

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
HOUSTON DIVISION**

DILORENZO BIOMEDICAL, LLC,	§	
	§	
Plaintiff,	§	
v.	§	<b>Civil Action No. 4:23-cv-1800</b>
	§	
LIVANOVA, INC. and LIVANOVA USA,	§	Patent Case
INC.,	§	Jury Trial Demanded
	§	
Defendants.	§	
	§	
	§	

**ORIGINAL COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff DiLorenzo Biomedical, LLC, for its complaint against Defendants LivaNova, Inc. and LivaNova USA, Inc., alleges as follows:

**INTRODUCTION**

1. Daniel J. DiLorenzo, President of Plaintiff DiLorenzo Biomedical, LLC (“DiLorenzo Biomedical”), is a pioneering developer of neurological and neurosurgical medical devices and inventor of numerous patents including without limitation U.S. Patent Nos. 6,366,813 (the “’813 patent”), 7,209,787 (the “’787 patent”), and 9,345,880 (the “’880 patent”). The ’813, ’787, and ’880 patents teach and claim systems and methods for neurostimulation, including without limitation “closed-loop” neurostimulation, wherein the neural stimulation is modulated responsive to outputs derived from sensors in communication with a modulating element. DiLorenzo Biomedical owns the ’880 patent and holds exclusive rights under the ’813 and ’787 patents as hereinafter alleged.

2. Defendants have used the technology described and claimed in the ’813, ’787, and ’880 patents to their substantial financial benefit, including without limitation in the development

and sale of neurostimulation devices that incorporate closed-loop features as claimed by the '813, '787, and '880 patents, and provide therapeutic neuromodulation to the sympathetic nervous system, such as the LivaNova Aspire SR™ (Model 106), SenTiva™ (Model 1000), and SenTiva Duo™ (Model 1000-D) VNS Therapy™ systems, and other of Defendants' products ("Accused Products"). Exhibit D hereto is a LivaNova Physician's Manual that generally reflects how the Accused Products operate.

3. DiLorenzo Biomedical alleges that Defendants' Accused Products have infringed the '813, '787, and '880 patents in violation of DiLorenzo Biomedical's exclusive rights therein, as more particularly specified herein.

#### **THE PARTIES**

4. Plaintiff DiLorenzo Biomedical, LLC is a Washington limited liability company with a principal office address at 522 West Riverside Avenue, Suite N, Spokane, Washington 99201-0580.

5. Defendant LivaNova, Inc. is a California corporation with a place of business at 100 Cyberonics Blvd., Suite 600, Houston, Texas 77058. LivaNova, Inc. is registered to do business in Texas and may be served via its registered agent Universal Registered Agents, Inc., 112 Maverick CT., Granbury, TX 79409.

6. Defendant LivaNova USA, Inc. is a Delaware corporation with a place of business at 100 Cyberonics Blvd., Suite 600, Houston, Texas 77058. LivaNova USA, Inc. is registered to do business in Texas and may be served via its registered agent Universal Registered Agents, Inc., 112 Maverick CT., Granbury, TX 79409.

7. Unless otherwise noted, Defendants LivaNova, Inc. and LivaNova USA, Inc. are hereinafter collectively referred to as "Defendants" or "LivaNova."

### **JURISDICTION AND VENUE**

8. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that this action arises under the patent laws of the United States, 35 U.S.C. §§ 1 et seq.

9. This Court has personal jurisdiction over Defendants because they have engaged in systematic and continuous business activities in this District, including acts of patent infringement within this District giving rise to the claims asserted herein.

10. Defendants have established minimum contacts with this forum such that the exercise of jurisdiction over Defendants would not offend traditional notions of fair play and substantial justice. Defendants are each registered to do business in the State of Texas. Defendants offer for sale and sell the Accused Products and offer services related thereto in this District. On information and belief, Defendants have a force of at least 500 employees in Texas, the majority of which are located in this District. On information and belief, a substantial portion of those employees in this District work on VNS Therapy™ systems, including the Accused Products.

11. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b) because Defendants have one or more regular and established places of business in this District and have committed acts of infringement in this District by reason, *inter alia*, of having acted in this District to offer for sale and sell the Accused Products.

### **THE PATENTS-IN-SUIT**

12. The '813 patent was duly and legally issued on April 2, 2002, and inventor Daniel J. DiLorenzo assigned the '813 patent to BioNeuronics Corporation on or about December 9, 2004. A copy of the '813 patent is attached hereto as Exhibit A and incorporated herein by reference. On information and belief, Defendants are the successors-in-interest to BioNeuronics Corporation's ownership rights in the '813 patent.

13. The '787 patent was duly and legally issued on April 24, 2007 to BioNeuronics

Corporation, as assignee of inventor Daniel J. DiLorenzo. A copy of the '787 patent is attached hereto as Exhibit B and incorporated herein by reference. On information and belief, Defendants are the successors-in-interest to BioNeuronics Corporation's ownership rights in the '787 patent.

14. The '880 patent was duly and legally issued on May 24, 2016 to Daniel J. DiLorenzo and is owned by DiLorenzo Biomedical. A copy of the '880 patent is attached hereto as Exhibit C and incorporated herein by reference. DiLorenzo Biomedical owns the right to sue for infringement of the '880 patent, including for past damages.

15. On May 23, 2005, LivaNova's predecessor-in-interest, BioNeuronics Corporation, granted DiLorenzo Biomedical's predecessor-in-interest, and its successors and assigns, an exclusive license to the '813 and '787 patents within fields including sympathetic nervous system modulation therapy (the "Exclusive Field of Use").

16. BioNeuronics Corporation did not retain a license or any other right to use, sell, offer for sale, make or have made, or import any product under the '813 or '787 patents in the Exclusive Field of Use.

17. On information and belief, Defendants, as successors-in-interest to BioNeuronics Corporation, have no license or any other right to use, sell, offer for sale, make or have made, or import any product under the '813 or '787 patents in the Exclusive Field of Use.

18. By reason of said exclusive grant, DiLorenzo Biomedical had ownership rights in the '813 and '787 patents within the Exclusive Field of Use and owns the right to sue for infringement of such rights, including for past damages that occurred during the period beginning May 23, 2005 and extending until the end of the respective terms of the '813 and '787 patents.

19. By virtue of DiLorenzo Biomedical's exclusive rights in the '813 and '787 patents, and because Defendants infringed those patents, DiLorenzo Biomedical has standing to assert the

claims herein against Defendants, under the '813 and '787 patents.

20. DiLorenzo Biomedical has complied with the marking provisions of 35 U.S.C. § 287(a) and also required those persons authorized to operate for or under DiLorenzo Biomedical to comply therewith.

21. Prior to the '813, '787, and '880 patents, electrical neurostimulation to treat disease required a set stimulus or periodic adjustment or re-programming by means external to the patient. The '813, '787, and '880 patents improved on the prior art by providing a capability to modulate the applied neurostimulation based on measurements from sensors that remain connected to the stimulation device. This improvement, within the scope and claims of the '813, '787, and '880 patents, has provided a significant advantage in the field of nerve stimulation therapy, as practiced by Defendants, in the case of the Accused Products, resulting in more effective treatment of drug-resistant epilepsy in reducing the frequency and length of seizures.

22. Modulation of the vagus nerve to treat seizure disorders, in the manner alleged herein to be performed by the Accused Products, is within the Exclusive Field of Use because a seizure such as an epileptic seizure has a massive impact on the sympathetic nervous system, and applying targeted stimulation to the vagus nerve in response to a determination based on sensor input that the patient is having an epileptic seizure, to alleviate the disruption caused by the seizure, as the Accused Products do, results in a decrease of activity of the sympathetic nervous system, thus modulating sympathetic nervous system activity, which is within the Exclusive Field of Use.

### **COUNT I: INFRINGEMENT OF THE '813 PATENT**

23. DiLorenzo Biomedical repeats and realleges the averments in paragraphs 1–22 above as if fully set forth at length herein.

24. Defendants have infringed DiLorenzo Biomedical's exclusive rights under the '813 patent under 35 U.S.C. § 271(a) by making, using, selling, and offering to sell systems and methods

in accordance with one or more claims thereof, in the United States, in the Exclusive Field of Use, during the term of the '813 patent.

25. For example, with reference to claim 1 of the '813 patent, Defendants manufacture, market, and sell in the U.S. (and continue to do so) nerve stimulation products, including without limitation, the Accused Products that apply neural modulation to the vagus nerve, as shown in Exhibit D.

26. The Accused Products share the feature that they each incorporate a signal conditioning circuit, *e.g.*, an “Input/Output” block, as shown in Fig. 6 of Exhibit D. For example, such Input/Output block “[p]rovides amplification of cardiac signals” as described in Table 19 of Exhibit D.

27. In each case, the Accused Products comprise a sensor array in electronic communication with the signal conditioning circuit, for example, lead electrodes as shown in Fig. 7 of Exhibit D.

28. Each Accused Product further comprises a signal processor in electronic communication with the signal conditioning circuit that performs disease state estimation. For example, disease state may depend on a relative increase in the heart rate of a patient. Such signal processing may be performed, for example, in the “Logic and Control” block shown in Fig. 6 of Exhibit D. *See* page 131 of Exhibit D (“The device performs Heartbeat Detection by detecting the R-wave of the ECG morphology”).

29. Each Accused Product further comprises a control circuit in electronic communication with the signal processor, which likewise may be found, *e.g.*, in said Logic and Control block.

30. Each Accused Product further comprises an output stage circuit in electronic

communication with the control circuit, as reflected, *e.g.*, in said Input/Output block.

31. Each Accused Product further comprises a stimulating electrode array in electronic communication with the output stage circuit, *e.g.*, said lead electrodes shown in said Fig. 7 of Exhibit D.

32. Defendants have committed the above alleged acts of infringement during the term of the '813 patent and during the entire six-year limitations period prior hereto, and continue to do so. Said infringement was within the Exclusive Field of Use, for at least the reasons stated in ¶ 21.

33. Pursuant to 35 U.S.C. § 284, DiLorenzo Biomedical is entitled to no less than a reasonable royalty for the use made by Defendants under the '813 patent, in an amount subject to proof at trial, together with interest and costs as fixed by the Court.

#### **COUNT II: INFRINGEMENT OF THE '787 PATENT**

34. DiLorenzo Biomedical repeats and realleges the averments of paragraphs 1–33 above as if fully set forth at length herein.

35. Defendants have infringed the '787 patent under 35 U.S.C. § 271(a) by making, using, selling, and offering to sell systems and methods in accordance with one or more claims thereof, in the United States, during the term of the '787 patent.

36. For example, with reference to claim 7 of the '787 patent, Defendants manufacture, market, and sell in the U.S. (and continue to do so) nerve stimulation products, including without limitation, the Accused Products, that modulate the activity of at least one nervous system component by way of stimulation of the vagus nerve.

37. The Accused Products share the feature that they each comprise means for monitoring parameters that are indicative or predictive of a seizure, including without limitation heart rate, *e.g.*, the above-described Logic and Control, Input/Output, and leads components as shown in Exhibit D and the description of heart rate detection at page 131.

38. In each case, as further reflected in the same components shown in Exhibit D, the Accused Products comprise means for delivering neural modulation signals to said nervous system component (vagus nerve) when the means for monitoring indicate or predict the onset of the seizure, such as a relative increase in the heart rate of a patient.

39. Each Accused Product further comprises means for sensing a neural response to said neural modulation signals, such as a change in heart rate, *e.g.*, by continuing to monitor R-wave signals coming into the device through the leads.

40. Each Accused Product further comprises controller means (*e.g.*, in said Logic and Control block) for modulating parameters of a subsequent neural modulation signal based on the sensed neural response to a previously delivered neural modulation signal, including a controller that modulates parameters of subsequent vagus nerve modulation signals based on the sensed heart rate response to a previously delivered vagus nerve modulation signal. *See, e.g.*, Exhibit D at 70.

41. Defendants have committed the above alleged acts of infringement during the term of the '787 patent and during the entire six-year limitations period prior hereto. Said infringement was within the Exclusive Field of Use, for at least the reasons stated in ¶ 21.

42. Pursuant to 35 U.S.C. § 284, DiLorenzo Biomedical is entitled to no less than a reasonable royalty for the use made by Defendants under the '787 patent, in an amount subject to proof at trial, together with interest and costs as fixed by the Court.

### **COUNT III: INFRINGEMENT OF THE '880 PATENT**

43. DiLorenzo Biomedical repeats and realleges the averments of paragraphs 1–42 above as if fully set forth at length herein.

44. Defendants have infringed the '880 patent under 35 U.S.C. § 271(a) by making, using, selling, and offering to sell systems and methods in accordance with one or more claims thereof, in the United States, and continuing to do so, during the term of the '880 patent.



45. For example, with reference to at least claim 56 of the '880 patent, Defendants manufacture, market, and sell in the U.S. (and continue to do so) nerve stimulation products, including without limitation, the Accused Products, that modulate the activity of at least one nervous system component by way of stimulation of the vagus nerve.

46. The Accused Products share the feature that they each comprise a sensor array, configured to sense activity of a component of the sympathetic nervous system, including without limitation heart rate, *e.g.*, the above-described leads components as shown in Figures 6 and 7 of Exhibit D and the description of heart rate detection at page 131.

47. The Accused Products share the feature that they each comprise a signal processor in electronic communication with said signal conditioning circuit, whereby said signal processor performs disease state estimation and generates a neural state representative of affect, including without limitation heart rate, and associated nervous system state indicative of the onset of a seizure, *e.g.*, the above-described Logic and Control and Input/Output components shown in Figure 6 of Exhibit D and the description of heart rate detection at page 131.

48. The Accused Products share the feature that they each comprise a control circuit in electronic communication with said signal processor and which is configured to generate a signal which modulates affect, including without limitation signals that modulate affect by reducing the effect of epileptic seizures, *e.g.*, the above-described Logic and Control component shown in Figure 6 of Exhibit D, which generates a signal which modulates affect.

49. The Accused Products share the feature that they each comprise an output stage circuit in electronic communication with said control circuit, *e.g.*, the above-described Input/Output component as shown in Figure 6 of Exhibit D.

50. The Accused Products share the feature that they each comprise a stimulating

electrode array, in electronic communication with said output stage circuit, *e.g.*, the above-described leads components as shown in Figures 6 and 7 of Exhibit D.

51. Defendants have committed the above alleged acts of infringement during the term of the '880 patent and continue to do so.

52. Pursuant to 35 U.S.C. § 284, DiLorenzo Biomedical is entitled to no less than a reasonable royalty for the use made by Defendants under the '880 patent, in an amount subject to proof at trial, together with interest and costs as fixed by the Court.

### **DEMAND FOR JURY TRIAL**

DiLorenzo Biomedical demands trial by jury on all issues.

### **PRAYER FOR RELIEF**

WHEREFORE, DiLorenzo Biomedical requests an entry of judgment in its favor and against Defendants as follows:

- i. Declaring that Defendants have infringed one or more claims of United States Patent Nos. 6,366,813, 7,209,787, and 9,345,880;
- ii. Awarding to DiLorenzo Biomedical the damages arising out of said infringement of United States Patent Nos. 6,366,813, 7,209,787, and 9,345,880 pursuant to 35 U.S.C. § 284;
- iii. Awarding DiLorenzo Biomedical permanent and other injunctive relief as to United States Patent No. 9,345,880;
- iv. Awarding attorneys' fees, costs, or other compensatory and/or enhanced damages pursuant to 35 U.S.C. §§ 284 or 285 or as otherwise permitted by law, against Defendants;
- v. Awarding costs in this action to DiLorenzo Biomedical; and
- vi. For such other and further relief as the Court may deem just and proper.

Dated: May 17, 2023

Respectfully submitted,

/s/ Wasif H. Qureshi  
*Attorney-in-Charge*  
Texas Bar No. 24048155  
SDTX No. 584650  
**JACKSON WALKER LLP**  
1401 McKinney Street, STE 1900  
Houston Texas 77010  
(713) 752-4521  
wqureshi@jw.com

*Counsel for Plaintiff DiLorenzo Biomedical, LLC*

OF COUNSEL:

**LISTON ABRAMSON LLP**

The Chrysler Building  
405 Lexington Ave, 46<sup>th</sup> Floor  
New York, New York 10174  
Tel: (212) 257-1630  
Ronald Abramson  
David G. Liston  
Ari J. Jaffess  
Alex G. Patchen  
M. Michael Lewis  
Gina K. Kim  
Email: *docket@listonabramson.com*