UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

DESIGN 408 LLC, a California Limited Liability Corporation,

Plaintiff,

v.

Jury Trial Demanded

Patent Case

Case No.

NEURONETICS, INC., a Delaware corporation,

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Design 408 LLC ("Design"), through its attorney, complains of Neuronetics,

Inc. ("Neuronetics"), and alleges the following:

PARTIES

- Plaintiff, Design 408 LLC is a domestic limited liability corporation organized and existing under the laws of Delaware.
- Defendant Neuronetics, Inc. is a corporation organized and existing under the laws of Delaware that maintains its principal place of business at 3222 Phoenixville Pike, Malvern, PA 19355.

JURISDICTION

- This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code.
- 4. This Court has exclusive subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).
- 5. This Court has personal jurisdiction over Neuronetics because it has engaged in systematic and continuous business activities in the District of Delaware. Specifically, Neuronetics

provides its full range of services to residents in this District. As described below,

Neuronetics has committed acts of patent infringement giving rise to this action within this District.

VENUE

6. Venue is proper in this District under 28 U.S.C. § 1400(b) because Neuronetics has committed acts of patent infringement in this District and has a regular and established place of business in this District. Specifically, Neuronetics provides its full range of services to residents in this District. In addition, Design has suffered harm in this district.

PATENT-IN-SUIT

7. Design is the assignee of assignee of all right, title and interest in United States Patent No. 7,548,779 (the "'779 Patent" or the "Patent-in-Suit"), including all rights to enforce and prosecute actions for infringement and to collect damages for all relevant times against infringers of the Patent-in-Suit. Accordingly, Design possesses the exclusive right and standing to prosecute the present action for infringement of the Patent-in-Suit by Neuronetics.

The '779 Patent

- 8. On June 16, 2009, the United States Patent and Trademark Office issued the '779 Patent. The '779 Patent is titled "Microwave Energy Head Therapy." The application leading to the '779 Patent was filed on November 15, 2005. A true and correct copy of the '779 Patent is attached hereto as Exhibit A and incorporated herein by reference.
- 9. The '779 Patent is valid and enforceable.

- 10. The invention in the '779 Patent relates to a method of therapy that administrates high frequency electromagnetic pulses, or microwaves, to a patient in varying frequencies, durations, areas, powers and angles. Ex. A at 3:19-22.
- 11. The inventors recognized that the human brain, like every conductive material, behaves like an antenna. *Id.* at 1:31-33. Through this capability, the invention acts similar to a cardiac pacemaker by employing electrical signals to normalize pathological functions of the brain. *Id.* at 1:41-44.

COUNT I: INFRINGEMENT OF THE '779 PATENT

- 12. Design incorporates the above paragraphs herein by reference.
- 13. **Direct Infringement.** Neuronetics has been and continues to directly infringe at least claim 1 of the '779 Patent in this District and elsewhere in the United States by providing products, for example, Neuronetics's NeuroStar Therapy System ("NeuroStar"), that perform the steps of treating a neural electrophysical pathology using a microwave generating device.
- 14. Neuronetics's NeuroStar performs the step adjusting the power of the device to a value between about 0 dB, and about 45 dBm. For example, Neuronetics's Neurostar optimizes the energy field, in order to precisely stimulate the targeted tissue. *See* Figure 1;

http://neurostar.com/en/neurostar-system-components/.

Precision Pulse TMS[™]—Patented coil design improves efficiency, which increases patient throughput



Precision Pulse TMS[™] Patented coll design improves efficiency which increases patient throughput

- Electromagnetic pulse duration designed to preferentially stimulate cortical, not sensory, neurons
- Energy field is optimized for precise stimulation of only the target tissue
- Efficient conversion of electricity to therapeutic magnetic energy allows higher treatment power levels

Figure 1. Neuronetics's NeuroStar optimizes the energy field, in order to precisely stimulate the targeted tissue.

15. Neuronetics's NeuroStar performs the step of adjusting the frequency of the device. For example, Neuronetics's NeuroStar adjusts the frequency of the device by changing the separation distance. *See* Figure 2; <u>https://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4273b1_15-NeuroStarUserManualRevision.pdf</u>.

Rated	Separation Distance According to Frequency of Transmitter (m)		
Maximum Output Power of Transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = (1.17)\sqrt{P}$	$d = (1.17)\sqrt{P}$	$d = (2.33)\sqrt{P}$
(W)			
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.7	11.7	23.3

Figure 2. Neuronetics's NeuroStar adjusts the frequency of the device by changing the separation distance.

- 16. Neuronetics's NeuroStar performs the step of adjusting the pulse duration of the device. For example, Neuronetics's NeuroStar has a pulse duration that is designed to preferentially stimulate a variety of cortical neurons. *See* Figure 1.
- 17. Neuronetics's NeuroStar performs the step of adjusting the duty cycle of the device. For example, Neuronetics's NeuroStar allows professionals to adjust the interval between the specific number of pulsations. *See* Figure 3; <u>https://mentalhealthdaily.com/2015/09/03/tms-transcranial-magnetic-stimulation-side-effects-adverse-reactions-list/.</u>
 - Pulsation intervals: The intervals between TMS pulsations can be adjusted by professionals conducting experiments. The FDA approved TMS device called the "Neurostar" has a specific interval of pulsations that must be followed. That said, any "off-label" or experimental adjustments in pulsation intervals (milliseconds) may increase and/or decrease likelihood of side effects.

Figure 3. Neuronetics's NeuroStar allows professionals to adjust the interval between the specific number of pulsations.

18. Neuronetics's NeuroStar performs the step of adjusting the range of emission of the device. For example, Neuronetics's NeuroStar has an algorithm that allows the System Operator to determine the proper Motor Threshold level, and therefore determine the appropriate treatment dose. *See* Figure 4; <u>http://neurostar.com/en/neurostar-system-components/</u>.

MT Assist[®]—Unique software makes finding the right depression treatment dose easy



MT Assist[®]

Unique software makes finding the right treatment dose easy

 Unique proprietary algorithm assists the system operator in accurately finding the right Motor Threshold level, which determines the appropriate TMS treatment dose

Figure 4. Neuronetics's NeuroStar has an algorithm that allows the System Operator to determine the proper Motor Threshold level, and therefore determine the appropriate treatment dose.

19. Neuronetics's NeuroStar performs the step of having the device sequentially followed by remotely positioning the device in close proximity to a subject's head and emitting microwaves from the device. For example, Neuronetics's NeuroStar is placed near the patient's head, and emits microwaves. *See* Figure 5 http://neurostar.com/en/how-neurostarworks/.



Figure 5. Neuronetics's NeuroStar is placed near the patient's head, and emits microwaves.

- 20. Induced Infringement. Neuronetics has also actively induced, and continues to induce, the infringement of at least claim 1 of the '779 Patent by actively inducing its customers, including merchants and end-users to use Neuronetics's products in an infringing manner as described above. Upon information and belief, Neuronetics has specifically intended that its customers use its products that infringe at least claim 1 of the '779 Patent by, at a minimum, providing access to support for, training and instructions for, its system to its customers to enable them to infringe at least claim 1 of the '779 Patent, as described above. Even where performance of the steps required to infringe at least claim 1 of the '779 Patent is accomplished by Neuronetics and Neuronetics's customer jointly, Neuronetics's actions have solely caused all of the steps to be performed.
- 21. Design is entitled to recover damages adequate to compensate it for such infringement in an amount no less than a reasonable royalty under 35 U.S.C. § 284.
- 22. Design will continue to be injured, and thereby caused irreparable harm, unless and until this Court enters an injunction prohibiting further infringement.

JURY DEMAND

23. Under Rule 38(b) of the Federal Rules of Civil Procedure, Design respectfully requests a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Design asks this Court to enter judgment against Neuronetics, granting the following relief:

- A. A declaration that Neuronetics has infringed the Patent-in-Suit;
- B. An award of damages to compensate Design for Neuronetics's direct infringement of the Patent-in-Suit;
- C. An order that Neuronetics and its officers, directors, agents, servants, employees, successors, assigns, and all persons in active concert or participation with them, be preliminarily and permanently enjoined from infringing the Patent-in-Suit under 35 U.S.C. § 283;
- D. An award of damages, including trebling of all damages, sufficient to remedy Neuronetics's willful infringement of the Patent-in-Suit under 35 U.S.C. § 284;
- E. A declaration that this case is exceptional, and an award to Design of reasonable attorneys' fees, expenses and costs under 35 U.S.C. § 285;
- F. An award of prejudgment and post-judgment interest; and
- G. Such other relief as this Court or jury may deem proper and just.

Respectfully submitted, /s/ Stamatios Stamoulis Counsel for Plaintiff

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