent Medical Ltd. has knowledge of the patents-in-suit and actively encourages and instructs Neurent Medical Inc. to import, manufacture, use, distribute, sell, and/or offer to sell infringing products with knowledge of the patents-in-suit and knowledge that such acts would constitute infringement. And, on information and belief, Neurent Medical Ltd. instructs physicians to use the Neuromark system in a manner that infringes the patents-in-suit, including in the Instructions for Use for the Neuromark Device, the Instructions for Use for the Neuromark Generator, product and marketing literature, and reports on clinical trials.

19. Alternatively, this Court has jurisdiction over Neurent Medical Ltd. under Federal Rule of Civil Procedure 4(k)(2) because, on information and belief, Neurent Medical Ltd. has extensive contacts with the United States, including but not limited to the contacts described above and below, is not subject to jurisdiction in any state, and exercising jurisdiction over

Neurent Medical Ltd. is consistent with the laws of the United States and the United States Constitution.

20. On information and belief, Neurent Medical Ltd. set up Neurent Medical Inc. and incorporated it in Delaware for the purpose of commercializing and selling the Neuromark system, the only product of Neurent Medical Ltd. On information and belief, Neurent Medical Inc. is the agent for Neurent Medical Ltd. to commercialize and sell the Neuromark system in the United States. On information and belief, Neurent Medical Ltd. refers to the principal place of business of Neurent Medical Inc. as its "US Office."

21. On information and belief, Neurent Medical Ltd. ran clinical trials in the United States for the Neuromark system and sought and obtained approval from the FDA for the Neuromark system. Ex. H (Letter from FDA dated Oct. 22, 2021 to Kenny Walsh of Neurent Medical, Galway Ireland, regarding Section 510(k) premarket notification for the Neuromark system); Ex. I (Letter from FDA dated Oct. 26, 2022 to Karen Peterson of Neurent Medical, Galway Ireland, regarding Section 510(k) premarket notification for the Neuromark system). Neurent Medical Ltd. conducted clinical evaluation of the Neuromark system throughout the United States with a multicenter study to support commercialization of the Neuromark system in the United States. Neurent Medical Ltd. refers to this study as the "Clarity" study. Neurent Medical Ltd. ran this trial "to drive a broader commercialization of the device." Ex. J ("Neurent Medical raises €20.6m to commercialise runny nose cure," Irish Times (Jan. 20, 2021)). The Instructions for Use for the Neuromark Device and for the Neuromark Generator identify Neurent Medical Ltd. as the source of the Instructions for Use in the United States. Ex. K (Instructions for Use, NEUROMARK® System); Ex. L (NEURENT Medical, NEUROMARK Generator, Instructions for Use).

22. On information and belief, Neurent Medical Ltd. has targeted the United States and only the United States for commercial release of Neuromark system. In February 2023, Neurent Medical Ltd. announced that it was releasing the Neuromark system in the United States and only in the United States. Ex. M (Neurent Medical Ltd. Press Release: Neurent Medical Announces Limited Market Release of NEUROMARK® System to treat Chronic Rhinitis, Feb. 3, 2023). After interviewing Neurent Medical Ltd.'s cofounder and CEO Brian Shields, the Irish Times reported that Neurent Medical Ltd. "is targeting the two million patients of ear, nose and throat (ENT) specialists in the United States for whom drug therapy to manage the condition is not working." Ex. J. The Irish Times also reported that "Neurent, which is based in Oranmore, Co Galway, will focus entirely on the US market in its early commercialisation efforts, with Mr. Shields noting: 'if you can prove that it can be done in the US then fundraising to go global with this becomes a lot easier.'" Ex. J.

23. On information and belief, Neurent Medical Ltd. and its officers in interviews and press releases target the United States for use and sales of the Neuromark system. Neurent Medical Ltd.'s cofounder and CEO has stated that, "[i]n the U.S. alone, [rhinitis] affects one in four individuals" and that FDA approval of the Neuromark system would be "followed by U.S. commercialization in select markets." Ex. N (Medgadget, "In-Office Treatment for Chronic Rhinitis: Interview with Brian Shields, Neurent Medical CEO," (Feb. 3, 2021)). On November 18, 2021, Neurent Medical Ltd. issued a press release announcing that it had received FDA clearance for the Neuromark system and that "[a]pproximately one in four Americans suffer from chronic rhinitis." Ex. O (Neurent Medical Ltd. Press Release: Neurent Medical Receives FDA Clearance for NEUROMARK™, a Novel Multi-Point Nerve Disruption Treatment for Chronic Rhinitis, Nov. 18, 2021). On February 3, 2023, Neurent Medical Ltd. issued a press

release stating that the Neuromark system "is now commercially available in limited U.S. markets" and offering the Neuromark system for sale in the United States, telling "HealthCare Professional[s]" to "Contact Customer Service to Place an Order." Ex. M. On March 21, 2003, Neurent Medical Ltd. issued a press release referencing the "Clarity" study, stating that "[a]pproximately one in four Americans suffer from chronic rhinitis," stating that "NEUROMARK is only available in the USA," and offering the Neuromark system for sale, telling "HealthCare Professional[s]" to "Contact Customer Service to Place an Order." Ex. P (Neurent Medical Ltd. Press Release: New Data Show NEUROMARK® Chronic Rhinitis Treatment Offers Significant Symptom Improvements, Mar. 21, 2023).

24. Defendants are properly joined under 35 U.S.C. § 299 at least because Defendants are jointly and severally liable for infringement of the patents-in-suit, because Defendants' infringement arises from making, using, selling, importing, and/or offering for sale the same Neuromark system in the United States, and because questions of fact common to all Defendants will arise in the action.

THE PATENTS-IN-SUIT

U.S. Patent No. 9,072,597

25. The '597 patent, titled "Methods and Devices to Treat Nasal Airways," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on July 7, 2015. A true and correct copy of the '597 patent is attached as Exhibit A.

26. Aerin is the assignee and owner of the '597 patent by way of assignment from inventors Scott J. Wolf and Andrew Frazier.

U.S. Patent No. 9,415,194

27. The ’194 patent, titled “Post Nasal Drip Treatment,” was duly and legally issued by the USPTO on August 16, 2016. A true and correct copy of the ’194 patent is attached as Exhibit B.

28. Aerin is the assignee and owner of the ’194 patent by way of assignment from inventors Scott J. Wolf and Andrew Frazier.

U.S. Patent No. 10,610,675

29. The ’675 patent, titled “Systems and Methods for Delivery of a Therapeutic Agent,” was duly and legally issued by the USPTO on April 7, 2020. A true and correct copy of the ’675 patent is attached as Exhibit C.

30. Foundry is the assignee and owner of the ’675 patent by way of assignment from inventors Mark E. Deem and Hanson Gifford. By way of grant from Foundry, Aerin is the exclusive licensee of the ’675 patent in the field of medical device treatments of the nasal cavity for any purpose, including without limitation rhinitis and any symptoms thereof, with the right to prosecute any infringement of the ’675 patent in that field.

U.S. Patent No. 10,894,011

31. The ’011 patent, titled “Systems and Methods for Delivery of a Therapeutic Agent,” was duly and legally issued by the USPTO on January 19, 2021. A true and correct copy of the ’011 patent is attached as Exhibit D.

32. Foundry is the assignee and owner of the ’011 patent by way of assignment from inventors Mark E. Deem and Hanson Gifford. By way of grant from Foundry, Aerin is the exclusive licensee of the ’011 patent in the field of medical device treatments of the nasal cavity

for any purpose, including without limitation rhinitis and any symptoms thereof, with the right to prosecute any infringement of the ’011 patent in that field.

U.S. Patent No. 11,033,318

33. The ’318 patent, titled “Methods and Devices to Treat Nasal Airways,” was duly and legally issued by the USPTO on June 15, 2021. A true and correct copy of the ’318 patent is attached as Exhibit E.

34. Aerin is the assignee and owner of the ’318 patent by way of assignment from inventors Scott J. Wolf and Andrew Frazier.

U.S. Patent No. 11,241,271

35. The ’271 patent, titled “Methods of Treating Nasal Airways,” was duly and legally issued by the USPTO on February 8, 2022. A true and correct copy of the ’271 patent is attached as Exhibit F.

36. Aerin is the assignee and owner of the ’271 patent by way of assignment from inventors Scott J. Wolf and Andrew Frazier.

U.S. Patent No. 11,679,077

37. The ’077 patent, titled “Systems and Methods for Delivery of a Therapeutic Agent,” was duly and legally issued by the USPTO on June 20, 2023. A true and correct copy of the ’077 patent is attached as Exhibit G.

38. Foundry is the assignee and owner of the ’077 patent by way of assignment from inventors Mark E. Deem and Hanson Gifford. By way of grant from Foundry, Aerin is the exclusive licensee of the ’077 patent in the field of medical device treatments of the nasal cavity for any purpose, including without limitation rhinitis and any symptoms thereof, with the right to prosecute any infringement of the ’077 patent in that field.

Neurent's Knowledge of the Patents-In-Suit

39. On information and belief, Neurent has knowledge of the patents-in-suit.

40. In connection with Neurent's intent to commercialize the Neuromark system for treatment of rhinitis in the United States, Aerin notified Neurent of at least U.S. Patent Nos. 9,072,597; 9,415,194; 10,610,675; 11,033,318; and 11,241,271 by way of letter dated September 28, 2022, to Brian Shields, cofounder and CEO of Neurent.

41. Foundry notified Neurent of at least U.S. Patent No. 10,610,675 on April 10, 2020, through communication with a member of Neurent's Board of Directors. Foundry also notified Neurent of at least U.S. Patent No. 10,610,675 on January 7, 2021, through correspondence to Brian Shields, cofounder and CEO of Neurent. Neurent declined any license to the '675 patent at that time.

42. On information and belief, Neurent is aware of the family of patents related to the patents-in-suit and tracks the applications and patents in those families. Neurent cited patents-in-suit and patents in the family of the patents-in-suit to the USPTO during prosecution of Neurent's own applications. During prosecution of U.S. Patent No. 11,547,473, Neurent cited at least the '597, '194, and '271 patents, as well as U.S. Publication No. 2019/0282289, which issued as the '318 patent. During prosecution of U.S. Patent No. 11,547,473, Neurent cited patents and applications related to the '597, '194, '271, and '318 patents, including U.S. Patent Nos. 8,936,594; 8,986,301; 9,197,964; 9,179,967; 9,433,463; 9,452,010; 9,486,278; 9,687,296; 9,788,886; 9,801,752; 10,335,221; and 10,389,489. During prosecution of U.S. Patent No. 11,547,473, Neurent cited at least U.S. Patent No. 7,608,275, which is a parent patent to the '675, '011, and '077 patents. During prosecution of U.S. Patent No. 11,547,473, Neurent cited at least U.S. Patent Nos. 7,655,243; 8,105,817; 8,636,684; and 9,700,707 and applications

published as U.S. Publication Nos. 2014/0114233 and 2017/0266422, which are related to the '675, '011, and '077 patents.

43. Neurent was aware of the '597 patent at least by February 18, 2020, when Neurent cited the '597 patent in its application for U.S. Patent No. 11,547,473. Neurent's knowledge of the '597 patent is further shown by Neurent's citation of the '597 patent on February 1, 2021, in its application serial no. 16/915,812, on December 28, 2021, in its application serial no. 17/623,456, and on November 29, 2021, in its application serial nos. 17/495,132; 17/495,144; 17/495,150; and 17/495,132.

44. Neurent was aware of the '194 patent at least by February 18, 2020, when Neurent cited the '194 patent in its application for U.S. Patent No. 11,547,473. Neurent's knowledge of the '194 patent is further shown by Neurent's citation of the '194 patent on February 1, 2021, in its application serial no. 16/915,812, on December 28, 2021, in its application serial no. 17/623,456, and on November 29, 2021, in its application serial nos. 17/495,132; 17/495,144; 17/495,150; and 17/495,132.

45. Neurent was aware of the application for the '318 patent at least by February 18, 2020, when Neurent cited the U.S. Publication No. 2019/0282289, which is the publication of the application for the '318 patent, Neurent's knowledge of the application for the '318 patent is further shown by Neurent's citation of U.S. Publication No. 2019/0282289 on February 1, 2021, in its application serial no. 16/915,812. Neurent knew or should have known that the '318 patent had issued when it cited U.S. Publication No. 2019/0282289 on December 28, 2021, in its application serial no. 17/623,456, and on November 29, 2021, in its application serial nos. 17/495,132; 17/495,144; 17/495,150; and 17/495,132.

46. Neurent was aware of the ’271 patent at least by August 22, 2022, when Neurent cited the ’271 patent in its application for U.S. Patent No. 11,547,473. Neurent’s knowledge of the ’271 patent is further shown by Neurent’s citation of the ’271 patent on January 24, 2023, in its application serial nos. 16/915,812; 17/495,132; 17/495,144; 17/495,150; and 17/495,132.

47. Neurent was aware of the ’675 patent by April 2020, when Foundry informed Neurent of at least the ’675 patent. On information and belief, Neurent was aware or should have been aware of the ’011 and ’077 patents around the time of their issuance on January 19, 2021 and June 20, 2023, respectively.

48. Neurent identified Aerin’s RhinAer as a predicate device substantially equivalent to the Neuromark system in a 510(k) submission to the FDA. Ex. H at 4. Neurent represented to the FDA that the Neuromark system and the RhinAer predicate device “have similar technological characteristics” and the “same technological elements,” including: “Device design comprises a handle, malleable shaft and treatment tip with bipolar electrodes, radiofrequency generator”; “Device inserted via the nostrils – target location is the nasal cavity in the area of the posterior nasal nerves”; and “Energy delivery,” including “Same energy type (bi-polar RF energy),” “Same energy operating range,” “Same energy delivery contact site,” and “Same energy delivery mechanism (via a surface contacting electrode array).” Ex. H at 4-6. Neurent represented to the FDA that the Neuromark system is “substantially equivalent” to the RhinAer. Ex. H at 8.

49. Pursuant to 35 U.S.C. § 287(a), Aerin marks the RhinAer with its patent numbers, including the ’597, ’194, and ’318 patents, as well as other patents. Aerin identifies the patents covering the RhinAer on its website. On information and belief, Neurent knows that the RhinAer is marked with patent numbers and has knowledge of the patents-in-suit and related patents.

THE ACCUSED PRODUCT

50. Neurent has made, used, sold, imported, and/or offered for sale, and continues to make, use, sell, import, and/or offer for sale the Neuromark system in the United States. Although Neurent was aware of the patents-in-suit and was given notice of patents-in-suit, Neurent went forward with the commercial launch of the Neuromark system in the United States without a license to the patents-in-suit.

51. At least as of February 3, 2023, Neurent publicly announced the commercial release of the Neuromark system in the United States and offered the Neuromark system for sale in the United States, telling "HealthCare Professional[s]" to "Contact Customer Service to Place an Order." Ex. M. Neurent confirmed that it had a commercial presence in the United States with the Neuromark system and that it sought to grow that presence, stating that the "new CPT code underscores the value of this technology as we further grow our commercial presence in the U.S. and work to make NEUROMARK more accessible to the millions of patients living with chronic rhinitis today." Ex. M.

52. The Neuromark system includes the Neuromark Device and the Neuromark Generator, which Neurent also refers to as the "NEUROMARK® Radiofrequency (RF) Console." Ex. H at 4; Ex. I at 4.

53. On information and belief, the Neuromark system is used on a person's nasal airway to treat a nasal condition, including rhinitis and post-nasal drip, and cause a reduction in mucus secretion and congestion and improving nasal airflow. Neurent stated that "[a]pproximately one in four Americans suffer from chronic rhinitis, which can result in irritating symptoms including rhinorrhea (runny nose), persistent congestion, swelling of the mucosal membrane in the nose, and sneezing and nasal itching caused by inflammation" and that

"NEUROMARK'S unique device and intelligent technology platform enable Otolaryngologists to treat chronic rhinitis patients with precision and control and enhance the patient experience from treatment through recovery." Ex. M.

54. According to Neurent, "[f]or many patients, chronic rhinitis may be caused by abnormal or overactive posterior nasal nerves in the nose. Those nerve signals can cause mucus creation to go into overdrive, creating a near-constant runny, stuffy nose and/or post-nasal drip." Ex. R (Neurent Brochure, NEUROMARK, Rhinitis Neurolysis Therapy, Posterior Nerves Matter) at 4. "The NEUROMARK device disrupts the nerves and may reduce core symptoms." Ex. R at 3. "The NEUROMARK™ System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis." Ex. H at 3; Ex. I at 3. Neurent intends the Neuromark system to "disrupt posterior nasal nerves to provide symptomatic improvements for patients with chronic rhinitis." Ex. Q (NEUROMARK® System Mechanism of Action) at 2. The Neuromark system is "an RF system that disrupts posterior nasal nerves, resulting in disruption of the neural signals, and so addresses the inflammatory process of the nasal mucosa." Ex. Q at 3. And based on studies funded by Neurent, the Neuromark system "demonstrated significant improvement at 1 and 3 months" in "[r]hinorrhea, nasal congestion, nasal itching, sneezing, and postnasal drip," with the greatest improvement "seen in rhinorrhea, nasal congestion, and postnasal drip." Ex. S ("Clinical evaluation of a novel multipoint radiofrequency ablation device to treat chronic rhinitis," Douglas D. Reh, MD et al., Laryngoscope Investigative Otolaryngology, 8:367-372 (2023)) at 369.

55. On information and belief, the Neuromark system applies radiofrequency energy to disrupt, ablate, and cause neurolysis of nasal nerves by changing the temperature of the target

tissue. According to Neurent, the Neuromark system "is designed to gently apply controlled low-power radio frequency (RF) energy to target regions of the nasal cavity, disrupting the parasympathetic nerve signals that can trigger an inflammatory response" and delivers "precision neurolysis of posterior nasal nerves." Ex. M. "The NEUROMARK™ System is intended for the application of Radiofrequency energy to create lesions in mucosal tissue in otolaryngological [also known as Ear, Nose and Throat (ENT)] procedures in patients with chronic rhinitis." Ex. H at 4; Ex. I at 4. Neurent intended the Neuromark system to "disrupt posterior nasal nerves to provide symptomatic improvements for patients with chronic rhinitis." Ex. Q at 2. The Neuromark system is "an RF system that disrupts posterior nasal nerves, resulting in disruption of the neural signals, and so addresses the inflammatory process of the nasal mucosa." Ex. Q at 3. The Neuromark system is indicated for use "for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis." Ex. R at 2; *see also* Exs. H, I, K.

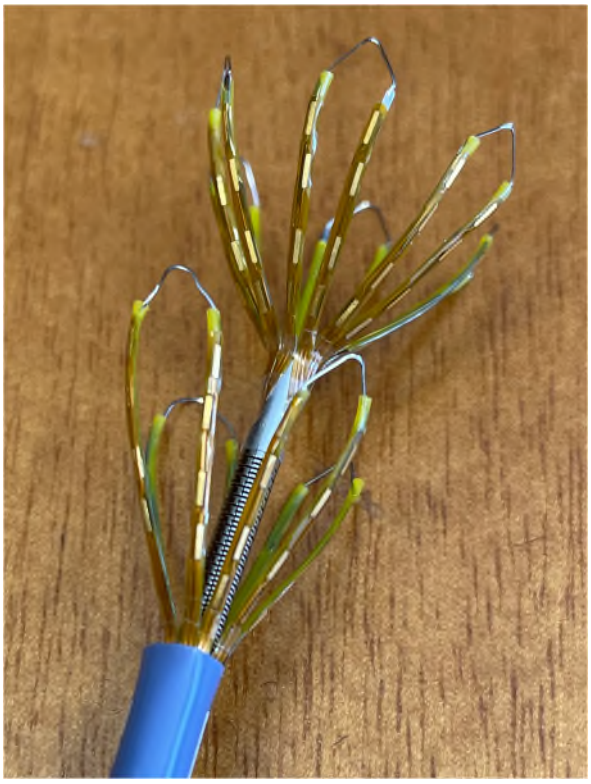
56. On information and belief, the Neuromark system includes a handheld radiofrequency device having an end effector with bipolar electrodes and a generator. Neurent described the Neuromark Device to the FDA as "a hand-held single-use bi-polar radiofrequency device which comprises a handle, shaft, and treatment tip." Ex. H at 4; *see also* Ex. I at 4. Neurent also represented to the FDA that the Neuromark "[d]evice design comprises a handle, malleable shaft and treatment tip with bipolar electrodes, radiofrequency generator" and stated the Neuromark Device was "designed for use with the NEUROMARK™ Radiofrequency Generator." Ex. H at 5, 6; *see also* Ex. I at 4, 5.

57. In its Instructions for Use for the Neuromark Device, Neurent states that the "NEUROMARK® Device is a hand-held, single-use, bipolar radiofrequency device which comprises a handle, shaft and treatment tip. The treatment tip, which is referred to as the end

effector, consists of an array of bipolar electrodes that deliver bipolar RF energy while monitoring feedback on tissue bio-impedance changes allowing for controlled RF energy delivery." Ex. K at 1. In marketing literature (Ex. Q), Neurent shows the Neuromark Device:

Figure 2: NEUROMARK Device

58. The end effector of the Neuromark Device "consists of multiple leaflets, each of which contain several bipolar electrode pairs allowing for the creation of several discrete ablation sites." Ex. Q at 3. A photograph of the Neuromark Device shows an array of multiple pairs of bipolar radiofrequency electrodes along the end effector.



59. On information and belief, the treatment tip of the Neuromark Device is inserted into a patient's nostril to treat tissue in the nasal passageway and deactivate posterior nasal nerves. The Neuromark Device is "introduced into the nasal cavity and advanced to the posterior recesses of the inferior/middle/superior meatus" and the "distal stage of the end effector is placed in the nasal choanae (posterior to the lateral attachment of the middle turbinate), while the proximal stage is placed in the middle meatus region." Ex. Q at 3.

60. Neurent demonstrates and instructs the placement of the Neuromark Device throughout its literature, including the following examples:

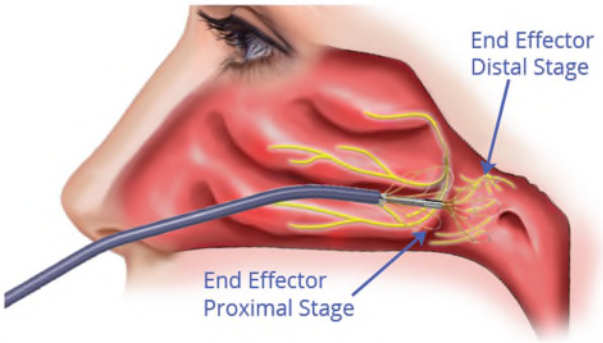


Figure 3: NEUROMARK Device with deployed end effector accommodating the area of the posterior nasal nerves.

Ex. Q at 3.

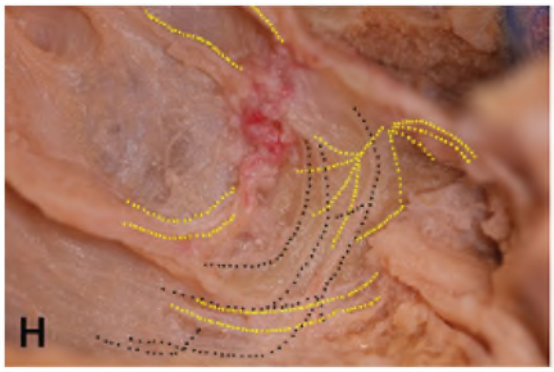
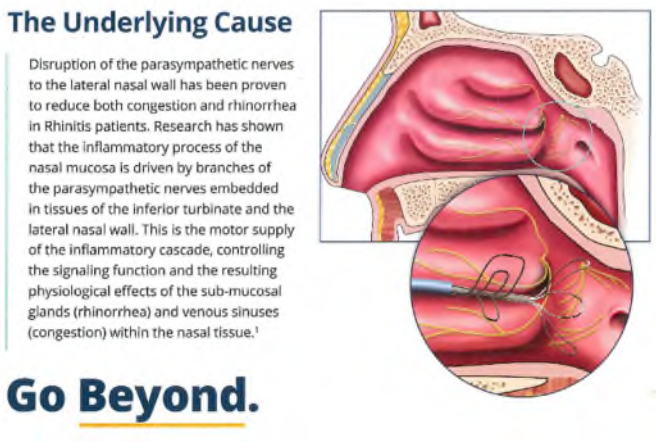


Figure 1: The nerves penetrating vertical plate of the palatine bone and innervating nasal lateral wall. Yellow dotted lines indicate the nerve fibres in the superficial layer and black dotted lines indicate the nerve fibres in the deep layer [8].

Ex. Q at 2.

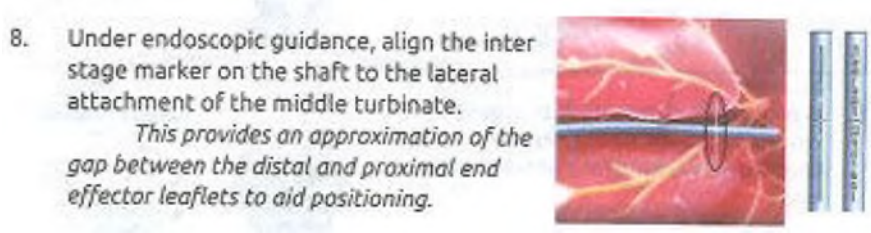


Ex. R.

61. On information and belief, Neurent instructs physicians to use the Neuromark system in a manner that is known to infringe the asserted claims.

62. In its Instructions for Use of the Neuromark Device, Neurent instructs physicians to "[a]dvance the device to the posterior recesses of the inferior/middle/superior meatus under endoscopic guidance." Ex. K at 3.

63. Neurent also instructs physicians to "align the inter stage marker on the shaft to the lateral attachment of the middle turbinate." Ex. K at 3.

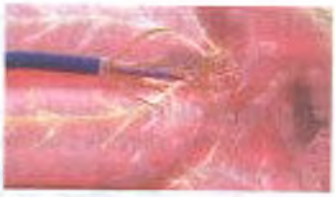


64. Neurent also instructs physicians to "[m]ove the slider backwards to deploy the end effector fully" and "[e]nsure that the slider is fully pulled back to allow for full deployment of the end effector." Ex. K at 3.

9. Move the slider backwards to deploy the end effector fully
CAUTION: *Ensure that the slider is fully pulled back to allow for full deployment of the end effector*

65. Neurent cautions physicians to "[e]nsure that the proximal end of the end effector wraps around the middle turbinate anterior to the attachment of the turbinate to the lateral wall." Ex. K at 3. Neurent also instructs that the leaflets on the end effector are "super elastic and spring out to enforce mucosal apposition on the lateral wall. The multi-stage elastic leaflet set-up accommodates the area of the posterior nasal nerves." Ex. K at 3.

10. Make any necessary minor adjustments to ensure that the device is positioned in the correct anatomical position. Verify the correct position endoscopically.
CAUTION: *Ensure that the proximal end of the end effector wraps around the middle turbinate anterior to the attachment of the turbinate to the lateral wall.*
NOTE: *The end effector consists of a distal and proximal stage. The leaflets are super elastic and spring out to enforce mucosal apposition on the lateral wall. The multi-stage elastic leaflet set-up accommodates the area of the posterior nasal nerves.*

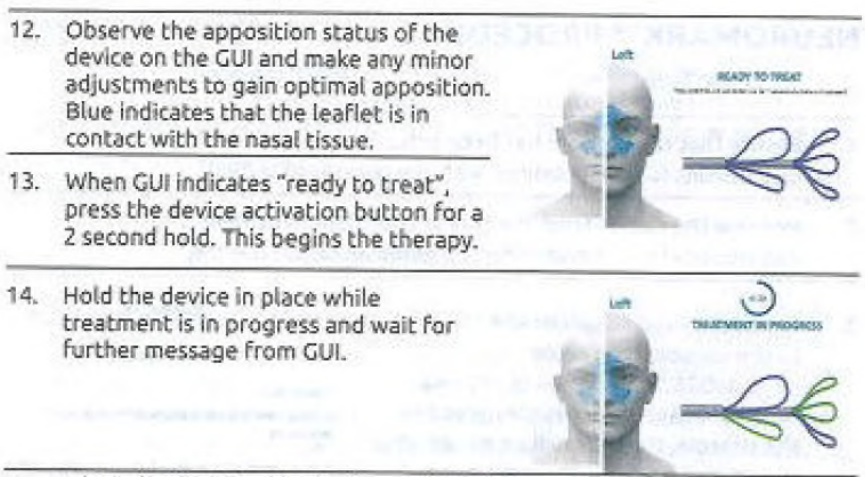


66. Neurent further instructs physicians to, "[o]nce fully deployed and positioned appropriately, press the device activation button to begin baseline bioelectric evaluation to confirm electrode apposition." Ex. K at 3.

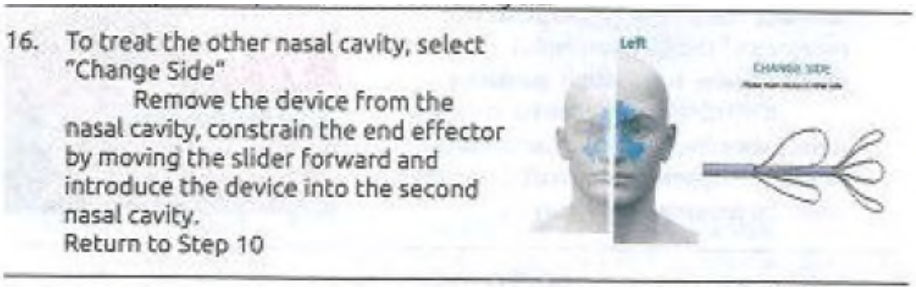
11. Once fully deployed and positioned appropriately, press the device activation button to begin baseline bioelectric evaluation to confirm electrode apposition.

67. Neurent instructs physicians to "[o]bserve the apposition status of the device on the GUI and make any minor adjustments to gain optimal apposition" and, "[w]hen GUI

indicates 'ready to treat,' press the device activation button for a 2 second hold," which "begins the therapy." Ex. K at 4. Neurent also instructs physicians to "[h]old the device in place while treatment is in progress and wait for further message from the GUI" that the treatment cycle is complete. Ex. K at 4.



68. Neurent instructs physicians to, after the treatment cycle is completed, "[r]emove the device from the nasal cavity," and repeat the process to "treat the other nasal cavity." Ex. K at 4.



69. Neurent's manufacture, use, sale, offer for sale, and/or importation of the Neuromark system constitute acts of direct infringement of the patents-in-suit.

70. Neurent's manufacture, use, sale, offer for sale, and/or importation of the Neuromark system, which is not a staple article of commerce and has no non-infringing uses, constitute acts of indirect infringement of the patents-in-suit.

71. Neurent's instruction and active encouragement to use the Neuromark system in a manner known to infringe the patents-in-suit constitute acts of indirect infringement of the patents-in-suit.

72. Neurent Medical Ltd.'s instruction and active encouragement of Neurent Medical Inc. to make, use, sell, offer for sale, and/or import the Neuromark system constitute acts of indirect infringement.

73. Neurent's commercial release of the Neuromark system in the United States with knowledge of the patents-in-suit and infringement and without a license constitutes willful infringement.

COUNT I FOR PATENT INFRINGEMENT

Infringement of the '597 Patent

74. In violation of 35 U.S.C. § 271(a), Neurent has infringed, and continues to infringe, literally and/or under the doctrine of equivalents, one or more claims of the '597 patent, including at least claims 9, 14, 16, 18, 20, 22, 23, 24, 44, and 46, by making, using, selling, offering for sale, and/or importing into the United States the Neuromark system. A claim chart demonstrating infringement of each of these claims is attached as Exhibit T.

75. Neurent's infringement of the '597 patent was and continues to be willful. On information and belief, Neurent has knowingly and willfully infringed the '597 patent by making, using, selling, offering for sale, and importing into the United States the Neuromark system and continues to willfully infringe the '597 patent by continuing to make, use, sell, offer for sale, and import into the United States the Neuromark system.

76. Despite its knowledge of the '597 patent and its knowledge of its infringement of the '597 patent, Neurent has continued to make, use, sell, offer for sale, and import into the

United States the Neuromark system and instructs its customers to use the Neuromark system in a manner that infringes the ’597 patent.

77. Neurent has been aware of and on notice of the ’597 patent since at least February 18, 2020. Neurent has also been on notice of the ’597 patent and its infringement since at least as early as the service of this Complaint. Neurent’s continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after knowledge of the ’597 patent, including after service of the Complaint, would be with Neurent’s knowledge of the ’597 patent, knowledge of infringement of the ’597 patent, intent to encourage others (e.g., its customers) to infringe the ’597 patent with the Neuromark system, and knowledge that Neurent’s encouraging acts actually result in direct infringement of the ’597 patent by Neurent’s customers.

78. Neurent, in violation of 35 U.S.C. 271(b), has indirectly infringed and continues to indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 9, 14, 16, 18, 20, 22, 23, 24, 44, and 46 of the ’597 patent by actively inducing others to use, make, sell, offer for sale, and/or import the Neuromark system in an infringing manner, knowing such acts would constitute infringement of the ’597 patent. Neurent’s customers who use, make, sell, offer for sale, and/or import the Neuromark system in accordance with Neurent’s instructions infringe at least claims 9, 14, 16, 18, 20, 22, 23, 24, 44, and 46 of the ’597 patent in violation of 35 U.S.C. § 271(a).

79. Neurent actively instructs, encourages, and/or aids such infringement through various activities, including by instructing physicians to use the Neuromark system in an infringing manner through Instructions for Use, product descriptions, promotional material, and other literature.

80. Neurent, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 9, 14, 16, 18, 20, 22, 23, 24, 44, and 46 of the ’597 patent by contributing to its customers’ use, making, selling, offer for sale, and/or importing of the Neuromark system in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the ’597 patent. Neurent’s customers who make, use, sell, offer for sale, and/or import the Neuromark system in accordance with Neurent’s instructions infringe at least claims 9, 14, 16, 18, 20, 22, 23, 24, 44, and 46 of the ’597 patent in violation of 35 U.S.C. § 271(a).

81. Neurent contributes to infringement by providing to its customers the Neuromark system, the Neuromark Device, the Neuromark Generator, or components thereof and instructing them how to assemble, install, make, and/or use the Neuromark system, knowing that those products are especially made or adapted for use in infringement of the ’597 patent.

82. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not staple articles of commerce.

83. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not suitable for substantial non-infringing uses.

84. Neurent’s infringement of the ’597 patent has damaged and continues to damage Aerin.

85. Neurent had knowledge of the ’597 patent or was willfully blind to the patented features of the ’597 patent before the filing and service date of this Complaint. Neurent’s failure to respond to Aerin’s September 28, 2022 letter providing notice, or take any remedial action demonstrates that Neurent’s infringement is wanton, deliberate, and willful.

86. Neurent knew or should have known of the ’597 patent and has acted, and continues to act, in an egregious and wanton manner by knowingly infringing the ’597 patent. Neurent’s infringement of the ’597 patent has been and continues to be willful and deliberate.

COUNT II FOR PATENT INFRINGEMENT

Infringement of the ’194 Patent

87. In violation of 35 U.S.C. § 271(a), Neurent has infringed, and continues to infringe, literally and/or under the doctrine of equivalents, one or more claims of the ’194 patent, including at least claims 1, 2, 3, 6, 12, 14, 16, 18, and 19, by making, using, selling, offering for sale, and/or importing into the United States the Neuromark system. A claim chart demonstrating infringement of each of these claims is attached as Exhibit U.

88. Neurent’s infringement of the ’194 patent was and continues to be willful. On information and belief, Neurent has knowingly and willfully infringed the ’194 patent by making, using, selling, offering for sale, and importing into the United States the Neuromark system and continues to willfully infringe the ’194 patent by continuing to make, use, sell, offer for sale, and import into the United States the Neuromark system.

89. Despite its knowledge of the ’194 patent and its knowledge of its infringement of the ’194 patent, Neurent has continued to make, use, sell, offer for sale, and import into the United States the Neuromark system and instructs its customers to use the Neuromark system in a manner that infringes the ’194 patent.

90. Neurent has been aware of and on notice of the ’194 patent since at least February 18, 2020. Neurent has also been on notice of the ’194 patent and its infringement since at least as early as the service of this Complaint. Neurent’s continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after

knowledge of the ’194 patent, including after service of the Complaint, would be with Neurent’s knowledge of the ’194 patent, knowledge of infringement of the ’194 patent, intent to encourage others (e.g., its customers) to infringe the ’194 patent with the Neuromark system, and knowledge that Neurent’s encouraging acts actually result in direct infringement of the ’194 patent by Neurent’s customers.

91. Neurent, in violation of 35 U.S.C. 271(b), has indirectly infringed and continues to indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 1, 2, 3, 6, 12, 14, 16, 18, and 19 of the ’194 patent by actively inducing others to use, make, sell, offer for sale, and/or import the Neuromark system in an infringing manner, knowing such acts would constitute infringement of the ’194 patent. Neurent’s customers who use, make, sell, offer for sale, and/or import the Neuromark system in accordance with Neurent’s instructions infringe at least claims 1, 2, 3, 6, 12, 14, 16, 18, and 19 of the ’194 patent in violation of 35 U.S.C. § 271(a).

92. Neurent actively instructs, encourages, and/or aids such infringement through various activities, including by instructing physicians to use the Neuromark system in an infringing manner through Instructions for Use, product descriptions, promotional material, and other literature.

93. Neurent, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents, at least claims 1, 2, 3, 6, 12, 14, 16, 18, and 19 of the ’194 patent by contributing to its customers’ use, making, selling, offer for sale, and/or importing of the Neuromark system in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the ’194 patent. Neurent’s customers who make, use, sell, offer for sale, and/or import the

Neuromark system in accordance with Neurent's instructions infringe at least claims 1, 2, 3, 6, 12, 14, 16, 18, and 19 of the '194 patent in violation of 35 U.S.C. § 271(a).

94. Neurent contributes to infringement by providing to its customers the Neuromark system, the Neuromark Device, the Neuromark Generator, or components thereof and instructing them how to assemble, install, make, and/or use the Neuromark system, knowing that those products are especially made or adapted for use in infringement of the '194 patent.

95. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not staple articles of commerce.

96. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not suitable for substantial non-infringing uses.

97. Neurent's infringement of the '194 patent has damaged and continues to damage Aerin.

98. Neurent had knowledge of the '194 patent or was willfully blind to the patented features of the '194 patent before the filing and service date of this Complaint. Neurent's failure to respond to Aerin's September 28, 2022 letter providing notice, or take any remedial action demonstrates that Neurent's infringement is wanton, deliberate, and willful.

99. Neurent knew or should have known of the '194 patent and has acted, and continues to act, in an egregious and wanton manner by knowingly infringing the '194 patent. Neurent's infringement of the '194 patent has been and continues to be willful and deliberate.

COUNT III FOR PATENT INFRINGEMENT

Infringement of the '675 Patent

100. In violation of 35 U.S.C. § 271(a), Neurent has infringed, and continues to infringe, literally and/or under the doctrine of equivalents, one or more claims of the '675 patent,

including at least claims 1, 2, 3, 7, 9, 10, 17, 18, 19, 20, 21, 22, 23, 24, and 25, by making, using, selling, offering for sale, and/or importing into the United States the Neuromark system. A claim chart demonstrating infringement of each of these claims is attached as Exhibit V.

101. Neurent's infringement of the '675 patent was and continues to be willful. On information and belief, Neurent has knowingly and willfully infringed the '675 patent by making, using, selling, offering for sale, and importing into the United States the Neuromark system and continues to willfully infringe the '675 patent by continuing to make, use, sell, offer for sale, and import into the United States the Neuromark system.

102. Despite its knowledge of the '675 patent and its knowledge of its infringement of the '675 patent, Neurent has continued to make, use, sell, offer for sale, and import into the United States the Neuromark system and instructs its customers to use the Neuromark system in a manner that infringes the '675 patent.

103. Neurent has been aware of and on notice of the '675 patent since April 2020 and also since at least January 7, 2021 and September 28, 2022. Neurent has also been on notice of the '675 patent and its infringement since at least as early as the service of this Complaint. Neurent's continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after knowledge of the '675 patent, including after service of the Complaint, would be with Neurent's knowledge of the '675 patent, knowledge of infringement of the '675 patent, intent to encourage others (e.g., its customers) to infringe the '675 patent with the Neuromark system, and knowledge that Neurent's encouraging acts actually result in direct infringement of the '675 patent by Neurent's customers.

104. Neurent, in violation of 35 U.S.C. 271(b), has indirectly infringed and continues to indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 1, 2, 3, 7,

9, 10, 17, 18, 19, 20, 21, 22, 23, 24, and 25 of the ’675 patent by actively inducing others to use, make, sell, offer for sale, and/or import the Neuromark system in an infringing manner, knowing such acts would constitute infringement of the ’675 patent. Neurent’s customers who use, make, sell, offer for sale, and/or import the Neuromark system in accordance with Neurent’s instructions infringe at least 1, 2, 3, 7, 9, 10, 17, 18, 19, 20, 21, 22, 23, 24, and 25 of the ’675 patent in violation of 35 U.S.C. § 271(a).

105. Neurent actively instructs, encourages, and/or aids such infringement through various activities, including by instructing physicians to use the Neuromark system in an infringing manner through Instructions for Use, product descriptions, promotional material, and other literature.

106. Neurent, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 1, 2, 3, 7, 9, 10, 17, 18, 19, 20, 21, 22, 23, 24, and 25 of the ’675 patent by contributing to its customers’ use, making, selling, offer for sale, and/or importing of the Neuromark system in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the ’675 patent. Neurent’s customers who make, use, sell, offer for sale, and/or import the Neuromark system in accordance with Neurent’s instructions infringe at least claims 1, 2, 3, 7, 9, 10, 17, 18, 19, 20, 21, 22, 23, 24, and 25 of the ’675 patent in violation of 35 U.S.C. § 271(a).

107. Neurent contributes to infringement by providing to its customers the Neuromark system, the Neuromark Device, the Neuromark Generator, or components thereof and instructing them how to assemble, install, make, and/or use the Neuromark system, knowing that those products are especially made or adapted for use in infringement of the ’675 patent.

108. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not staple articles of commerce.

109. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not suitable for substantial non-infringing uses.

110. Neurent's infringement of the '675 patent has damaged and continues to damage Foundry and Aerin.

111. Neurent had knowledge of the '675 patent or was willfully blind to the patented features of the '675 patent before the filing and service date of this Complaint. Neurent's failure to take a license in response to Foundry's communication with Neurent or take any remedial action and Neurent's failure to respond to Aerin's September 28, 2022 letter providing notice, or take any remedial action demonstrates that Neurent's infringement is wanton, deliberate, and willful.

112. Neurent knew or should have known of the '675 patent and has acted, and continues to act, in an egregious and wanton manner by knowingly infringing the '675 patent. Neurent's infringement of the '675 patent has been and continues to be willful and deliberate.

COUNT IV FOR PATENT INFRINGEMENT

Infringement of the '011 Patent

113. In violation of 35 U.S.C. § 271(a), Neurent has infringed, and continues to infringe, literally and/or under the doctrine of equivalents, one or more claims of the '011 patent, including at least claims 1, 2, 5, 8, 9, 10, 12, and 14, by making, using, selling, offering for sale, and/or importing into the United States the Neuromark system. A claim chart demonstrating infringement of each of these claims is attached as Exhibit W.

114. Neurent's infringement of the '011 patent was and continues to be willful. On information and belief, Neurent has knowingly and willfully infringed the '011 patent by making, using, selling, offering for sale, and importing into the United States the Neuromark system and continues to willfully infringe the '011 patent by continuing to make, use, sell, offer for sale, and import into the United States the Neuromark system.

115. Despite its knowledge of the '011 patent and its knowledge of its infringement of the '011 patent, Neurent has continued to make, use, sell, offer for sale, and import into the United States the Neuromark system and instructs its customers to use the Neuromark system in a manner that infringes the '011 patent.

116. Neurent has been aware of or should have been aware of the '011 patent since before the service of this Complaint. Neurent has also been on notice of the '011 patent and its infringement since service of this Complaint. Neurent's continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after knowledge of the '011 patent, including after service of the Complaint, would be with Neurent's knowledge of the '011 patent, knowledge of infringement of the '011 patent, intent to encourage others (e.g., its customers) to infringe the '011 patent with the Neuromark system, and knowledge that Neurent's encouraging acts actually result in direct infringement of the '011 patent by Neurent's customers.

117. Neurent, in violation of 35 U.S.C. 271(b), has indirectly infringed and continues to indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 1, 2, 5, 8, 9, 10, 12, and 14 of the '011 patent by actively inducing others to use, make, sell, offer for sale, and/or import the Neuromark system in an infringing manner, knowing such acts would constitute infringement of the '011 patent. Neurent's customers who use, make, sell, offer for

sale, and/or import the Neuromark system in accordance with Neurent's instructions infringe at least claims 1, 2, 5, 8, 9, 10, 12, and 14 of the '011 patent in violation of 35 U.S.C. § 271(a).

118. Neurent actively instructs, encourages, and/or aids such infringement through various activities, including by instructing physicians to use the Neuromark system in an infringing manner through Instructions for Use, product descriptions, promotional material, and other literature.

119. Neurent, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 1, 2, 5, 8, 9, 10, 12, and 14 of the '011 patent by contributing to its customers' use, making, selling, offer for sale, and/or importing of the Neuromark system in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the '011 patent. Neurent's customers who make, use, sell, offer for sale, and/or import the Neuromark system in accordance with Neurent's instructions infringe at least claims 1, 2, 5, 8, 9, 10, 12, and 14 of the '011 patent in violation of 35 U.S.C. § 271(a).

120. Neurent contributes to infringement by providing to its customers the Neuromark system, the Neuromark Device, the Neuromark Generator, or components thereof and instructing them how to assemble, install, make, and/or use the Neuromark system, knowing that those products are especially made or adapted for use in infringement of the '011 patent.

121. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not staple articles of commerce.

122. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not suitable for substantial non-infringing uses.

123. Neurent's infringement of the '011 patent has damaged and continues to damage Foundry and Aerin.

124. Neurent had knowledge of the '011 patent or was willfully blind to the patented features of the '011 patent before the filing and service date of this Complaint. Neurent's failure to take any remedial action demonstrates that Neurent's infringement is wanton, deliberate, and willful.

125. Neurent knew or should have known of the '011 patent and has acted, and continues to act, in an egregious and wanton manner by knowingly infringing the '011 patent. Neurent's infringement of the '011 patent has been and continues to be willful and deliberate.

COUNT V FOR PATENT INFRINGEMENT

Infringement of the '318 Patent

126. In violation of 35 U.S.C. § 271(a), Neurent has infringed, and continues to infringe, literally and/or under the doctrine of equivalents, one or more claims of the '318 patent, including at least claims 1, 4, 5, 6, 9, 10, 12, 13, 15, 16, and 17, by making, using, selling, offering for sale, and/or importing into the United States the Neuromark system. A claim chart demonstrating infringement of each of these claims is attached as Exhibit X.

127. Neurent's infringement of the '318 patent was and continues to be willful. On information and belief, Neurent has knowingly and willfully infringed the '318 patent by making, using, selling, offering for sale, and importing into the United States the Neuromark system and continues to willfully infringe the '318 patent by continuing to make, use, sell, offer for sale, and import into the United States the Neuromark system.

128. Despite its knowledge of the '318 patent and its knowledge of its infringement of the '318 patent, Neurent has continued to make, use, sell, offer for sale, and import into the

United States the Neuromark system and instructs its customers to use the Neuromark system in a manner that infringes the ’318 patent.

129. Neurent has been aware of and on notice of or should have been aware and on notice of the ’318 patent by December 2021. Neurent has also been aware of and on notice of the ’318 patent at least by September 28, 2022. Neurent has also been on notice of the ’318 patent and its infringement since at least as early as the service of this Complaint. Neurent’s continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after knowledge of the ’318 patent, including after service of the Complaint, would be with Neurent’s knowledge of the ’318 patent, knowledge of infringement of the ’318 patent, intent to encourage others (e.g., its customers) to infringe the ’318 patent with the Neuromark system, and knowledge that Neurent’s encouraging acts actually result in direct infringement of the ’318 patent by Neurent’s customers.

130. Neurent, in violation of 35 U.S.C. 271(b), has indirectly infringed and continues to indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 1, 4, 5, 6, 9, 10, 12, 13, 15, 16, and 17 of the ’318 patent by actively inducing others to use, make, sell, offer for sale, and/or import the Neuromark system in an infringing manner, knowing such acts would constitute infringement of the ’318 patent. Neurent’s customers who use, make, sell, offer for sale, and/or import the Neuromark system in accordance with Neurent’s instructions infringe at least claims 1, 4, 5, 6, 9, 10, 12, 13, 15, 16, and 17 of the ’318 patent in violation of 35 U.S.C. § 271(a).

131. Neurent actively instructs, encourages, and/or aids such infringement through various activities, including by instructing physicians to use the Neuromark system in an

infringing manner through Instructions for Use, product descriptions, promotional material, and other literature.

132. Neurent, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 1, 4, 5, 6, 9, 10, 12, 13, 15, 16, and 17 of the ’318 patent by contributing to its customers’ use, making, selling, offer for sale, and/or importing of the Neuromark system in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the ’318 patent. Neurent’s customers who make, use, sell, offer for sale, and/or import the Neuromark system in accordance with Neurent’s instructions infringe at least claims 1, 4, 5, 6, 9, 10, 12, 13, 15, 16, and 17 of the ’318 patent in violation of 35 U.S.C. § 271(a).

133. Neurent contributes to infringement by providing to its customers the Neuromark system, the Neuromark Device, the Neuromark Generator, or components thereof and instructing them how to assemble, install, make, and/or use the Neuromark system, knowing that those products are especially made or adapted for use in infringement of the ’318 patent.

134. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not staple articles of commerce.

135. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not suitable for substantial non-infringing uses.

136. Neurent’s infringement of the ’318 patent has damaged and continues to damage Aerin.

137. Neurent had knowledge of the ’318 patent or was willfully blind to the patented features of the ’318 patent before the filing and service date of this Complaint. Neurent’s failure

to respond to Aerin's September 28, 2022 letter providing notice, or take any remedial action demonstrates that Neurent's infringement is wanton, deliberate, and willful.

138. Neurent knew or should have known of the '318 patent and has acted, and continues to act, in an egregious and wanton manner by knowingly infringing the '318 patent. Neurent's infringement of the '318 patent has been and continues to be willful and deliberate.

COUNT VI FOR PATENT INFRINGEMENT

Infringement of the '271 Patent

139. In violation of 35 U.S.C. § 271(a), Neurent has infringed, and continues to infringe, literally and/or under the doctrine of equivalents, one or more claims of the '271 patent, including at least claims 1, 2, 3, 4, 6, 7, 11, 12, and 16, by making, using, selling, offering for sale, and/or importing into the United States the Neuromark system. A claim chart demonstrating infringement of each of these claims is attached as Exhibit Y.

140. Neurent's infringement of the '271 patent was and continues to be willful. On information and belief, Neurent has knowingly and willfully infringed the '271 patent by making, using, selling, offering for sale, and importing into the United States the Neuromark system and continues to willfully infringe the '271 patent by continuing to make, use, sell, offer for sale, and import into the United States the Neuromark system.

141. Despite its knowledge of the '271 patent and its knowledge of its infringement of the '271 patent, Neurent has continued to make, use, sell, offer for sale, and import into the United States the Neuromark system and instructs its customers to use the Neuromark system in a manner that infringes the '271 patent.

142. Neurent has been aware of and on notice of the '271 patent since at least August 22, 2022. Neurent has also been on notice of the '271 patent and its infringement since at least as

early as the service of this Complaint. Neurent's continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after knowledge of the '271 patent, including after service of the Complaint, would be with Neurent's knowledge of the '271 patent, knowledge of infringement of the '271 patent, intent to encourage others (e.g., its customers) to infringe the '271 patent with the Neuromark system, and knowledge that Neurent's encouraging acts actually result in direct infringement of the '271 patent by Neurent's customers.

143. Neurent, in violation of 35 U.S.C. 271(b), has indirectly infringed and continues to indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 1, 2, 3, 4, 6, 7, 11, 12, and 16 of the '271 patent by actively inducing others to use, make, sell, offer for sale, and/or import the Neuromark system in an infringing manner, knowing such acts would constitute infringement of the '271 patent. Neurent's customers who use, make, sell, offer for sale, and/or import the Neuromark system in accordance with Neurent's instructions infringe at least claims 1, 2, 3, 4, 6, 7, 11, 12, and 16 of the '271 patent in violation of 35 U.S.C. § 271(a).

144. Neurent actively instructs, encourages, and/or aids such infringement through various activities, including by instructing physicians to use the Neuromark system in an infringing manner through Instructions for Use, product descriptions, promotional material, and other literature.

145. Neurent, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly, infringe literally and/or under the doctrine of equivalents, at least claims 1, 2, 3, 4, 6, 7, 11, 12, and 16 of the '271 patent by contributing to its customers' use, making, selling, offer for sale, and/or importing of the Neuromark system in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the

’271 patent. Neurent’s customers who make, use, sell, offer for sale, and/or import the Neuromark system in accordance with Neurent’s instructions infringe at least claims 1, 2, 3, 4, 6, 7, 11, 12, and 16 of the ’271 patent in violation of 35 U.S.C. § 271(a).

146. Neurent contributes to infringement by providing to its customers the Neuromark system, the Neuromark Device, the Neuromark Generator, or components thereof and instructing them how to assemble, install, make, and/or use the Neuromark system, knowing that those products are especially made or adapted for use in infringement of the ’271 patent.

147. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not staple articles of commerce.

148. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not suitable for substantial non-infringing uses.

149. Neurent’s infringement of the ’271 patent has damaged and continues to damage Aerin.

150. Neurent had knowledge of the ’271 patent or was willfully blind to the patented features of the ’271 patent before the filing and service date of this Complaint. Neurent’s failure to respond to Aerin’s September 28, 2022 letter providing notice, or take any remedial action demonstrates that Neurent’s infringement is wanton, deliberate, and willful.

151. Neurent knew or should have known of the ’271 patent and has acted, and continues to act, in an egregious and wanton manner by knowingly infringing the ’271 patent. Neurent’s infringement of the ’271 patent has been and continues to be willful and deliberate.

COUNT VII FOR PATENT INFRINGEMENT

Infringement of the ’077 Patent

152. In violation of 35 U.S.C. § 271(a), Neurent has infringed, and continues to infringe, literally and/or under the doctrine of equivalents, one or more claims of the ’077 patent, including at least claims 1, 2, 3, 4, 5, 6, 7, 8, and 11, by making, using, selling, offering for sale, and/or importing into the United States the Neuromark system. A claim chart demonstrating infringement of each of these claims is attached as Exhibit Z.

153. Neurent’s infringement of the ’077 patent was and continues to be willful. On information and belief, Neurent has knowingly and willfully infringed the ’077 patent by making, using, selling, offering for sale, and importing into the United States the Neuromark system and continues to willfully infringe the ’077 patent by continuing to make, use, sell, offer for sale, and import into the United States the Neuromark system.

154. Despite its knowledge of the ’077 patent and its knowledge of its infringement of the ’077 patent, Neurent has continued to make, use, sell, offer for sale, and import into the United States the Neuromark system and instructs its customers to use the Neuromark system in a manner that infringes the ’077 patent.

155. Neurent has been or should have been aware of and on notice of the application for the ’077 and of the ’077 patent before the service of this Complaint. Neurent has also been on notice of the ’077 patent and its infringement since service of this Complaint. Neurent’s continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after knowledge of the ’077 patent, including after service of the Complaint, would be with Neurent’s knowledge of the ’077 patent, knowledge of infringement of the ’077 patent, intent to encourage others (e.g., its customers) to infringe the

’077 patent with the Neuromark system, and knowledge that Neurent’s encouraging acts actually result in direct infringement of the ’077 patent by Neurent’s customers.

156. Neurent, in violation of 35 U.S.C. 271(b), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents at least claims 1, 2, 3, 4, 5, 6, 7, 8, and 11 of the ’077 patent by actively inducing others to use, make, sell, offer for sale, and/or import the Neuromark system in an infringing manner, knowing such acts would constitute infringement of the ’077 patent. Neurent’s customers who use, make, sell, offer for sale, and/or import the Neuromark system in accordance with Neurent’s instructions infringe at least claims 1, 2, 3, 4, 5, 6, 7, 8, and 11 of the ’077 patent in violation of 35 U.S.C. § 271(a).

157. Neurent actively instructs, encourages, and/or aids such infringement through various activities, including by instructing physicians to use the Neuromark system in an infringing manner through Instructions for Use, product descriptions, promotional material, and other literature.

158. Neurent, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 1, 2, 3, 4, 5, 6, 7, 8, and 11 of the ’077 patent by contributing to its customers’ use, making, selling, offer for sale, and/or importing of the Neuromark system in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the ’077 patent. Neurent’s customers who make, use, sell, offer for sale, and/or import the Neuromark system in accordance with Neurent’s instructions infringe at least claims 1, 2, 3, 4, 5, 6, 7, 8, and 11 of the ’077 patent in violation of 35 U.S.C. § 271(a).

159. Neurent contributes to infringement by providing to its customers the Neuromark system, the Neuromark Device, the Neuromark Generator, or components thereof and instructing

them how to assemble, install, make, and/or use the Neuromark system, knowing that those products are especially made or adapted for use in infringement of the ’077 patent.

160. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not staple articles of commerce.

161. The Neuromark system, including the Neuromark Device and Neuromark Generator, are not suitable for substantial non-infringing uses.

162. Neurent’s infringement of the ’077 patent has damaged and continues to damage Foundry and Aerin.

163. Neurent had knowledge of the ’077 patent or was willfully blind to the patented features of the ’077 patent before the filing and service date of this Complaint. Neurent’s failure to take any remedial action demonstrates that Neurent’s infringement is wanton, deliberate, and willful.

164. Neurent knew or should have known of the ’077 patent and has acted, and continues to act, in an egregious and wanton manner by knowingly infringing the ’077 patent. Neurent’s infringement of the ’077 patent has been and continues to be willful and deliberate.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in its favor and against Neurent and grant the following relief:

A. Adjudge and enter judgment that Neurent Medical Ltd. and Neurent Medical Inc. directly infringe, literally or under the doctrine of equivalents, at least one claim of each of the patents-in-suit under at least 35 U.S.C. § 271(a);

B. Adjudge and enter judgment that Neurent Medical Ltd. and Neurent Medical Inc. induced and contributed to infringement of at least one claim of each of the patents-in-suit under at least 35 U.S.C. §§ 271(b) and (c);

C. Award Plaintiffs damages adequate to compensate Plaintiffs for Neurent's acts of patent infringement, together with prejudgment and post-judgment interest under 35 U.S.C. § 284 and other permitted costs, expenses, and disbursements;

D. Declare that Neurent's infringement is willful and award to Plaintiffs all other damages permitted by 35 U.S.C. § 284, including enhanced damages up to three times the amount of compensatory damages found;

E. Permanently enjoin Neurent, all persons acting in concert or participation with Neurent, all parent and subsidiary corporations and affiliates, and their assigns and successors in interest from continuing acts of infringement of the patents-in-suit;

F. Enter judgment that this is an exceptional case and awarding to Plaintiffs their reasonable attorneys' fees and costs pursuant to 35 U.S.C. § 285; and

G. Such other and further relief in law or equity as the Court deems just and appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs respectfully request a trial by jury on all claims and issues so triable.

Dated: July 11, 2023

MCCARTER & ENGLISH, LLP

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