

PATENT ASSIGNMENT COVER SHEET

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SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	ASSIGNMENT
CONVEYING PARTY DATA	
Name	Execution Date
Daniel John DiLorenzo	08/01/2005
RECEIVING PARTY DATA	
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State/Country:	WASHINGTON
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PROPERTY NUMBERS Total: 1	
Property Type	Number
Patent Number:	7974696
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NAME OF SUBMITTER:	Kimberly Washnesky
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DATE SIGNED:	02/16/2024
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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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ASSIGNMENT OF APPLICATION

Docket Number 31685-704.201

Whereas, the undersigned:

1. DILORENZO, Daniel John
Seattle, WA

hereinafter termed "Inventors", have invented certain new and useful improvements in

**APPARATUS AND METHOD FOR CLOSED-LOOP INTRACRANIAL STIMULATION FOR OPTIMAL CONTROL OF
NEUROLOGICAL DISEASE**

- ☐ for which an application for United States Patent was filed on _____ Application No. _____
☒ for which a United States Patent issued on April 2, 2002, U.S. Patent No. 6,366,813.

WHEREAS, BioNeuronics Corporation, a corporation of the State of Delaware, having a place of business at 140 Fourth Avenue North, Suite 370, Seattle, WA 98109, (hereinafter termed "Assignee"), is desirous of acquiring the entire right, title and interest in and to said application and the invention disclosed therein, and in and to all embodiments of the invention, heretofore conceived, made or discovered jointly or severally by said Inventors (all collectively hereinafter termed "said invention"), and in and to any and all patents, inventor's certificates and other forms of protection (hereinafter termed "patents") thereon granted in the United States and foreign countries.

NOW, THEREFORE, in consideration of good and valuable consideration acknowledged by said Inventors to have been received in full from said Assignee:

1. Said Inventors do hereby sell, assign, transfer and convey unto said Assignee the entire right, title and interest (a) in and to said application and said invention; (b) in and to all rights to apply for foreign patents on said invention pursuant to the International Convention for the Protection of Industrial Property or otherwise; (c) in and to any and all applications filed and any and all patents granted on said invention in the United States or any foreign country, including each and every application filed and each and every patent granted on any application which is a divisional, substitution, continuation, or continuation-in-part of any of said applications; and (d) in and to each and every reissue or extensions of any of said patents.

2. Said Inventors hereby jointly and severally covenant and agree to cooperate with said Assignee to enable said Assignee to enjoy to the fullest extent the right, title and interest herein conveyed in the United States and foreign countries. Such cooperation by said Inventors shall include prompt production of pertinent facts and documents, giving of testimony, execution of petitions, oaths, specifications, declarations or other papers, and other assistance all to the extent deemed necessary or desirable by said Assignee (a) for perfecting in said Assignee the right, title and interest herein conveyed; (b) for prosecuting any of said applications; (c) for filing and prosecuting substitute, divisional, continuing or additional applications covering said invention; (d) for filing and prosecuting applications for reexamination of any said patents; (e) for interference or other priority proceedings involving said invention; and (f) for legal proceedings involving said invention and any applications therefor and any patents granted thereon, including without limitation reissues and reexaminations, opposition proceedings, cancellation proceedings, priority contests, public use proceedings, infringement actions and court actions; provided, however, that the expense incurred by said Inventors in providing such cooperation shall be paid for by said Assignee.

3. The terms and covenants of this assignment shall inure to the benefit of said Assignee, its successors, assigns and other legal representatives, and shall be binding upon said Inventors, their respective heirs, legal representatives and assigns.

4. Said Inventors hereby jointly and severally warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

IN WITNESS WHEREOF, said Inventors have executed and delivered this instrument to said Assignee as of the dates written below:

Date:

8/1/05


 DILORENZO, DANIEL JOHN

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Daniel John DiLorenzo

Title: Closed-loop autonomic
neuromodulation for optimal
control of neurological and
metabolic disease

Application No.: 11/187,315

Filing Date: July 23, 2005

Patent No.: 7,974,696

Grant Date: July 5, 2011

Examiner: Scott M. Getzow

Art Unit: 3762

Confirmation No.: 8985

LETTER ACCOMPANYING ASSIGNMENT DOCUMENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

LivaNova USA Inc. (“LivaNova”) has recorded several documents in the U.S. Patent and Trademark Office (“the Office”) Assignment Database for U.S. Patent No. 7,974,696 (“the ’696 patent”) that apply to the ’696 patent at least because the application that matured into the ’696 patent claims priority as a continuation-in-part to U.S. Patent App. No. 09/340,326, now U.S. Pat. No. 6,366,813. *See* Assignment of U.S. Pat. No. 6,366,813, dated Aug. 1, 2005, at Reel/Frame 016610/0086, executed by Dr. Daniel John DiLorenzo (“Dr. DiLorenzo”), which states, in part, “[s]aid Inventors do hereby sell, assign, transfer and convey unto said Assignee the entire right, title and interest (a) in and to said application and said invention; ... (c) in and to

any and all applications filed and any and all patents granted on said invention in the United States or any foreign country, including each and every application filed and each and every patent granted on any application which is a divisional, substitution, continuation, or continuation-in-part of any of said applications.” Additionally, Dr. DiLorenzo assigned to LivaNova’s predecessor-in-interest, NeuroBionics Corporation (“NeuroBionics”) all inventions, patent applications, and patents relating to NeuroBionics’ business. *See, e.g., infra* Exhibit B, Defendants’ Motion To Dismiss Pursuant To Federal Rule Of Civil Procedure 12(b)(1) And 12(b)(7), at pp. 3-4. The aforementioned inventions, patent applications, and patents were subsequently assigned to LivaNova, as evidenced by the documents recorded herewith.

LivaNova USA Inc. (“LivaNova”) wishes to call the Office’s attention to the fact that U.S. Patent No. 9,345,880 (“the ’880 patent”) is the subject of litigation in the United States District Court for the Southern District of Texas. *See DiLorenzo Biomedical, LLC v. LivaNova, Inc.*, No. 4:23-cv-01800 (S.D. Tex. 2023). The application that matured into the ’880 patent claims priority as a continuation to the application that matured into the ’696 patent. LivaNova has provided copies of publicly accessible pleadings from the litigation as exhibits to this letter, as follows:¹

1. Exhibit A: Original Complaint For Patent Infringement. *DiLorenzo Biomedical, LLC v. LivaNova, Inc.*, No. 4:23-cv-01800, Dkt. 1 (S.D. Tex. May 17, 2023).²
2. Exhibit B: Defendants’ Motion To Dismiss Pursuant To Federal Rule Of Civil Procedure 12(b)(1) And 12(b)(7). *DiLorenzo Biomedical, LLC v. LivaNova, Inc.*, No. 4:23-cv-01800, Dkt. 22 (S.D. Tex. Oct. 19, 2023).

¹ Note that certain of the exhibits include redactions. Publicly accessible versions of the documents have been provided in accordance with confidentiality provisions of certain agreements.

² The exhibits to this document have been omitted for brevity. The exhibits are available within the public docket record of the litigation.

3. Exhibit C: DiLorenzo Biomedical's Opposition To Defendant's Motion To Dismiss Pursuant To Federal Rule Of Civil Procedure 12(b)(1) And 12(b)(7). *DiLorenzo Biomedical, LLC v. LivaNova, Inc.*, No. 4:23-cv-01800, Dkt. 34 (S.D. Tex. Nov. 10, 2023).
4. Exhibit D: Defendant's Reply In Support Of Motion To Dismiss Pursuant To Federal Rule Of Civil Procedure 12(b)(1) And 12(b)(7). *DiLorenzo Biomedical, LLC v. LivaNova, Inc.*, No. 4:23-cv-01800, Dkt. 36 (S.D. Tex. Nov. 20, 2023).

Respectfully submitted,

Date 2/16/2024

By /Brett P. Belden/

FOLEY & LARDNER LLP
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Brett P. Belden
Attorney for LivaNova USA Inc.
Registration No. 57,705

EXHIBIT A

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

DILORENZO BIOMEDICAL, LLC,	§	
	§	
Plaintiff,	§	
v.	§	Civil Action No. 4:23-cv-1800
	§	
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

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EXHIBIT B

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

DILORENZO BIOMEDICAL, LLC,

Plaintiffs,

v.

LIVANOVA, INC. and LIVANOVA USA,
INC.,

Defendants.

Civil Action No. 4:23-cv-1800

Patent Case
Jury Trial Demanded



DEFENDANTS' MOTION TO DISMISS
PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1) AND 12(b)(7)

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND	3
A.	Background of the Agreements and Patents	3
1.	Dr. Daniel J. DiLorenzo Conveyed His Rights in the Asserted Patents to LivaNova’s Predecessor-in-Interest	3
2.	NeuroBionics Successor, BioNeuronics, Granted DiLorenzo’s Company Limited Rights to the Asserted Patents in His Field of Use	4
3.	In April 2006, Dr. DiLorenzo Ceased Working for BioNeuronics.....	5
B.	LivaNova Owns the ’880 Patent	6
C.	Correspondence between Dr. DiLorenzo and LivaNova’s Predecessor-in-Interest Confirms DiLorenzo’s Narrowly Held Interest	7
D.	Correspondence between Dr. DiLorenzo and LivaNova Further Confirms DiLorenzo’s Narrowly Held Interest	8
III.	LEGAL STANDARDS	9
IV.	ARGUMENT	9
A.	The Court Should Dismiss DiLorenzo’s Complaint for Failure to Join LivaNova as a Plaintiff	10
B.	The Court Should Dismiss DiLorenzo’s Complaint for Lack of Standing Because DiLorenzo Has No Ownership Rights Outside the Narrow “Field of Use” of Treating Obesity and Metabolic Disorders	12
1.	The Subject Matter, Objective, and Circumstances Surrounding the Making of the Contract Support LivaNova’s Position	14
2.	The Subsequent Conduct and Course of Dealing Between the Parties to the Contract Support LivaNova’s Position	16
3.	The Reasonableness of LivaNova’s Interpretation (and Unreasonableness of DiLorenzo’s Interpretation) Support LivaNova’s Position.....	19
V.	CONCLUSION.....	20

TABLE OF AUTHORITIES

Cases	Page(s)
<i>Alps South, LLC v. Ohio Willow Wood Co.</i> , 787 F.3d 1379 (Fed. Cir. 2015).....	2, 9, 10, 11
<i>DDB Techs., L.L.C. v. MLB Advanced Media, L.P.</i> , 517 F.3d 1284 (Fed. Cir. 2008).....	9
<i>Int’l Gamco, Inc. v. Multimedia Games, Inc.</i> , 504 F.3d 1273 (Fed. Cir. 2007).....	12
<i>Microsoft Corp. v. Motorola, Inc.</i> , 864 F. Supp.2d 1023 (W.D. Wash. 2012).....	13
<i>Rite-Hite Corp. v. Kelley Co.</i> , 56 F.3d 1538 (Fed. Cir. 1995) (<i>en banc</i>)	9
<i>Textile Prods., Inc. v. Mead Corp.</i> , 134 F. 3d 1481 (Fed. Cir. 1998).....	12
<i>TransUnion LLC v. Ramirez</i> , 141 S. Ct. 2190 (2021).....	9
<i>Waterman v. Mackenzie</i> , 138 U.S. 252 (1891).....	9

TABLE OF EXHIBITS

Exhibit	Description
A	2004-03-31 NeuroBionics Founder Agreement
B	2004-12-14 NeuroBionics Amended and Restated Founder Agreement
C	2014-12-14 Dr. DiLorenzo Assignment to NeuroBionics
D	2005-02-08 NeuroBionics Proprietary Information, Inventions Assignment and Noncompete Agreement
E	2005-05-23 Exclusive License Agreement between BioNeuronics and DiLorenzo
F	2006-04-18 Separation Agreement between Dr. DiLorenzo and BioNeuronics
G	Feb 2009–Feb 2013 emails between Dr. DiLorenzo and Cyberonics
H	2012-11-22 Dr. DiLorenzo email to Cyberonics
I	2013-02-11 Bill of Sale (Cyberonics Acquisition of NeuroVista)
J	2013-03-13 email to Cyberonics from Dr. DiLorenzo
K	Aug 2013–Nov 2013 emails between Dr. DiLorenzo and Cyberonics
L	2020-11-18 Letter to Rowell from Gibson (Dr. DiLorenzo’s attorney)
M	June 2022–Aug 2022 emails between Dr. DiLorenzo and LivaNova
N	2022-12-01 Option Agreement between Dr. DiLorenzo and LivaNova

I. INTRODUCTION

The Asserted Patents are owned by the Defendants, LivaNova. Dr. Daniel J. DiLorenzo, the individual behind Plaintiff, DiLorenzo Biomedical LLC (“DiLorenzo”), assigned the asserted ’813 patent and any provisional applications, continuations, and continuations in part naming the ’813 patent as a parent case to LivaNova’s predecessor-in-interest in 2004 [REDACTED]. After this assignment, Dr. DiLorenzo made another assignment to the same entity, relating more broadly to inventions in the field of neurodiagnostics and/or neuromodulation. The ’813, and the two other asserted patents, the ’787 and ’880 patents, fall under both assignments. In a 2005 agreement between LivaNova’s predecessor-in-interest and DiLorenzo, LivaNova granted back a license to the ’813 patent and its progeny for use in the field of treating obesity and metabolic disorders (“License Grant”).

Dr. DiLorenzo ultimately separated from LivaNova’s predecessor-in-interest, but for the past fifteen years, the parties maintained a line of communication. In every pertinent correspondence between the parties, Dr. DiLorenzo unequivocally recognizes that his rights in the Asserted Patents are limited and that he *does not* have rights to the Asserted Patents in the field of epilepsy treatment. In fact, just over a year ago Dr. DiLorenzo attempted to purchase the Asserted Patents *from LivaNova*. LivaNova refused and now DiLorenzo relies on an improper read of the License Grant in a baseless attempt to assert the very patent rights Dr. DiLorenzo contracted away. DiLorenzo’s interpretation of the License Grant is not grounded in the Agreement itself, nor when viewed in the context of the other relevant documents, the history of the parties, and their correspondence following the execution of the License Grant. DiLorenzo’s claims cannot stand for at least two reasons.

First, under well-settled Supreme Court case law, a licensee cannot sue for patent infringement without joining the patent owner if the license grants merely “an undivided part or

share of th[e] exclusive right [granted under the patent].” *Alps South, LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1383–84 (Fed. Cir. 2015) (citing *Waterman v. Mackenzie*, 138 U.S. 252, 255 (1891)). DiLorenzo’s own Complaint admits DiLorenzo is merely a licensee in a Field of Use. Dkt. 1, ¶ 15. Because DiLorenzo failed to join LivaNova as a plaintiff in this suit, DiLorenzo lacks standing to bring this suit and its Complaint should be dismissed. As LivaNova will not join any lawsuit against itself, the Court’s dismissal should be with prejudice.

Second, notwithstanding the fact that DiLorenzo lacks standing to bring this lawsuit without joining LivaNova as a plaintiff, the Court should also dismiss DiLorenzo’s Complaint with prejudice for lack of standing because DiLorenzo is attempting to assert rights it does not own. Namely, DiLorenzo has filed suit for infringement of the Asserted Patents against LivaNova’s epilepsy treatment products, which fall squarely outside of DiLorenzo’s Field of Use. Each of the relevant agreements consistently display the parties’ intent to convey to LivaNova’s predecessors-in-interest rights to the Asserted Patents in the field of epilepsy treatment, and the Agreement containing the License Grant clearly conveys to DiLorenzo *only* a license in the field of treatment of obesity and metabolic disorders. Furthermore, Dr. DiLorenzo’s extensive correspondence with LivaNova and its predecessors regarding potential collaboration on projects relating to epilepsy treatment confirms that Dr. DiLorenzo has always known that he did not retain any rights to the Asserted Patents in epilepsy treatment.

Based on the evidence discussed, DiLorenzo lacks standing for its claims, and LivaNova respectfully requests the Court dismiss DiLorenzo’s Complaint with prejudice.¹

¹ Furthermore, based on the parties’ significant pre-suit correspondence on these issues, DiLorenzo knew its Rule 11 basis for filing the instant action was specious. LivaNova reserves all rights to request the Court order DiLorenzo to pay fees and costs under Fed. R. Civ. P. 11, 35 U.S.C. § 285, WASH. REV. CODE § 4.84.185 (1991), and *Octane Fitness LLC v. Icon Health & Fitness, Inc.*, 572 U.S. 559 (2014).

II. BACKGROUND

A. Background of the Agreements and Patents

1. Dr. Daniel J. DiLorenzo Conveyed His Rights in the Asserted Patents to LivaNova's Predecessor-in-Interest

In March 2004, Dr. DiLorenzo helped found NeuroBionics Corporation, a medical device company that focused on epilepsy treatment. [REDACTED]

[REDACTED], Dr. DiLorenzo assigned his rights in the Asserted Patents when he executed a “Founder Agreement” and, later, an “Amended and Restated Founder Agreement.” Ex. A (Mar. 31, 2004, Founder Agrmt.); Ex. B (Dec. 14, 2004, Am. Founder Agrmt.). Per those agreements, Dr. DiLorenzo assigned his rights in the ’813 patent *and all provisionals, continuations, partial continuations, and divisionals* to NeuroBionics. Ex. A, § 2(a), Schedule I; Ex. B, § 2(a); Schedule I. U.S. Patent Nos. 7,209,787 and 9,345,880 claim priority to the ’813 patent and are therefore covered by the assignment. *See* Dkt. 1-2 at field (63); Dkt 1-3, field (63). Dr. DiLorenzo also assigned any inventions he might make during his employment by NeuroBionics that either related to NeuroBionics’ business, resulted from tasks NeuroBionics assigned, or used NeuroBionics resources, and to promptly disclose all such work to NeuroBionics. Ex. A, § 2(b); Ex. B, § 2(b). On December 14, 2004, Dr. DiLorenzo executed a broader “Assignment” conveying to NeuroBionics “all of the right, title and interest of the undersigned in and to any and all inventions, original works of authorship, developments, improvements, trade secrets, patents, patent applications, and other intellectual property, including clinical and preclinical data, related to [NeuroBionics’] business of neurodiagnostics and/or neuromodulation.” Ex. C (Dec. 14, 2004 Assignment to NeuroBionics).

On February 8, 2005, Dr. DiLorenzo and NeuroBionics entered a “Proprietary Information, Inventions Assignment, and Noncompete Agreement.” Ex. D. In the Proprietary Information,

Inventions Assignment, and Noncompete Agreement, Dr. DiLorenzo agreed “promptly to disclose to [NeuroBionics], during and after [his] employment, all Inventions and Works” that Dr. DiLorenzo invents during the term of his employment. *Id.*, § 4(b). “Company Inventions and Works” is defined as any invention that “pertain[s] to any actual or projected line of business activity of [NeuroBionics]; (ii) are aided by the use of time, material, facilities, or trade secrets of [NeuroBionics]; or (iii) relate to any of my work during the period of my employment by [NeuroBionics].” *Id.* This section also assigns to NeuroBionics “all right, title, and interest that [Dr. DiLorenzo has] or may acquire in such [NeuroBionics] Inventions and Works.” *Id.* Exhibit A to the agreement contains a list of all “Inventions and Works . . . that may be relevant to [NeuroBionics]’ actual or projected business.” *Id.*, § 4(c).

2. NeuroBionics Successor, BioNeuronics, Granted DiLorenzo’s Company Limited Rights to the Asserted Patents in His Field of Use

On May 23, 2005, BioNeuronics (the successor-in-interest to NeuroBionics and a predecessor-in-interest of LivaNova) entered into an “Exclusive License Agreement and Amendments to Founder Agreement, Assignment Agreement and Proprietary Information, Inventions Assignment and Noncompete Agreement” (hereinafter, “the Agreement”) with DiLorenzo Biomedical, LLC and Dr. DiLorenzo. Ex E. The Agreement codifies that on December 14, 2004, Dr. DiLorenzo assigned to NeuroBionics U.S. Patent No. 6,366,813 and its progeny, which by then included U.S. Patent Application No. 10/718,248, filed on November 20, 2003, which later issued as U.S. Patent No. 7,209,787 (asserted here) and which later included U.S. Patent No. 9,345,880.

The Agreement states that its goal is to clarify the previous agreements and to return to DiLorenzo a narrow scope of rights to “obesity and metabolism.” *See* Ex. E, 2. Specifically, Section 4 of the Agreement is the License Grant from BioNeuronics to DiLorenzo’s limited

liability company, DiLorenzo Biomedical LLC (defined as the sole “Licensee”), to “make use, sell, offer for sale, import, export and sublicense devices and methods for sympathetic nervous system modulation therapy and for neuromodulation therapy *for treating obesity and other metabolic disorders . . .*” (the “Field of Use”). *Id.*, § 4. The License Grant does not contain a right to sue for patent infringement. *Id.* Rather, Section 10 of the Agreement lays out the requirements for bringing patent infringement actions against others. *Id.*, § 10.

3. In April 2006, Dr. DiLorenzo Ceased Working for BioNeuronics

On April 18, 2006, Dr. DiLorenzo and BioNeuronics executed a “Separation Agreement,” which reaffirmed that certain obligations continue through Dr. DiLorenzo’s separation from BioNeuronics. Ex. F, § 7. This includes the Assignment of Intellectual Property obligations of Section 2 of the Amended Founders Agreement (Ex. B, § 2) and Dr. DiLorenzo’s license agreement in favor of BioNeuronics in the field of epilepsy in the Inventions Agreement. Ex. D. The Separation Agreement also “specifically acknowledges” that the Agreement between the parties contains “a perpetual, fully paid up, worldwide, exclusive license to make, use, sell, offer for sale, import, export and sublicense *devices and methods for the treatment, diagnosis or amelioration of epilepsy and or the symptoms thereof.*” Ex. F, § 7.3. This section further describes the grant-back in Section 4 of the Agreement as related to “certain rights and licenses in the Field of Use of *treating obesity and other metabolic disorders.*” *Id.*

The Separation Agreement also reiterates that the “actual or projected line of business activity of [BioNeuronics]” means “Inventions and Works that pertain to *neurological monitors, neurological stimulators, monitoring and stimulation leads, and medical telemetry apparatus that may be used with neurological monitors and neurological stimulators to diagnose, monitor and/or manage neurological and physiological disorders,*” except for Inventions and Works “in the field of autonomic modulation and neuromodulation *for obesity and metabolism.*” *Id.*, § 8.1.

B. LivaNova Owns the '880 Patent

Before Dr. DiLorenzo separated from BioNeuronics, Dr. DiLorenzo filed U.S. Patent Application No. 11/333,979 on January 17, 2006, which later issued as U.S. Patent No. 9,345,880. Dkt. 1-3, fields (22), (21), (10). The '880 patent is titled "Closed-Loop Feedback-Driven Sympathetic Neuromodulation for Affect Control" and lists Daniel John DiLorenzo as both the Inventor and the Assignee. *Id.*, fields (54), (75), (73). The '880 patent's "Related U.S. Application Data" shows that the '880 patent is a continuation-in-part of '787 and '813 patents. *Id.*, field (63).

As stated in every agreement, Dr. DiLorenzo was required to disclose to BioNeuronics any invention relating to BioNeuronics' business (devices and methods for the treatment, diagnosis, or amelioration of epilepsy). Ex. A, § 2(b); Ex. B, §§ 2(b), 2(c); Ex C; Ex. D, § 4(b); *see generally* Ex. E; Ex. F, §§ 7.3, 8.2. The Agreement also codifies the prior assignment of U.S. Patent No. 6,366,813 and "Provisional Applications, Continuations and Continuations in Part naming U.S. Patent No. 6,366,813 or any of its filings as the parent case." Ex. E, pg. 1. LivaNova thus owns the '880 patent because the '880 patent names the '813 patent as the parent case.

Furthermore, Dr. DiLorenzo should have disclosed the '880 patent to BioNeuronics and executed an assignment of the '880 patent to BioNeuronics. According to the Complaint, the '880 patent "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*." Dkt. 1, ¶ 21. The Complaint identifies the LivaNova Aspire SR™ (Model 106), SenTiva™ (Model 1000), and SenTiva Duo™ (Model 1000-D) VNS Therapy™ systems as the "Accused Products," all of which are products used to treat epilepsy. *Id.*, ¶ 2. Therefore, by DiLorenzo's assertions of the '880 patent against LivaNova's epilepsy treatment products, Dr. DiLorenzo has stated that the '880 patent relates to

the field of epilepsy treatment and should have been disclosed and a formal assignment executed to BioNeuronics.

C. Correspondence between Dr. DiLorenzo and LivaNova's Predecessor-in-Interest Confirms DiLorenzo's Narrowly Held Interest

Cyberonics is a medical device company specializing in epilepsy treatment through stimulation of the Vagus nerve. Cyberonics acquired BioNeuronics' patent portfolio (which included the Asserted Patents) in 2012, making Cyberonics the successor-in-interest to the Asserted Patents. Ex. I. On March 13, 2013, Dr. DiLorenzo sent correspondence to Cyberonics inquiring as to its "[REDACTED]" and whether Cyberonics would "[REDACTED]". Ex. J. As part of that conversation, in an April 22, 2013 email, Dr. DiLorenzo acknowledged that "the IP is divided along fields of use, *mine being metabolism and autonomic structures* (amygdala, hypothalamus, etc) and NeuroVista/Cyberonics being *in epilepsy and other areas.*" *Id.*

Between August 2013 and November 2013, Dr. DiLorenzo corresponded with the then-General Counsel of Cyberonics. Ex. K. On August 25, 2013, Dr. DiLorenzo suggested "[REDACTED]". *Id.* Following additional correspondence, Cyberonics responded on September 23, 2013, clarifying that Dr. DiLorenzo only has rights relating to its Field of Use, and that Dr. DiLorenzo lacked the requisite standing to maintain a legal action for patent infringement without Cyberonics' consent. *Id.* Dr. DiLorenzo did not respond to contest these points. *Id.*

² Following Dr. DiLorenzo's separation from BioNeuronics, BioNeuronics changed its name to "NeuroVista."

D. Correspondence between Dr. DiLorenzo and LivaNova Further Confirms DiLorenzo's Narrowly Held Interest

Cyberonics merged with the Sorin Group in 2015 and later underwent a name change to “LivaNova USA Inc.” On November 18, 2020, an attorney for Dr. DiLorenzo sent correspondence to LivaNova. Ex. L. Dr. DiLorenzo’s attorney stated that Dr. DiLorenzo [REDACTED]

[REDACTED]

[REDACTED]. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].” *Id.*

Between June 2022 and August 2022, Dr. DiLorenzo sent further correspondence to LivaNova. Ex. M. Dr. DiLorenzo inquired about obtaining full rights in the intellectual property LivaNova “acquired as part of NeuroVista” and proposed that Dr. DiLorenzo ***purchase*** the patents ***from LivaNova***. *Id.* On July 8, 2022, Dr. DiLorenzo offered [REDACTED] to purchase the patents formerly owned by NeuroBionics from LivaNova, with a [REDACTED] payment for the option to purchase. *Id.* After further discussion, Dr. DiLorenzo ***agreed to increase his offer and pay LivaNova*** [REDACTED] for the intellectual property with a [REDACTED] option lasting five years. Dr. DiLorenzo sent an Option Agreement summarizing these terms dated December 1, 2022. Ex. N. In that Option Agreement, Dr. DiLorenzo acknowledged that “[LivaNova] has not itself ever made, offered for sale, or sold any patented articles covered by the [patents] in the United States, nor imported any patented article covered by the [patents] into the United States.” *Id.*, § 4(c).³

³ This and other correspondence between the parties shows that, in addition to lacking standing to bring this lawsuit, Dr. DiLorenzo and DiLorenzo understand that LivaNova's products do not infringe the Asserted Patents.

III. LEGAL STANDARDS

Standing to sue is a prerequisite to federal subject matter jurisdiction. Only the patent owner (or, in some cases, an exclusive licensee) may sue for damages; suits by others must be dismissed for lack of standing. *Waterman v. Mackenzie*, 138 U.S. 252, 255 (1891); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1551–52 (Fed. Cir. 1995) (*en banc*). Where a “licensee does not hold all substantial rights [in a patent], it may ‘sue third parties only as a co-plaintiff with the patentee.’” *Alps South, LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1382–83 (Fed. Cir. 2014). The plaintiff bears the burden of pleading and proving that it has standing to assert its claim. *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2207–10 (2021). Standing is for the Court to decide. *DDB Techs., L.L.C. v. MLB Advanced Media, L.P.*, 517 F.3d 1284, 1290–91 (Fed. Cir. 2008) (“The sole jury trial issue in this case concerns whether DDB is entitled to a jury trial on the jurisdictional issue of standing. We hold that it is not.”).

IV. ARGUMENT

DiLorenzo was required to join LivaNova as a co-plaintiff in this action because DiLorenzo only has rights as a licensee in a limited field of use. Because DiLorenzo failed to do so, and because LivaNova will not join this lawsuit as a plaintiff against itself, the Court must dismiss DiLorenzo’s Complaint with prejudice for lack of standing. The Court should also dismiss DiLorenzo’s Complaint with prejudice for lack of standing because DiLorenzo is attempting to assert rights it does not own. Namely, DiLorenzo has filed suit for infringement of the Asserted Patents against LivaNova’s epilepsy treatment products, which fall squarely outside of DiLorenzo’s Field of Use.

A. The Court Should Dismiss DiLorenzo’s Complaint for Failure to Join LivaNova as a Plaintiff

DiLorenzo was required to add LivaNova as a plaintiff in this action and, in failing to do so, lacks standing to file this action. “The Supreme Court has long recognized that an exclusive licensee cannot sue for infringement without joining the patent owner if the license grants merely ‘an undivided part or share of the[e] exclusive right [granted under the patent].’” *Alps South, LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1383–84 (Fed. Cir. 2015) (citing *Waterman v. Mackenzie*, 138 U.S. 252, 255 (1891)).

The facts of *Alps South* are instructive here. In *Alps South*, an inventor assigned a patent to a company he created (“AEI”). *Id.* at 1381. AEI then licensed certain rights in the patent for a particular “field of use” to the plaintiff, Alps. *Id.* at 1381, 1383. Alps then sued defendant Ohio Willow Wood (“OWW”) for infringement, relying on its license in the field of use (which included the right to sue) as its basis for standing. *Id.* Because Alps failed to join AEI as a co-plaintiff, OWW filed a motion to dismiss for lack of standing. *Id.* at 1381. The district court originally denied OWW’s motion to dismiss, finding the terms of the license (which granted Alps the right to sue for patent infringement in its field of use) were sufficient to provide Alps with standing. *Id.* Shortly before trial, the district court *sua sponte* reconsidered the standing issue and invited Alps to join AEI as a co-plaintiff. *Id.* at 1382. Alps declined, and despite the district court’s concerns, the case proceeded to trial, after which a jury found the patent valid and infringed. *Id.*

OWW appealed, arguing the license to Alps did not convey sufficient rights to confer standing without joining AEI as a co-plaintiff. *Id.* The Federal Circuit agreed, finding that “the original agreement’s field of use restriction [was] fatal to Alps’s argument that it had standing to file this action.” *Id.* at 1383. The Federal Circuit explained that “finding that a field of use licensee has standing ‘to sue in its own name alone poses a substantial risk of multiple suits and multiple

liabilities against an alleged infringer for a single act of infringement.” *Id.* at 1384 (citing *Int’l Gamco, Inc. v. Multimedia Games, Inc.*, 504 F.3d 1273, 1278 (Fed. Cir. 2007)). Federal Circuit standing jurisprudence, therefore, “compels an exclusive licensee with less than all substantial rights, *such as a field of use licensee*, to join the patentee before initiating suit.” *Id.* (citing *Int’l Gamco*, 504 F.3d at 1278 (internal quotations omitted; emphasis original)). The Federal Circuit held that “[b]ecause the license restricted Alps’s rights in the ’109 patent to the field of [use], Alps lacked standing to pursue this litigation without naming AEI as a co-plaintiff.” *Id.*

Nearly identical circumstances are present here. In 2004, Dr. DiLorenzo assigned all rights in the Asserted Patents to LivaNova’s predecessors-in-interest. *See generally* Ex. B, Ex. C. BioNeuronics granted back to DiLorenzo “a perpetual, fully paid up, worldwide, exclusive license to make, use, sell, offer for sale, import, export and sublicense devices and methods for sympathetic nervous system modulation therapy and for neuromodulation therapy for treating obesity and other metabolic disorders (hereinafter referred to as the Field of Use), which inventions are covered by one or more claims of the Assigned Patents.” Ex. E, § 4. Thus, DiLorenzo only owns a license to make, use, sell, offer for sale, import, export, and sublicense devices and methods in the Field of Use of the Asserted Patents. Importantly, the License Grant does not include a right to sue for patent infringement. Procedures for bringing a lawsuit for patent infringement are governed by Section 10 of the Agreement, including acknowledging that LivaNova may need to be named as a plaintiff in a patent infringement lawsuit to maintain standing. *Id.*, § 10.

DiLorenzo acknowledges in the Complaint that it is only a licensee in a field of use: “LivaNova’s predecessor-in-interest, BioNeuronics Corporation, granted DiLorenzo Biomedical’s predecessor-in-interest, in its successors and assigns, an exclusive license” to the Asserted Patents *within an “Exclusive Field of Use.”* Dkt. 1, ¶ 15. Therefore, because DiLorenzo is a “licensee

with less than all substantial rights,” DiLorenzo was compelled “to join the patentee[, LivaNova,] before initiating suit.” *Int’l Gamco*, 504 F.3d at 1278. DiLorenzo failed to do so. Because LivaNova does not consent to be joined as a plaintiff against itself in this action, the Court should dismiss DiLorenzo’s Complaint with prejudice.

The facts here also do not meet the criteria for the limited exception to this rule, that “an exclusive licensee that does not have all substantial rights does have standing to sue in his own name when ‘necessary to prevent an absolute failure of justice, as where the patentee is the infringer, and cannot sue himself.’” *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998). First, the License Grant does not include a right to sue. Rather, the right to sue (for both parties) is governed by Section 10 of the Agreement. Ex. E, § 10. In fact, Section 10 of the Agreement acknowledges that LivaNova may be required to be joined to any patent infringement suit as a party for standing purposes. *Id.*, § 10(c). Only when certain conditions are met is DiLorenzo allowed to bring a suit for patent infringement. *Id.* Second, despite the use of the term, DiLorenzo is **not** an exclusive licensee as to the entire set of rights in the Asserted Patents but only a licensee to make and sell products in its “Field of Use,” which, as discussed below, unquestionably **does not** include products for the treatment of epilepsy.

B. The Court Should Dismiss DiLorenzo’s Complaint for Lack of Standing Because DiLorenzo Has No Ownership Rights Outside the Narrow “Field of Use” of Treating Obesity and Metabolic Disorders

Should the Court not dismiss DiLorenzo’s Complaint for failure to join LivaNova, the Court should dismiss DiLorenzo’s Complaint for lack of standing because DiLorenzo’s rights are limited to DiLorenzo’s narrow Field of Use for treating obesity and metabolic disorders. DiLorenzo’s Complaint is predicated on an inaccurate interpretation of the License Grant. Namely, DiLorenzo’s position is that the License Grant conveyed to DiLorenzo rights in the Asserted Patents “for sympathetic nervous system modulation therapy” **and separately**

“neuromodulation therapy for treating obesity and other metabolic disorders.” Based on this read of the License Grant, DiLorenzo argues LivaNova’s products are products “for sympathetic nervous system modulation therapy” that meet the claims of the Asserted Patents. Putting aside whether LivaNova’s products are products “for sympathetic nervous system modulation therapy” (which they are not), such a read of the License Grant cannot stand, as it would defeat the objectives of the Agreement and the parties’ previous agreements, as discussed below.

Under Washington law, courts interpret a contract in accordance with the “context rule.”⁴ *Microsoft Corp. v. Motorola, Inc.*, 864 F. Supp.2d 1023, 1033 (W.D. Wash. 2012). Under the context rule, extrinsic evidence is admissible to assist the court in ascertaining the parties’ intent and interpreting the contract. *Id.* “The court may consider (1) the subject matter and objective of the contract, (2) the circumstances surrounding the making of the contract, (3) the subsequent conduct of the parties to the contract, (4) the reasonableness of the parties’ respective interpretations, (5) statements made by the parties in preliminary negotiations, (6) usages of trade, and (7) the course of dealing between the parties.” *Id.* Such evidence is admissible regardless of whether the contract is deemed ambiguous. *Id.* Based on an analysis of these factors, it is clear that the Field of Use means “for sympathetic nervous system modulation therapy and for neuromodulation therapy” **both** “for treating obesity and other metabolic disorders.” DiLorenzo’s rights are limited to the Field of Use of treating obesity and other metabolic disorders and cannot be used to maintain an action against the accused products, which are used to treat epilepsy.

⁴ Section 20 of the Agreement states that the “Agreement shall be governed and enforced in accordance with laws of the state of Washington.” Ex. E, § 20.

1. The Subject Matter, Objective, and Circumstances Surrounding the Making of the Contract Support LivaNova's Position

The subject matter, objective, and circumstances surrounding the making of the Agreement support LivaNova's position that the License Grant is limited to the Field of Use of treating obesity and metabolic disorders through the use of sympathetic nervous system modulation therapy and neuromodulation therapy. Page one of the Agreement confirms that DiLorenzo assigned to BioNeuronics "U.S. Patent No. 6,366,813 . . . and Provisional Applications, Continuations and Continuations in Part naming US Patent No. 6,366,813 or any of its filings as the parent case" (the "Assigned Patents"), which is a family of patents relating to epilepsy treatment. Ex. E, pg. 1. Page one of the Agreement also reiterates that DiLorenzo's assignment excluded certain patents (*not* in the family of the '813 patent) relating to "Autonomic Modulation and Neuromodulation for Obesity & Metabolism." *Id.* Page two of the Agreement further explains that, in part, the purpose of the Agreement is to accomplish the parties' goal of using "their best efforts" to "grant back to DiLorenzo certain of the assigned intellectual property *relating to obesity and metabolism.*" Ex. E, pg. 2. This establishes that DiLorenzo only intended to retain for himself rights in his patents insofar as they relate to the treatment of obesity and metabolism. The License Grant itself states that DiLorenzo was granted an "exclusive license to make, use, sell, offer for sale, import, export and sublicense devices and methods for sympathetic nervous system modulation therapy and for neuromodulation therapy *for treating obesity and other metabolic disorders* (hereinafter referred to as the Field of Use), which inventions are covered by one or more claims of the Assigned Patents." Ex. E, § 4.

Other clauses in the early agreements between Dr. DiLorenzo, NeuroBionics, and BioNeuronics confirm the parties' objectives were to assign to NeuroBionics all inventions and

intellectual property relating to the treatment of epilepsy and to only allow DiLorenzo to retain the same in the field of treatment of obesity and metabolic disorders. Specifically:

- The Founder Agreement requires that Dr. DiLorenzo assign any invention that “*relates to the business of the Company.*” Ex. A, § 2(b). NeuroBionics’ business was the treatment of epilepsy. *See, e.g.*, Ex. C.
- In the Amended and Restated Founder Agreement, Dr. DiLorenzo carves out certain inventions relating to “Autonomic Modulation and Neuromodulation for *Obesity & Metabolism.*” showing Dr. DiLorenzo only intended to retain rights in intellectual property relating to the treatment of obesity and metabolism, not epilepsy treatment. Ex. B, § 2(b).
- The Amended and Restated Founder Agreement assigns any invention by Dr. DiLorenzo relating to *NeuroBionics’ business* (epilepsy treatment) to NeuroBionics. Ex. B, §§ 2(b), 2(c).
- The Assignment by Dr. DiLorenzo to NeuroBionics Corporation lists NeuroBionics business as “*neurodiagnostics and/or neuromodulation.*” Ex. C.
- The Inventions Assignment requires that Dr. DiLorenzo assign any invention relating to “*any actual or projected line of business activity of the Company*” (epilepsy treatment) to BioNeuronics. Ex. D, § 4.

The objectives of the Agreement and the License Grant are clear. The parties wished to (1) confirm the assignment of the ’813 and its progeny to BioNeuronics; (2) confirm DiLorenzo’s retention of certain unrelated patents relating to the field of obesity and metabolic disorders; and (3) grant to DiLorenzo a *new right* to the Asserted Patents in the field of treating obesity and metabolism. The context of the subject matter and objective of the Agreement and earlier agreements show that through the License Grant, the parties intended to convey to DiLorenzo rights to the Asserted Patents *only* in the field of treating obesity and metabolism.

Nothing in the Agreement supports DiLorenzo’s interpretation, which is that the License Grant conveyed to DiLorenzo rights in “sympathetic nervous system modulation therapy” (for the treatment of epilepsy or otherwise) *and separately* “neuromodulation therapy for treating obesity and other metabolic disorders.” In other words, DiLorenzo is arguing that BioNeuronics retained

the rights to the Asserted Patents for the treatment of epilepsy through the *parasympathetic* nervous system but not the *sympathetic* nervous system. DiLorenzo can point to no evidence that would support any intent by BioNeuronics to give away any of its rights to the Asserted Patents for the treatment of epilepsy, let alone divided along the lines of sympathetic versus parasympathetic neuromodulation therapy. In fact, such an interpretation would *defeat* the objectives of the Agreement, which were clearly to grant to BioNeuronics all rights in the Asserted Patents for use in the treatment of epilepsy.

Thus, the subject matter, objective, and circumstances surrounding the Agreement show DiLorenzo's license in the "Field of Use" clearly means "for sympathetic nervous system modulation therapy and for neuromodulation therapy" *both* "for treating obesity and other metabolic disorders."

2. The Subsequent Conduct and Course of Dealing Between the Parties to the Contract Support LivaNova's Position

LivaNova's position that "Field of Use" means "for sympathetic nervous system modulation therapy and for neuromodulation therapy" *both* "for treating obesity and other metabolic disorders" is also supported by a wealth of evidence following the execution of the Agreement. In particular, the Separation Agreement executed after the Agreement and the parties' later correspondence show that DiLorenzo knew it only had rights to the Asserted Patents in the limited Field of Use of treating obesity and metabolic disorders.

The Separation Agreement reiterates that the "actual or projected line of business activity of [BioNeuronics]" means "Inventions and Works that pertain to neurological monitors, neurological stimulators, monitoring and stimulation leads, and medical telemetry apparatus that may be used with neurological monitors and neurological stimulators to diagnose, monitor and/or manage neurological and physiological disorders, except for Inventions and Works "in the field of

autonomic modulation and neuromodulation for obesity and metabolism.” *Id.*, § 8.1. It also describes Dr. DiLorenzo’s “Field of Use” as “*treating obesity and other metabolic disorders.*” *Id.*, § 7.3. Again, there is no reference to DiLorenzo retaining any rights whatsoever relating to the treatment of epilepsy, much less any division of rights along the lines of sympathetic versus parasympathetic neuromodulation. On the contrary, the Separation Agreement again draws the line of the parties’ rights between the treatment of epilepsy and other physiological disorders, and the treatment of obesity and metabolism. The Separation Agreement further confirms LivaNova’s interpretation of the License Grant.

Dr. DiLorenzo also had significant correspondence with LivaNova and its predecessor-in-interest, Cyberonics, relating to parties’ rights in the Asserted Patents. All of this correspondence supports LivaNova’s interpretation of the License Grant, and none of it supports DiLorenzo’s.

On March 13, 2013, Dr. DiLorenzo sent Cyberonics follow-up correspondence in which Dr. DiLorenzo acknowledged that “the IP is divided along fields of use, mine being metabolism and autonomic structures (amygdala, hypothalamus, etc) and [NeuroBionics]/Cyberonics being in epilepsy and other areas.” Ex. J. Dr. DiLorenzo’s correspondence with Cyberonics confirms that Dr. DiLorenzo understood the fields of use to be divided along the lines of “metabolism and autonomic structures” and “epilepsy and other areas,” and that those rights did *not* cover Cyberonics’ vagus nerve stimulation devices, which treat epilepsy. This is consistent with the parties original agreements, and further confirms that the intent of those agreements was to divide the rights in the Asserted Patents between epilepsy treatment and the treatment of obesity and metabolic disorders.

Beginning in November 2020, Dr. DiLorenzo began contacting LivaNova with the goal of

[REDACTED]. Ex. L. On November

18, 2020, Dr. DiLorenzo's counsel, Stanley Gibson, sent correspondence to LivaNova stating Dr.

DiLorenzo [REDACTED]

Id. [REDACTED]

[REDACTED]. Ex. K, pg. 7, 8. Dr. DiLorenzo requested that LivaNova [REDACTED]

[REDACTED]. Ex. L. However, if LivaNova was not [REDACTED]

[REDACTED] *Id.* In other words, Dr. DiLorenzo **knew** that he did not have rights in the patents relating to the field of epilepsy treatment or the right to bring a patent infringement lawsuit without the consent of LivaNova.

Beginning in June 2022, Dr. DiLorenzo sent correspondence to LivaNova, requesting to purchase the NeuroBionics patents **from LivaNova** so that Dr. DiLorenzo could pursue [REDACTED]. Ex. M. On July 8, 2022, Dr. DiLorenzo offered [REDACTED] to purchase the patents formerly owned by NeuroBionics from LivaNova, with a [REDACTED] payment for the option to purchase. *Id.* After further discussion, Dr. DiLorenzo **agreed to increase his offer and pay LivaNova** [REDACTED] for the intellectual property with a [REDACTED] option lasting five years. Dr. DiLorenzo sent an Option Agreement summarizing these terms dated December 1, 2022. Ex. N. This reaffirms that Dr. DiLorenzo knew he did not have full rights in the Asserted Patents and was willing to pay LivaNova to secure those rights.

Finally, Dr. DiLorenzo's silence relating to any alleged infringement by LivaNova speaks volumes. As previously explained, the parties corresponded for years relating to Dr. DiLorenzo's limited rights in the Asserted Patents. *See generally* Ex. G; Ex. J; Ex. K; Ex. L and Ex. M. This

included colloquial correspondence regarding Cyberonics' business of epilepsy treatment, as well as more serious correspondence sent by Dr. DiLorenzo's attorney relating to his limited rights in the Asserted Patents and a request to pursue patent litigation against a third party. *Id.* Never, in over a decade of correspondence with LivaNova and its predecessors, did Dr. DiLorenzo suggest that he had rights in the field of epilepsy treatment (or even outside the field of treating obesity and metabolic disorders) or that LivaNova's products may infringe DiLorenzo's limited rights in the Asserted Patents. On the contrary, Dr. DiLorenzo's own statements show that (1) Dr. DiLorenzo understood he did not have rights in the Asserted Patents relating to the treatment of epilepsy and was therefore required to join LivaNova as a plaintiff in any patent infringement lawsuit relating to products that treat epilepsy; (2) the rights in the intellectual property were divided between "metabolism and autonomic structures" and "epilepsy and other areas," and (3) in order to obtain full rights in the Asserted Patents, he would have to purchase those rights from LivaNova. Only after Dr. DiLorenzo's attempt to purchase the Asserted Patents (and relatedly, [REDACTED]) fell through did Dr. DiLorenzo threaten (and ultimately file) litigation against LivaNova. Thus, the subsequent conduct and course of dealing between Dr. DiLorenzo and LivaNova shows that even Dr. DiLorenzo understands his recently formed interpretation of the License Grant is untenable.

3. The Reasonableness of LivaNova's Interpretation (and Unreasonableness of DiLorenzo's Interpretation) Support LivaNova's Position

Finally, the unreasonableness of DiLorenzo's interpretation of the License Grant supports LivaNova's position that DiLorenzo's Field of Use only relates to the treatment of obesity and metabolic disorders. *First*, DiLorenzo's interpretation of the License Grant in the Agreement would frustrate the intent of the Agreement, and all the agreements before it. Multiple clauses in each of the agreements explain that BioNeuronics' business related to the treatment of epilepsy

and that Dr. DiLorenzo was required to, and did, assign to BioNeuronics all rights in any inventions or intellectual property relating to BioNeuronics' business. If the objective of all of the agreements was to convey to BioNeuronics inventions and intellectual property for purposes of developing epilepsy treatments, why would BioNeuronics grant a license to DiLorenzo for that exact right?

Second, DiLorenzo's interpretation of the License Grant would read into the agreements a division of the intellectual property rights in epilepsy treatment between sympathetic nervous system neuromodulation therapy and parasympathetic nervous system neuromodulation therapy. Nowhere in any of the agreements do the parties discuss the sympathetic and parasympathetic systems, much less delineate between the two for purposes of dividing intellectual property rights. Every pertinent agreement states or reiterates that BioNeuronics' business was the treatment of epilepsy, not the treatment of epilepsy solely through neuromodulation of the parasympathetic nervous system.

As such, DiLorenzo knows and has known for nearly two decades that he does not have rights in the field of the treatment of epilepsy and does not have standing to bring this lawsuit.

V. CONCLUSION

As shown above, DiLorenzo lacks standing to bring this suit against LivaNova because DiLorenzo failed to join LivaNova as a plaintiff, as required by Supreme Court and Federal Circuit precedent. DiLorenzo further lacks standing to bring this suit because DiLorenzo does not have rights to the Asserted Patents in the field of epilepsy treatment. DiLorenzo's Complaint should be dismissed with prejudice.

Dated: October 16, 2023

Respectfully submitted,

FISH & RICHARDSON P.C.

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COUNSEL FOR DEFENDANTS,

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CERTIFICATE OF CONFERENCE

The undersigned hereby certifies that counsel for LivaNova, Benjamin Elacqua and Kathryn Quisenberry, met and conferred with counsel for DiLorenzo Biomedical LLC, David Liston, Ron Abramson, and Alex Patchen, met and conferred on October, 6 2023. Plaintiff indicated that it is opposed to this motion.

/s/ Benjamin C. Elacqua

Benjamin C. Elacqua

CERTIFICATE OF SERVICE


The undersigned attorney hereby certifies that on October 16, 2023, a true and correct copy of the foregoing document was served via electronic mail on all counsel of record.

/s/ Benjamin C. Elacqua

Benjamin C. Elacqua

EXHIBIT C

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

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

**DILORENZO BIOMEDICAL’S OPPOSITION TO
DEFENDANTS’ MOTION TO DISMISS PURSUANT TO
FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1) AND 12(b)(7)**

Table of Contents

INTRODUCTION	1
NATURE AND STAGE OF THE PROCEEDINGS	2
STATEMENT OF THE ISSUES TO BE RULED UPON BY THE COURT	2
SUMMARY OF THE ARGUMENT	2
BACKGROUND	3
A. Patent in suit	3
B. Relevant technical background.....	4
C. The exclusive license agreement between DBM and LivaNova’s predecessor-in-interest 4	
D. The ’880 patent.....	7
LEGAL STANDARDS	9
A. Motion to dismiss	9
B. Standing requirements for patent infringement claims	9
ARGUMENT	10
A. DBM does not need to join LivaNova as a party in order to sue it for infringement within the Field of Use.	10
1. DBM holds an exclusive license to the ’813 and ’787 patents within the Field of Use.....	10
2. An exclusive licensee has prudential standing to bring suit against the patentee. ..	10
B. DBM’s Field of Use is not limited to treating obesity and other metabolic disorders. ..	12
1. The plain grammatical reading of the Field of Use demonstrates the grant of two separate branches.....	12
2. LivaNova’s interpretation of the field of use would give no effect to the words “sympathetic nervous system modulation therapy.”	13
C. LivaNova fails to note the limitations of the “context rule.”	14
1. Determining intent must proceed from what was written.	15
a) Subject matter and objective of the agreement	15
b) Circumstances surrounding the making of the contract.....	16
c) Subsequent acts and conduct of the parties.....	17
d) Reasonableness of respective interpretations urged by the parties	20
D. DBM owns the ’880 patent.....	20
CONCLUSION.....	20

Table of Authorities

Cases

<i>Alnylam Pharms., Inc. v. Tekmira Pharms. Corp.</i> , No. 12-10087-RWZ, 2012 WL 4857580, (D. Mass. Sept. 24, 2012)	12
<i>Alps S., LLC v. Ohio Willow Wood Co.</i> , 787 F.3d 1379 (Fed. Cir. 2015)	11
<i>Berg v. Hudesman</i> , 801 P.2d 222 (Wash. 1990)	14
<i>Clark v. Tarrant County, Texas</i> , 798 F.2d 736 (5th Cir. 1986)	9
<i>Diamondback Indus., Inc. v. Repeat Precision, LLC</i> , No. 6:19-CV-00034-ADA, 2019 WL 8501017 (W.D. Tex. Sept. 11, 2019)	11
<i>Grey v. Leach</i> , 244 P.3d 970 (Wash. Ct. App. 2010)	13, 14
<i>Hearst Commc'ns, Inc. v. Seattle Times Co.</i> , 115 P.3d 262 (Wash. 2005)	14
<i>King v. Rice</i> , 191 P.3d 946 (Wash. Ct. App. 2008)	16
<i>Microsoft Corp. v. Motorola, Inc.</i> , 864 F. Supp. 2d 1023 (W.D. Wash. 2012)	14
<i>In re Sehome Park Care Ctr., Inc.</i> , 903 P.2d 443 (Wash. 1995)	12
<i>Waterman v. Mackenzie</i> , 138 U.S. 252 (1891)	10
<i>Wilhite v. Reg'l Employers' Assurance Leagues VEBA Tr.</i> , No. CV B-11-059, 2011 WL 13254064 (S.D. Tex. Nov. 15, 2011)	9

Rules

Fed. R. Civ. P. 12(b)(1)	9
Fed. R. Civ. P. 12(b)(7)	9

INTRODUCTION

Plaintiff DiLorenzo Biomedical, LLC (“DBM”) holds an exclusive license from a predecessor of Defendants LivaNova, Inc. and LivaNova USA, Inc. (together referred to as “LivaNova”) with respect to two of the three patents asserted in this case under an “Agreement” that LivaNova has identified as Ex. E.¹ LivaNova claims that because the exclusive license is limited to a specified field of use, it had to be joined as a co-plaintiff in order for a suit by the licensee to go forward. Under long-established precedent, however, this objection does not hold where, as here, the party accused of infringement is also the patent owner and is already present as a defendant and thus situated adequately to protect its own interests.

LivaNova also contests the scope of exclusivity, asserting that it does not cover the “sympathetic nervous system modulation therapy” that DBM sues about. DBM’s exclusive rights under the Agreement extend to a “Field of Use” “for sympathetic nervous system modulation therapy and for neuromodulation therapy for treating obesity and other metabolic disorders.” The Field of Use reads as comprising (i) sympathetic nervous system modulation therapy and (ii) neuromodulation therapy for treating obesity and other metabolic disorders. LivaNova erroneously asserts that the entire grant is nevertheless limited to “treating obesity and other metabolic disorders.” For this, it relies on (A) an earlier agreement to negotiate (as opposed to the words of the later agreement actually reached) and (B) extrinsic documents that LivaNova misreads, which are in fact contrary to LivaNova’s position. Moreover, further documents LivaNova did not submit, including the sequence of drafts of the Agreement itself, as well as other correspondence with LivaNova’s predecessors-in-interest, undercut LivaNova’s theories.

Furthermore, there is a *third* patent in the case, which is owned outright by DBM, as to

¹ References to Exs. A–N herein are to those Exs. A–N LivaNova attached to its Motion.

which LivaNova overlooks other material terms of the Agreement. In sum, this is not a meritorious dispositive motion.

NATURE AND STAGE OF THE PROCEEDINGS

DBM filed its Complaint for patent infringement (Dkt. No. 1) on May 17, 2023.

LivaNova filed its Motion to Dismiss (Dkt. No. 21) on October 16, 2023.

STATEMENT OF THE ISSUES TO BE RULED UPON BY THE COURT

1. Does DBM, as a licensee of two of the three patents-in-suit, lack standing to sue on those patents without having joined LivaNova as a co-plaintiff?

Response: No, DBM has both Art. III and prudential standing without the necessity to join LivaNova as a co-plaintiff.

2. Is DBM's exclusively granted Field of Use as to sympathetic nervous system modulation therapy limited only to treatment of obesity and other metabolic disorders?

Response: No, by ordinary grammatical and applicable contract interpretation principles, the words "for treating obesity and other metabolic disorders" do not limit the preceding grant provision, "for sympathetic nervous system modulation therapy." The extrinsic evidence only confirms this.

3. Is DBM the owner of the '880 patent?

Response: Yes. The '880 patent is owned of record by DBM, and DBM duly complied with any obligations it had to LivaNova's predecessor-in-interest that would otherwise have affected ownership of that patent.

SUMMARY OF THE ARGUMENT

DBM has both Art. III and prudential standing to sue LivaNova, for LivaNova's own infringement of the licensed patents within the scope of the exclusive license to DBM. Because it holds an exclusive license, DBM suffers actual injury from the conduct alleged, representing a justiciable case or controversy under Art. III. Because LivaNova's presence in the case as a defendant provides an adequate basis for LivaNova to protect its own interests in the matter, and because LivaNova cannot sue itself, DBM has prudential standing as well.

It is clear from the grant language itself that DBM's Field of Use of sympathetic nervous system modulation therapy is not limited to treating obesity and other metabolic disorders. LivaNova fails to cite objective evidence concerning the formation of the Agreement that establishes a contrary intent, or evidence confirming any later understanding to the contrary.

Moreover, to the extent extrinsic evidence is considered, there is also substantial written evidence, which LivaNova fails to address, reflecting that DBM specifically brought to LivaNova's predecessor's attention that DBM was applying for and intended to own patents with claims concerning sympathetic nervous system modulation, solicited the predecessor's views with regard to these being within DBM's Field of Use, and that the predecessor confirmed it would consider the issue, and raised no objection. This record is completely inconsistent with LivaNova's theories herein.

DBM further has standing to bring claims of infringement of the '880 patent against LivaNova because DBM is the owner of the '880 patent. There were contractual provisions obligating its principal, Dr. Daniel J. DiLorenzo, to disclose such inventions to NeuroBionics Corporation ("NeuroBionics," which was later renamed BioNeuronics Corporation ("BioNeuronics")), with which he complied. He also notified BioNeuronics of his patent applications within the Field of Use, disclosing the applications themselves, and carried the cost of patent prosecution and maintenance—leaving no basis for LivaNova years later to claim any ownership interest whatsoever in the '880 patent.

BACKGROUND

A. Patents-in-suit

DBM is the exclusive licensee of U.S. Pat. Nos. 6,366,813 (the "'813 patent") and 7,209,787 (the "'787 patent") under an exclusive license granted by LivaNova's predecessor-in-interest. DBM owns of the third patent in suit, U.S. Pat. No. 9,345,880 (the "'880 patent").

B. Relevant technical background

The patents-in-suit relate generally to neuromodulation, which is the delivery of a stimulus to the nervous system.² The relevant hierarchy of the nervous system is that it comprises the central nervous system (brain, spinal cord) and the peripheral nervous system. *See Organization of the Nervous System*, NAT'L CANCER INST., <https://training.seer.cancer.gov/anatomy/nervous/organization/> (Abramson Decl., Ex. 2). The peripheral nervous system subdivided into an afferent (sensory) division and an efferent (motor) division. *Id.* The efferent (motor) division is again subdivided into the somatic nervous system and the autonomic nervous system. *Id.* The autonomic nervous system is further subdivided into the sympathetic nervous system and the parasympathetic nervous system. *Id.*

C. The exclusive license agreement between DBM and LivaNova's predecessor-in-interest

On June 25, 1999, Dr. DiLorenzo filed a patent application relating to closed-loop neuromodulation, which issued as the '813 patent.³ Dkt. No. 1-1 at 1. On November 20, 2003, he filed a further application claiming priority to the '813 patent, which issued as the '787 patent. Dkt. No. 1-2 at 1.

LivaNova's interests involve a succession of entities beginning with NeuroBionics, which LivaNova ultimately acquired. Dr. DiLorenzo founded NeuroBionics in November 2002 and later executed a Founder Agreement, dated March 31, 2004 (Ex. A).⁴ Dr. DiLorenzo assigned a set of patents, including the '813 patent and later patent applications claiming priority thereto

² *See* <https://www.neuromodulation.com/neuromodulation-defined> (attached as Ex. 1 to the Declaration of Ronald Abramson, dated November 6, 2023 ("Abramson Decl.")).

³ In its Motion, LivaNova incorrectly refers to the '813 patent family as "relating to epilepsy treatment." Mot. at 14. The scope of the patents' claims is by no means so limited.

⁴ *See* Declaration of Daniel J. DiLorenzo ¶ 2, dated November 6, 2023 ("DiLorenzo Decl.").

(the “Licensed Patents”) to NeuroBionics. Ex. A ¶ 2(a), Schedule I. The Founder Agreement provided that Dr. DiLorenzo would execute a “Non-Disclosure and Developments Agreement,” in a form attached. *Id.* ¶ 14 (emphasis in original). That agreement excluded certain developments from the obligation to assign, including those relating to “Autonomic Modulation and Neuromodulation for Obesity & Metabolism.”⁵ Ex. A, Schedule III ¶ 4(b), Appendix.

On December 14, 2004, in connection with [REDACTED], Dr. DiLorenzo and NeuroBionics amended the Founder Agreement (Ex. B) and executed a formal assignment agreement (Ex. C). Around this time, the parties were also negotiating what rights in the Licensed Patents that Dr. DiLorenzo would retain. DiLorenzo Decl. ¶ 2. However, because the parties were unable to resolve these issues by the time of the execution of the December 14, 2004 documents, the parties memorialized an intent to “use best efforts” to come to terms in the future. *See* Agreement at 2; Ex. C at 1.

A draft of a license agreement, dated January 25, 2005 (DiLorenzo Decl., Ex. 1), incorporated an exclusive license of the Licensed Patents by NeuroBionics in favor of Dr. DiLorenzo’s newly formed company, DBM,⁶ which would have been limited to a Field of Use defined as:

Neuromodulation for Obesity and Metabolism and Modulation of the
Sympathetic [sic] Nervous System

Id. ¶ 3, Ex. 1 at 1 (emphasis added). This definition shows that the Field of Use would have two separate and distinct branches: (1) neuromodulation for obesity and metabolism and (2)

⁵ This exclusion was later incorporated into the Proprietary Information, Inventions Agreement and Noncompete Agreement executed on February 8, 2005. *See* Ex. D ¶ 4(c).

⁶ There have been two companies named DiLorenzo Biomedical, LLC. The first, formed April 24, 2005, was administratively dissolved on September 2, 2014. Its property was assigned in dissolution to Dr. DiLorenzo who assigned such property on March 23, 2021 to the second so-named corporation formed March 3, 2021 (Plaintiff herein).

modulation of the sympathetic nervous system.

A later draft from on or around March 2005 (*id.*, Ex. 2) shows that the parties had made significant changes to the definition of the Field of Use. In particular, this draft shows Dr. DiLorenzo's edits to the definition in tracked changes. The definition of the Field of Use prior to Dr. DiLorenzo's edits is shown below:

devices and methods for neuromodulation therapy and sympathetic nervous system modulation therapy for treating obesity and other metabolism disorders

Id. at 1. This definition appears to have jumbled the words of the prior draft. The "obesity" modifier no longer followed "neuromodulation" but rather "sympathetic nervous system modulation [therapy]."

Dr. DiLorenzo's edits to the Field of Use are shown in tracked changes below:

devices and methods for sympathetic nervous system modulation therapy and
for neuromodulation therapy ~~and sympathetic nervous system modulation therapy~~
for treating obesity and other metabolic disorders

Id. This revision corrected the error in the previous version and associated the broader "neuromodulation therapy" with the "obesity" modifier. *Id.* ¶ 5. Further, in order to avoid any confusion that "sympathetic nervous system modulation therapy" would also be modified by the "obesity" phrase, Dr. DiLorenzo inserted an additional "for" so that both branches of the Field of Use were parallel in their introduction by the word "for." *Id.*

Dr. DiLorenzo's changes were incorporated into the final Agreement, which was executed on May 23, 2005 by DBM and NeuroBionics (by then, BioNeuronics). Agreement ¶ 4. Under the Agreement (and in accordance with Dr. DiLorenzo's edits referenced above), BioNeuronics granted DBM a "perpetual, fully paid up, worldwide, exclusive license" to the Licensed Patents (with rights to sublicense) in a field of use comprising,

devices and methods for sympathetic nervous system modulation therapy and
for neuromodulation therapy for treating obesity and other metabolic disorders

Agreement ¶ 4 (the “Field of Use”).

The Agreement further addressed new IP in the Field of Use. Under a series of agreements going back to March 2004, Dr. DiLorenzo was obligated to disclose his inventions to the company. When the Agreement was later executed on May 23, 2005, ¶ 6 thereof provided that DBM would solely own any future patent application “claim[ing] priority to one of more of the Licensed Patents and claim[ing] exclusively an invention within the [Exclusive] Field of Use.” *Id.* ¶ 6. This provision further stated that “[DBM] shall be responsible for all costs of filing and prosecution of the patent application and subsequent maintenance of the patent issuing from such patent application.” *Id.*

DBM and BioNeuronics further included in the Agreement the procedure by which they could sue for infringement of the Licensed Patents by third parties. *Id.* ¶ 10. This provision addresses events where (1) both DBM and BioNeuronics wanted to sue, (2) the parties did not agree but BioNeuronics wanted to sue, or (3) (absent either of the foregoing) DBM nevertheless wanted to sue the third party, in which case it could institute the suit, including, if required “for standing purposes,” joining BioNeuronics as a party (*id.*).

D. The ’880 patent

On January 17, 2006, DBM filed a patent application, entitled “Closed-loop feedback-driven sympathetic neuromodulation for affect control,” that issued as the ’880 patent. Dkt. No. 1-3 at 1. This application claimed priority to the ’813 and ’787 patents. *Id.* The claims in the application related exclusively to an invention within the Field of Use, under ¶ 6 of the Agreement, concerning sympathetic nervous system modulation therapy. *See, e.g.*, Dkt. No. 1-3 at claim 56 (“A system for *neural modulation of the sympathetic nervous system*”). The application’s internal docket number was “ANSTIM 01.02,” in which “ANSTIM” stood for “Autonomic Nervous System Stimulation.” DiLorenzo Decl. ¶ 7. Dr. DiLorenzo filed this

application himself, whereas other applications listing him as an inventor were filed by counsel for BioNeuronics. *Id.* DBM paid for the preparation and prosecution of this application and the maintenance of the '880 patent. *Id.* ¶ 8. BioNeuronics made no payment related to the '880 patent. *Id.*

Because the claims in the application pertained to DBM's Exclusive Field of Use, ownership thereof would be DBM's. *See* Agreement ¶ 6. As such, per the Agreement, DBM would be responsible for costs of filing and prosecuting the patents and subsequent patent maintenance, and in fact DBM carried those payments. DiLorenzo Decl. ¶ 8.

Dr. DiLorenzo duly gave John Harris, CEO of BioNeuronics, written notice of the application that issued as the '880 patent, along with several other of his applications, on or around April 21, 2006. *Id.* ¶ 10. Dr. DiLorenzo expressed the position that the applications disclosed therein were owned by DBM pursuant to ¶ 6 of the Agreement. *Id.* Dr. DiLorenzo further asked Mr. Harris to confirm that these applications were properly within DBM's ownership. *Id.*

In a letter dated May 25, 2006, Mr. Harris responded to Dr. DiLorenzo's written notice. DiLorenzo Decl., Ex. 4. Mr. Harris stated therein that BioNeuronics was "[REDACTED]

[REDACTED]" DiLorenzo Decl., Ex. 4 at 1. However, because the applications were still pending, Mr. Harris expressed that they would defer determining "[REDACTED]

[REDACTED]" until the patents issued. DiLorenzo Decl., Ex. 4 at 2. Mr. Harris stated, "[REDACTED]

[REDACTED]" *Id.* At no time after this letter did

BioNeuronics (or any of its successors-in-interest) contact Dr. DiLorenzo to transfer or change record ownership of the '880 patent. Nor can he recall any instance, at any time prior to LivaNova's responding to this lawsuit (seven years after the '880 patent issued), in which LivaNova or its predecessors brought to his attention any suggestion that this should be done. *Id.*

LEGAL STANDARDS

A. Motion to dismiss

A Rule 12(b)(1) motion may be based on: (1) the complaint alone; (2) the complaint supplemented by undisputed facts of record; or (3) the complaint supplemented by undisputed facts and the court's resolution of disputed facts. *Clark v. Tarrant County, Texas*, 798 F.2d 736, 741 (5th Cir. 1986). However, the Court need not look beyond the complaint or resolve disputed facts unless it chooses to do so.⁷

Where the jurisdictional facts are intertwined with the merits, such as where “where the statute provides both the basis of federal court subject matter jurisdiction and the cause of action” (*id.* at 742), “the case should not be dismissed for lack of subject matter jurisdiction unless the alleged claim is immaterial or is wholly insubstantial and frivolous.” *Id.* at 741–42. Moreover, in this case, LivaNova has not authenticated any of its exhibits, raising a question as to whether the Court should even consider them.⁸

B. Standing requirements for patent infringement claims

The requirements for an exclusive patent licensee to bring a suit for infringement were

⁷ LivaNova also moves under Rule 12(b)(7). LivaNova's only argument as to this ground is that it follows from its assertions regarding Rule 12(b)(1) that DBM has also failed to join an indispensable party under Rule 12(b)(7).

⁸ *See, e.g., Wilhite v. Reg'l Employers' Assurance Leagues VEBA Tr.*, No. CV B-11-059, 2011 WL 13254064, at *4–5 (S.D. Tex. Nov. 15, 2011) (Hanen, J.) (denying motion to dismiss based in part on Rule 12(b)(1) where movant relied on documents that had “not been authenticated or proven up”).

broadly set out by the Supreme Court in *Waterman v. Mackenzie*, 138 U.S. 252 (1891), addressed in detail below. *Waterman* holds that an exclusive licensee of less than the entire interest in a patent must ordinarily join the patentee as a co-plaintiff—but that an exception exists where (as here) it is the patentee itself that is accused of infringement. 138 U.S. at 255.

ARGUMENT

A. **DBM does not need to join LivaNova as a party in order to sue it for infringement within the Field of Use.**

Under a long-held exception recognized in *Waterman*, an exclusive licensee that does not have all substantial rights *does* have standing to sue in its own name when “necessary to prevent an absolute failure of justice, as where the patentee is the infringer, and cannot sue himself.” *Waterman*, 138 U.S. at 255. The present case falls squarely within this exception.

1. DBM holds an exclusive license to the '813 and '787 patents within the Field of Use.

Paragraph 4 of the Agreement expressly conveys to DBM exclusive rights with respect to the '813 and '787 patents in the specified Field of Use. LivaNova points to the mere fact that the licensed Field of Use covers less than the entire interest, which is clearly acknowledged in the Complaint. Notably, however, LivaNova does *not* dispute that the grant nevertheless constitutes as “exclusive” license within the specified field.

2. An exclusive licensee has prudential standing to bring suit against the patentee.

LivaNova argues “a substantial risk of multiple suits and multiple liabilities against an alleged infringer for a single act of infringement” (Mot. at 10–11, citing *Alps S., LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1383–84 (Fed. Cir. 2015)), which goes to what is referred to as “prudential standing.” The entire answer to this contention is that, unlike the defendant in *Alps*, which was a third-party infringer, LivaNova is the patent owner and is already in this case as a defendant, and as such can adequately represent its own interests herein.

In a more recent case, a court faced an argument similar to that made by LivaNova (*see* Mot. at 11–12) that the exclusive licensee lacked “substantial rights” and thus lacked standing without joining the patent owner. *Diamondback Indus., Inc. v. Repeat Precision, LLC*, No. 6:19-CV-00034-ADA, 2019 WL 8501017, at *4 (W.D. Tex. Sept. 11, 2019). The court noted both the general rule and exception articulated above and found that the case fell “squarely into that exception [because] the exclusive licensee in this case ... is suing the patentee ... for infringement of the [licensed] Patent, which is exactly the situation covered by the exception to the prudential standing requirement.” *Id.*

LivaNova’s argument that DBM is “merely a licensee in a Field of Use” (*see, e.g.*, Mot. at 2, 9) and thus was required to join LivaNova is unavailing because LivaNova is not a third party but rather the patentee and is already the defendant in this case. For example, in the *Alps* case, the Federal Circuit held that “our standing jurisprudence required that [plaintiff] Alps join the patent owner, AEI, as a co-plaintiff” in order to have standing to sue defendant and third party Ohio Willow Wood. *Alps S., LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1386 (Fed. Cir. 2015). In so holding, the court cited reasoning from its own precedent that “finding that a field of use licensee has standing to sue in its own name alone poses a substantial risk of multiple suits and multiple liabilities against an alleged infringer for a single act of infringement.” *Id.* at 1384 (internal quotations and citations omitted). Here, this rationale does not apply. Because the “alleged infringer” in this case is LivaNova, the patent owner, there is no “substantial risk of multiple suits and multiple liabilities.”

Remarkably, the Motion (at 12) actually *references* the well-established exception stated in *Waterman* but seeks to avoid it with a supposed *further* requirement that in addition to providing exclusive rights, the license grant itself must expressly recite a right to sue. LivaNova

points to no authority for such a further requirement, and no such further requirement exists. *See Alnylam Pharms., Inc. v. Tekmira Pharms. Corp.*, No. 12-10087-RWZ, 2012 WL 4857580, at *2 (D. Mass. Sept. 24, 2012) (finding explicit grant to an exclusive licensee within a field of use the right to sue third parties did not implicitly deny it the right to sue the patent owner). LivaNova also relies on ¶ 10 of the Agreement, which concerns infringements by third parties but is irrelevant because LivaNova is not a third party.

B. DBM's Field of Use is not limited to treating obesity and other metabolic disorders.

1. The plain grammatical reading of the Field of Use demonstrates the grant of two separate branches.

LivaNova bases most of its motion on the interpretation that Plaintiff's exclusive Field of Use is limited to obesity and metabolic disorders. This is simply fallacious. From a grammatical perspective, the Field of Use separately recites two distinct branches:

devices and methods *for* sympathetic nervous system modulation therapy and
for neuromodulation therapy for treating obesity and other metabolic disorders

Agreement ¶ 4 (emphasis added). “For” is used in the Field of Use “as a function word to indicate purpose.”⁹ The Field of Use recites a first purpose for the recited “devices and methods,” followed by a second and distinct purpose, both introduced with a “for” and separated by an “and.”

LivaNova argues that the phrase “for treating obesity and other metabolic disorders” modifies *both* “sympathetic nervous system modulation therapy” *and* “neuromodulation therapy.” *See, e.g.*, Mot. at 13. However, such an interpretation violates the last antecedent rule applied in Washington, which instructs that “qualifying word and phrases refer to the last

⁹ *See For Definition & Meaning*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/for> (Abramson Decl., Ex. 3).

antecedent.” *See, e.g., In re Sehome Park Care Ctr., Inc.*, 903 P.2d 443, 447 (Wash. 1995). If the parties to the Agreement had indeed intended the qualifying phrase “for treating obesity and other metabolic disorders” to apply to **both** “sympathetic nervous system modulation therapy” **and** “neuromodulation therapy,” they would have inserted a comma before said qualifying phrase (*i.e.*, an inserted comma before “for treating obesity ...”). *See id.* (“[T]he presence of a comma before the qualifying phrase is evidence the qualifier is intended to apply to all antecedents instead of only the immediately preceding one.” (citation omitted)).

2. LivaNova’s interpretation of the Field of Use would give no effect to the words “sympathetic nervous system modulation therapy.”

Washington courts require “giv[ing] lawful effect to all the provisions in a contract,” rather than “render[ing] some of the language meaningless or ineffective.” *Grey v. Leach*, 244 P.3d 970, 976 (Wash. Ct. App. 2010). LivaNova’s interpretation of the Field of Use would render the words “sympathetic nervous system modulation therapy” therein ineffective.

As described above, neuromodulation generally means any stimulation of the nervous system. *See supra* p. 4. The nervous system includes the peripheral nervous system, which includes the autonomic nervous system, which in turn includes the sympathetic nervous system. *Id.* Thus, just as the sympathetic nervous system is subsumed by the nervous system, “sympathetic nervous system modulation therapy” is entirely subsumed by “neuromodulation therapy.”

LivaNova’s interpretation is that **both** “sympathetic nervous system modulation therapy” **and** “neuromodulation therapy” are limited by the words “for treating obesity and other metabolic disorders.” However, because “sympathetic nervous system modulation therapy” is a subset of “neuromodulation therapy” and wholly subsumed thereby, the words “sympathetic nervous system modulation therapy” would add nothing to what the grant would cover without

those words. LivaNova's interpretation would thus render those ineffective. Such a reading is contrary to Washington canons of contract interpretation and thus should be rejected.

C. LivaNova fails to note the limitations of the “context rule.”

LivaNova invokes the “context rule” under Washington law (Mot. at 13), citing *Microsoft Corp. v. Motorola, Inc.*, 864 F. Supp. 2d 1023 (W.D. Wash. 2012), which in turn relied on *Berg v. Hudesman*, 801 P.2d 222 (Wash. 1990). The Court should be aware, however, that in 2005, the Supreme Court of Washington, sitting *en banc*, addressed “confusion over the implications of *Berg* [and the context rule].” *Hearst Communications, Inc. v. Seattle Times Co.*, 15 P.3d 262, 266 (Wash. 2005) (*en banc*). Some courts in Washington had initially viewed *Berg* as “authorizing unrestricted use of extrinsic evidence in contract analysis.” *Id.* Rather, the *Hearst* court clarified that “surrounding circumstances and other extrinsic evidence are to be used to determine the meaning of *specific words and terms used* and not to show an intention independent of the instrument or to vary, contradict or modify the written word.” *Id.* at 267 (emphasis in original) (internal quotations and citation omitted).

Acknowledging that “[its] holding in *Berg* may have been misunderstood as it implicates the admission of parol and extrinsic evidence,” the *Hearst* court stated:

We take this opportunity to acknowledge that Washington continues to follow the objective manifestation theory of contracts. Under this approach, we attempt to determine the parties’ intent by ***focusing on the objective manifestations of the agreement***, rather than on the unexpressed subjective intent of the parties.

Id. (emphasis added) (citation omitted). “Thus, when interpreting contracts, the subjective intent of the parties is generally irrelevant if the intent can be determined from the actual words used.” *Hearst*, 115 P.3d at 267. Washington courts must also “giv[e] lawful effect to all the provisions in a contract,” rather than “render[ing] some of the language meaningless or ineffective.” *Grey*, 244 P.3d at 976. “***We do not interpret what was intended to be written but what was written.***”

Hearst, 115 P.3d at 267 (emphasis added).

1. Determining intent must proceed from what was written.

a) *Subject matter and objective of the agreement*

The first factor of the context rule under *Berg* and *Hearst* concerns “the subject matter and objective of the contract.” No one can dispute that the subject matter was of course a grant back of some of the rights that Dr. DiLorenzo had transferred to NeuroBionics months earlier. With regard to “objective,” LivaNova proposes the wrong approach, focusing on how it now characterizes the alleged future needs of NeuroBionics’ business,¹⁰ rather than what the Agreement expressly recites. As to the latter, the recital (at page 2 of the Agreement) lays out only what an *earlier agreement* said (the Ex. C Assignment, dated December 14, 2004), which was that “By January 31, 2005, or as soon as practicable thereafter, the Company and the undersigned [Dr. DiLorenzo] will use their best efforts” to negotiate a license back of the assigned IP, which broadly related to “neurodiagnostics and neuromodulation” generally. The 2004 Assignment (Ex. C) contemplated that this negotiation would relate to a license back for “obesity and metabolism”—words that LivaNova now seizes upon as controlling for all time. However, akin to a letter of intent, the LOI does not control the scope of the final agreement actually reached, certainly not to the point of changing how one would construe the final agreed written terms, where ordinary rules of construction render the final terms unambiguous.

LivaNova’s brief also fails to mention that the Agreement contains an integration clause (§ 17), stating that it (and not any earlier agreement) represents the “final” agreement on the subject matter. Washington courts have cautioned that, where a contract contains an integration

¹⁰ See Mot. at 17 (“[T]he intent of those agreements was to divide the rights in the Asserted Patents between epilepsy treatment and the treatment of obesity and metabolic disorders.”).

clause, extrinsic evidence may only be used “to explain undefined contract terms, not to modify, vary, or contradict terms of the written contract.” *King v. Rice*, 191 P.3d 946, 951 (Wash. Ct. App. 2008) (emphasis added).

LivaNova’s arguments regarding Exs. A–D (Mot. at 15) largely relate to Dr. DiLorenzo’s obligation to assign the ’813 and ’787 patents to BioNeuronics. There is no question that Dr. DiLorenzo did so. LivaNova’s remaining argument regarding certain inventions Dr. DiLorenzo “carve[d] out” relating to “Autonomic Modulation and Neuromodulation for Obesity & Metabolism” (*id.*) only serves as another example of LivaNova’s revisionism. LivaNova’s selective emphasis on the phrase “Obesity & Metabolism” again ignores that autonomic modulation is a subset of neuromodulation. *See supra* at p. 4. Therefore “Obesity & Metabolism” cannot modify both “Autonomic Modulation” and “Neuromodulation” without rendering the former without effect.

b) Circumstances surrounding the making of the contract

Dr. DiLorenzo’s accompanying declaration addresses the ***actual relevant context*** of the disputed license grant, which is that it arose in the wake of [REDACTED] in December 2004. That deal left the parties with a mutually acknowledged gap in their agreements reached at the time, as to the grant-back of patent rights, which was left to “best efforts” to reach a future agreement. This mere expression of intent to negotiate a future agreement did not dictate the terms of the future agreement itself, reached five months later. The provisions memorializing the parties’ intent to negotiate cannot be used to override the terms of the written agreement that was ultimately reached as a result of the negotiation. And negotiate they did, as reflected in the series of drafts reviewed above. The revisions reflected in the drafts leave no doubt that “sympathetic nervous system modulation therapy” was specifically intended to be a distinct part of the license grant. The parties were free to negotiate in good faith, and

where that negotiation landed is best understood by the words they finally agreed to as a result, as made even more clear in this case by the course of drafting.

c) Subsequent acts and conduct of the parties

LivaNova again turns to extrinsic documents. Washington law allows such consultation within the limitations of *Hearst*. But the extrinsic documents that LivaNova cites do not at all support its position, and furthermore, there are additional documents that LivaNova fails to mention, which are flatly inconsistent with its position.

LivaNova raises Sec. 7.3 of the Separation Agreement (Ex. F). That provision, however, does **not** in fact address the scope of the exclusive license grant under Sec. 4 of the Agreement (Ex. E). Rather, it addresses the scope of a **different** license, a license from Dr. DiLorenzo to NeuroBionics in connection with the Inventions Agreement (Ex. D), as to which the parties agreed (in the Separation Agreement) to **import** terms used in Sec. 4 of the Agreement to govern the exclusive license under that provision **to** Dr. DiLorenzo. The language from Ex. F that LivaNova relies on serves merely to **identify** the un-numbered clause within Sec. 4 of Ex. E to be used as the source for the terms to be imported, **not to define or redefine** the substance of the source clause itself (and indeed so as to *avoid* doing so). The mere words chosen only **to identify** provisions to be adapted from a different agreement cannot be taken as defining the substantive scope of the full clause to be imported.

LivaNova also argues NeuroBionics' "actual or projected line of business activity" recited in Ex. F (Mot. at 16), again as to a different agreement (Ex. D), but Dr. DiLorenzo had **already assigned** the '813 and '787 patents to NeuroBionics.

LivaNova quotes from a March 13, 2013 email, in which Dr. DiLorenzo states that "the

ownership of ¹¹ the IP is divided along fields of use, mine being metabolism and autonomic structures (amygdala, hypothalamus, etc.) and NeuroVista [a new corporate name for BioNeuronics]/Cyberonics [sic] being in epilepsy and other areas.” Ex. J at 2. Yet again, LivaNova glosses over “autonomic structures,” which plainly reference Dr. DiLorenzo’s ownership of his inventions in “Autonomic Modulation and Neuromodulation for Obesity & Metabolism.” *See, e.g.*, Ex. A, Schedule III, Appendix.

LivaNova then turns to correspondence (Exs. K–N) about ways to commercialize Dr. DiLorenzo’s inventions, including by pursuing patent infringement litigations against a third-party infringer “in the field of epilepsy treatment.” Mot. at 17–18. LivaNova argues that “Dr. DiLorenzo *knew* that he did not have rights in the patents relating to the field of epilepsy treatment.” *Id.* at 18 (emphasis in original). But no one has asserted that Dr. DiLorenzo’s exclusive rights cover any and all epilepsy treatment. Rather, DBM’s exclusive rights in the ’813 and ’787 patents extend to sympathetic nervous system modulation therapy, whether used to treat epilepsy or otherwise.

Additionally, Dr. DiLorenzo’s correspondence with Cyberonics demonstrates that Cyberonics understood that DBM’s Field of Use was not limited to treating obesity and other metabolic disorders. On August 21, 2013, Dr. DiLorenzo emailed David Wise, who LivaNova identified as “the then-General Counsel of Cyberonics” regarding [REDACTED] [REDACTED] Ex. K at 9–12; Mot. at 7. In response, Mr. Wise asked whether Dr. DiLorenzo was “referring to [REDACTED] that pertain to the obesity / metabolic disorder indication.” Ex. K at 9. Dr. DiLorenzo responded, “[REDACTED]

¹¹ LivaNova’s quotation (Mot. at 17) omits this these three words addressing “ownership,” trying to represent the email as addressing the scope of a license.

_____.” *Id.* (emphasis added). Rather than correcting Dr. DiLorenzo that autonomic modulation (in particular, sympathetic modulation) was not within Dr. DiLorenzo’s Field of Use, Mr. Wise agreed that it, together with the “_____,” made up the Field of Use (*id.* at 8):

Exs. M and N, relating to Dr. DiLorenzo's [REDACTED]
[REDACTED], reflects nothing more than the fact that LivaNova would not agree to join as a plaintiff
in an infringement suit against a third party.¹²

LivaNova argues that “Dr. DiLorenzo’s silence relating to any alleged infringement by LivaNova” shows he did not believe he had rights “outside the field of treating obesity and metabolic disorders.” Mot. at 18–19. Dr. DiLorenzo repeatedly stated that his rights were ***not*** so limited, *e.g.*, directly claiming ownership in the ’880 patent, overtly claiming sympathetic nervous system modulation therapy (DiLorenzo Decl. ¶ 10); Ex. J at 2 (“[REDACTED] [REDACTED]”) (emphasis added)); Ex. K at 8 (Dr. DiLorenzo’s Field of Use included “[REDACTED],” not just “[REDACTED]”). DBM had not pursued a claim of patent infringement against LivaNova until now because it had hoped to find

¹² In its Motion, LivaNova references the statement in the draft Option Agreement that “[LivaNova] has not itself ever made, offered for sale, or sold any patented articles covered by the [patents] in the United States, nor imported any patented article covered by the [patents] into the United States.” Mot. at 8 (quoting Ex. N ¶ 4(c)). This representation does not reflect DBM’s subsequent allegations of infringement against LivaNova. In any event, the option agreement was not executed by either party.

a way to collaborate with LivaNova, as well documented in LivaNova's exhibits.

d) Reasonableness of respective interpretations urged by the parties

As addressed *supra* at pp. 12–13, DBM's interpretation aligns with an interpretation in accordance with ordinary rules of grammar, whereas LivaNova's interpretation fails to give effect to the words "sympathetic nervous system modulation therapy."¹³

D. DBM owns the '880 patent.

As described *supra* at pp. 7–9, pursuant to ¶ 6 of the Agreement, DBM is the owner of the '880 patent. It claims priority to the Licensed Patents, and all of its claims are for "sympathetic nervous system modulation therapy" and within the Field of Use. DBM's ownership is further evidenced by its payment for the prosecution and the maintenance.

DBM did what the parties' agreements required and duly notified LivaNova's predecessor-in-interest in writing of the filing of the '880 patent. DiLorenzo Decl. ¶ 7. DBM, and not BioNeuronics, paid for the preparation and prosecution of the application and the maintenance of the '880 patent. *Id.* ¶¶ 7–8. As expressed above, while it initially expressed "concerns" about the scope of some of Dr. DiLorenzo's pending claims, BioNeuronics has never contacted DBM to transfer or change record ownership of the '880 patent, or, at any time prior to responding to this lawsuit in 2023, express that this should be done. *Id.* ¶ 11. The '880 patent belongs to DBM. This Court cannot rule otherwise on a motion to dismiss, certainly not on the present record.

CONCLUSION

For the foregoing reasons, LivaNova's Motion should be denied.

¹³ LivaNova did not address the remaining "context" factors identified in Washington decisions.

Dated: November 6, 2023

Respectfully submitted,

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EXHIBIT D

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

DILORENZO BIOMEDICAL, LLC,

Plaintiffs,

v.

LIVANOVA, INC. and LIVANOVA USA,
INC.,

Defendants.

Civil Action No. 4:23-cv-1800

Patent Case
Jury Trial Demanded



**DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS
PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1) AND 12(b)(7)**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	ARGUMENT	2
A.	The Court Should Dismiss DiLorenzo’s Complaint for Lack of Standing Because DiLorenzo Is Not an Exclusive Licensee with the Right to Sue Absent LivaNova’s Consent	2
B.	The Court Should Dismiss DiLorenzo’s Complaint for Lack of Standing Because DiLorenzo Has No Ownership Rights Outside His “Field of Use,” Which Does Not Include Epilepsy Treatment	4
1.	DiLorenzo’s Newly Produced “Evidence” Does Not Negate Nearly Twenty Years of Conduct Demonstrating DiLorenzo’s Intent to Only Retain a License for the Treatment of Obesity and Metabolic Disorders	4
2.	The Plain Language of the Agreement Confirms DiLorenzo’s Intent; DiLorenzo’s Ignores It	8
3.	The Court Should Ignore DiLorenzo’s Self-Serving Declaration and Questionable Exhibits	9
C.	The ’880 Patent Is Owned by LivaNova, Despite That DiLorenzo Failed to Execute an Assignment to LivaNova	12
III.	CONCLUSION	13

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>A123 Sys., Inc. v. Hydro-Quebec</i> , 626 F.3d 1213 (Fed. Cir. 2010).....	2
<i>Alnylam Pharms., Inc. v. Tekmira Pharms. Corp.</i> , No. 12-10087-RWZ, 2012 WL 4857580 (D. Mass. Sept. 24, 2012).....	3, 4
<i>Central Flyway Air, Inc. v. Grey Ghost Int’l, LLC</i> , No. 3:20-CV-05506-BJR, 2022 WL 4534402 (W.D. Wa. Sept. 28, 2022).....	10
<i>Diamondback Indus., Inc. v. Repeat Precision, LLC</i> , No. 6:19-CV-00034-ADA, 2019 WL 8501017 (W.D. Tex. Sept. 11, 2019)	3
<i>F.T.C. v. Publ’g Clearing House, Inc.</i> , 104 F.3d 1168 (9th Cir. 1997), <i>as amended</i> (Apr. 11, 1997).....	10
<i>Hubacek v. Ennis State Bank</i> , 317 S.W.2d 30 (Tex. 1958).....	5
<i>King v. Rice</i> , 191 P.3d 946 (Wash. Ct. App. 2008).....	5, 6
<i>Lone Star Silicon Innovations LLC v. Nanya Tech. Corp.</i> , 925 F.3d 1225 (Fed. Cir. 2019).....	2, 3
<i>Matter of Marriage of Cardwell</i> , 479 P.3d 1188 (Ct. App. Wa. 2021)	9
<i>Textile Productions, Inc. v. Mead Corp.</i> , 134 F. 3d 1481 (Fed. Cir. 1998).....	3
Other Authorities	
37 C.F.R. § 3.54.....	12
Fed. R. Civ. P. 19.....	3

TABLE OF EXHIBITS

Exhibit	Description
O	May 26, 2023 Correspondence from Carlson Caspers to Liston Abramson
P	September 14, 2023 Correspondence from Fish & Richardson to Liston Abramson
Q	November 6-November 8, 2023 Correspondence between Fish & Richardson and Liston Abramson

I. INTRODUCTION

DiLorenzo's response to LivaNova's Motion to Dismiss fails to address key issues with its Complaint. *First*, DiLorenzo admits it was required to seek LivaNova's consent to initiate a patent infringement suit. Resp. at 18-19. This confirms DiLorenzo understood what the license granted: a license to DiLorenzo *only* to "make, use, sell, offer for sale, import, export and sublicense." Ex. E, § 4. DiLorenzo *did not* retain the right to sue absent consent from LivaNova and thus lacks standing to bring this lawsuit. *Id.*, § 20. DiLorenzo attempts to argue an exception to the standing requirement for cases where the accused infringer is the patentee, but that exception only applies when the patentee is an exclusive licensee, which DiLorenzo is not.

Second, any rights DiLorenzo has in the Asserted Patents are limited to DiLorenzo's Field of Use of treating obesity and metabolic disorders. DiLorenzo's strained reading of the License Grant ignores both the plain language of the agreement and the wealth of contextual evidence surrounding the agreement, both of which make clear the License Grant was never intended to cover LivaNova's business relating to epilepsy treatment.

Moreover, for nearly twenty years, Dr. DiLorenzo behaved in a manner consistent with LivaNova's interpretation. In fact, [REDACTED]
[REDACTED]. When LivaNova
[REDACTED]
[REDACTED]. And never, in the years of correspondence, did Dr. DiLorenzo suggest that he retained rights to the Asserted Patents in the field of epilepsy treatment or that LivaNova's products may be infringing. Only now that DiLorenzo has initiated litigation does DiLorenzo claim rights in the field of epilepsy treatment.

As outlined below and in LivaNova's Motion, DiLorenzo's Complaint should be dismissed with prejudice for lack of standing as to all Asserted Patents.

II. ARGUMENT

A. The Court Should Dismiss DiLorenzo's Complaint for Lack of Standing Because DiLorenzo Is Not an Exclusive Licensee with the Right to Sue Absent LivaNova's Consent

DiLorenzo repeatedly and incorrectly refers to itself as an “exclusive licensee.” DiLorenzo is not an exclusive licensee and did not retain the right to sue in his Field of Use. “In determining ownership for purposes of standing, labels given by the parties do not control. Rather, the court must determine whether the party alleging effective ownership has in fact received all substantial rights from the patent owner.” *A123 Sys., Inc. v. Hydro-Quebec*, 626 F.3d 1213, 1218 (Fed. Cir. 2010). The Federal Circuit’s analysis in *Lone Star Silicon* is governing here. *Lone Star Silicon Innovations LLC v. Nanya Tech. Corp.*, 925 F.3d 1225 (Fed. Cir. 2019). In *Lone Star Silicon*, the Federal Circuit considered whether a transfer agreement reflected a transfer of all substantial rights such that the plaintiff, Lone Star, had the right to sue. *Id.* at 1231. The Federal Circuit explained that in analyzing this question, the Federal Circuit has “often focused on two salient rights: enforcement and alienation.” *Id.* (citing *Intellectual Property Development, Inc. v. TCI Cablevision of California, Inc.*, 248 F.3d 1333 (Fed. Cir. 2001)). The Federal Circuit explained: “a transferee that receives all substantial patent rights from a transferor would *never* need consent from the transferor to file suit.” *Id.* (citing same; emphasis original). The Federal Circuit went on to hold the plaintiff did not hold all the substantial rights in the asserted patents and could not assert the patents in its own name because (1) the plaintiff did not have the right to sue any entity without the consent of the original patent owner and (2) because the plaintiff could not sell the patents without an agreement to be bound by the same restrictions as Lone Star. *Id.* at 1333-38.

The same scenario is present here. The fact that the Agreement includes “exclusive license” in its lengthy title is irrelevant because the License Grant does not convey all substantial rights in the Asserted Patents. **First**, the License Grant does not include the right of “enforcement”

without LivaNova's consent. The License Grant only includes the rights to "make, use, sell, offer for sale, import, export and sublicense devices and methods." Ex. E, § 4. The right of "enforcement" (the right to sue) is contained in Section 10 of the Agreement, which both parties agree includes a requirement that LivaNova consent to any patent infringement action. *Id.*, § 10; Resp. at 11-12; 18-19. **Second**, the License Grant contains restrictions on "alienation" because any sublicensing by DiLorenzo "shall be subject and subordinate to terms and conditions of [the] Agreement." Ex. E, § 11. In other words, similar to the plaintiff in *Lone Star Silicon*, DiLorenzo can only transfer its limited rights in the Asserted Patents to another. *Lone Star Silicon*, 925 F.3d at 1232-33. These facts are not disputed and establish that DiLorenzo does not hold all substantial rights in the Asserted Patents and is, therefore, not an exclusive licensee with the right to sue.¹

The exception to *Waterman*, where an exclusive licensee has prudential standing to bring suit against the patentee (Resp. at 10-12), is inapplicable because it only applies to a party who *is an exclusive licensee*. In *Textile Productions*, the Federal Circuit explained that "only an exclusive licensee has standing to sue for infringement, even under the exception outlined above." *Textile Productions, Inc. v. Mead Corp.*, 134 F. 3d 1481, 1484 (Fed. Cir. 1998). The Federal Circuit held that because the agreement between the parties did not convey an exclusive license to the plaintiff, they "had no standing to assert patent infringement." *Id.* at 1485. In *Diamondback Industries*, the court found the license granted to the plaintiff was an exclusive license, including the right to enforce. *Diamondback Indus., Inc. v. Repeat Precision, LLC*, No. 6:19-CV-00034-ADA, 2019 WL 8501017, at *4 (W.D. Tex. Sept. 11, 2019). And in *Alnylam Pharms. Corp.*, the

¹ The key difference between *Lone Star Silicon* and this case is that Lone Star sought leave to join AMD as a necessary party under Fed. R. Civ. P. 19 before the case was dismissed and the Federal Circuit agreed that was appropriate. *Lone Star Silicon*, 925 F.3d at 1236-37. Joinder of LivaNova is not feasible under Rule 19(a).

parties *agreed* that the plaintiff was an exclusive licensee. *Alnylam Pharms., Inc. v. Tekmira Pharms. Corp.*, No. 12-10087-RWZ, 2012 WL 4857580, at *2 (D. Mass. Sept. 24, 2012). As explained, Federal Circuit case law counsels that DiLorenzo is *not* an exclusive licensee with all substantial rights in the Asserted Patents and the exception to *Waterman* does not apply.

DiLorenzo also erroneously argues that because Section 10 of the agreement references infringement by a “third party,” it is irrelevant. To the contrary, this confirms LivaNova’s position that DiLorenzo is not an exclusive licensee and has *no rights to sue LivaNova at all*. If the License Grant does not include a right to sue in the Field of Use, and Section 10 only covers the right to sue third parties (with LivaNova’s consent), that means the licensor retained those rights to sue and DiLorenzo retained none. Simply put, DiLorenzo did not receive all rights in the Asserted Patents and is therefore not an exclusive licensee.

B. The Court Should Dismiss DiLorenzo’s Complaint for Lack of Standing Because DiLorenzo Has No Ownership Rights Outside His “Field of Use,” Which Does Not Include Epilepsy Treatment

1. DiLorenzo’s Newly Produced “Evidence” Does Not Negate Nearly Twenty Years of Conduct Demonstrating DiLorenzo’s Intent to Only Retain a License for the Treatment of Obesity and Metabolic Disorders

DiLorenzo does not address, head-on, the wealth of evidence corroborating LivaNova’s interpretation of the License Grant and the many instances in which Dr. DiLorenzo himself confirmed the parties’ intent. Rather, DiLorenzo gives a series of excuses for why the Court should ignore it. None are availing.

a) The Objective and Circumstances Surrounding the Making of the Contract Support LivaNova’s Position

The Agreement’s objective, as made clear from the Agreement and the documents discussed therein, was to grant back to DiLorenzo a license in the field of use of treating obesity and metabolism. Ex. E, pg. 2 (“Licensor would grant back to DiLorenzo certain of the assigned

intellectual property relating to obesity and metabolism”). DiLorenzo contends this was merely laying out what was said in an earlier agreement that does not “control the scope of the final agreement...where ordinary rules of construction render the final terms unambiguous.” Resp. at 15. First, whether that phrase was used in an earlier agreement is irrelevant. The fact is that the phrase was also used in *this Agreement* to explain the parties’ objective in entering into the Agreement. If DiLorenzo wanted to clarify that the License Grant was intended to cover sympathetic nervous system modulation therapy outside the field of treating obesity and metabolic disorders, DiLorenzo could have clarified as much in this recitation of the objective of the agreement (or elsewhere in the agreement, for that matter).

Second, it is not clear to which “ordinary rule of construction” DiLorenzo is referring. *Id.* If DiLorenzo is referring to the prohibition on considering extrinsic evidence under Texas’s parol evidence rule (*see, e.g., Hubacek v. Ennis State Bank*, 317 S.W.2d 30, 32 (Tex. 1958)), that is not applicable here, and clearly DiLorenzo agrees as evidenced by Dr. DiLorenzo’s declaration and exhibits. Under Washington law, “[e]xtrinsic evidence may be considered regardless of whether the contract terms are ambiguous.” *King v. Rice*, 191 P.3d 946, 951 (Wash. Ct. App. 2008). It is for this reason that it is appropriate for the Court to consider Exhibits A through D of LivaNova’s motion, which further supports that LivaNova’s predecessor-in-interest would *never* have given back to DiLorenzo field of use rights relating to its own business. *See generally*, Mot. at IV.B.1 (reciting the many instances in which the parties agreed that DiLorenzo was assigning to BioNeuronics all interests in DiLorenzo’s intellectual property relating to the business of the company, which was epilepsy treatment). In fact, Exhibit 4 to Dr. DiLorenzo's declaration reiterates that “any patent claim based (wholly or in part) on inventions you assigned to BioNeuronics Corporation belongs to BioNeuronics Corporation.” Dkt. 33-9, pg. 1. The scope of

the assignment includes any inventions that “pertain to any actual or projected line of business activity of the Company.” *Id.*

Additionally, DiLorenzo’s discussion of the integration clauses under Washington case law is incorrect. As the court explained in *King*, “extrinsic evidence may be considered regardless of whether the contract terms are ambiguous,” and “[t]his is the case *even when there is an integration clause*, as long as the court uses the extrinsic evidence to explain undefined contract terms, not to modify, vary, or contradict terms of the written contract.” *Id.* (emphasis added). Thus, the fact that the Agreement contains an integration clause is irrelevant.

The definition of “Second Field of Use” in the Agreement serves as another example of this clear division. When licensing back certain of DiLorenzo’s non-assigned patents to LivaNova’s predecessor-in-interest, Dr. DiLorenzo stated that he was “retaining ownership of items listed in section 1 of that Appendix but will exclusive license such items (hereafter termed Licensed Autonomic Patents) to the company *for use in epilepsy applications* (hereafter termed Second Field of Use).” Ex. E, § 3 (citing Ex. B). The parties did not identify the license back to LivaNova as “epilepsy applications using parasympathetic neuromodulation.” The parties simply said, “epilepsy applications.” In sum, the Agreement itself, other related agreements, and correspondence between the parties support the parties’ intent to only grant back to DiLorenzo rights in the field of treating obesity and metabolic disorders and for LivaNova’s predecessor-in-interest to maintain its rights in the field of epilepsy treatment.

b) The Subsequent Conduct and Course of Dealing Between the Parties Support LivaNova’s Position

DiLorenzo’s attempts to explain away the parties’ subsequent correspondence and course of dealing do not contradict and, in fact, support LivaNova’s position. First, with respect to Dr. DiLorenzo’s March 13, 2013 email, DiLorenzo does not address the fact that Dr. DiLorenzo *agrees*

LivaNova's ownership interest is in treating "epilepsy and other areas." Ex. J at 2. Even if Dr. DiLorenzo was referencing Dr. DiLorenzo's ownership in the field of "Autonomic Modulation and Neuromodulation for Obesity & Metabolism," it does not diminish the fact that Dr. DiLorenzo confirmed the parties' intent to divide the intellectual property between "metabolism and autonomic structures" and "epilepsy and other areas." *Id.*

Second, with respect to Dr. DiLorenzo's correspondence with Cyberonics regarding [REDACTED], DiLorenzo only argues that DiLorenzo's rights "extend to sympathetic nervous system modulation therapy, whether used to treat epilepsy other otherwise." Resp. at 18. Presumably, in DiLorenzo's view, it follows that [REDACTED]. But there is no evidence of that, and Dr. DiLorenzo's [REDACTED] [REDACTED] shows Dr. DiLorenzo understood he did not have rights to pursue litigation in the field of epilepsy treatment. In fact, Cyberonics clarified as much in its response. When Dr. DiLorenzo first inquired about licensing [REDACTED], Cyberonics asked, "Are you referring to sub-licenses that pertain to the obesity/metabolic disorder indication?" Ex. K. at 9. Dr. DiLorenzo said, "[t]hose as well as autonomic modulation." *Id.* Cyberonics responded by clarifying that "you are free to grant sublicenses within your exclusive fields of use without our consent. Thus, I assume that you are proposing a sub-license that requires our consent." *Id.* at 8. DiLorenzo argues this supports DiLorenzo's view that the License Grant included "autonomic modulation," but it does not. Dr. DiLorenzo continued to seek Cyberonics' consent [REDACTED]. *See generally*, Exs. L-N. If it was clear to Dr. DiLorenzo that he had the right to license and assert the patents in the field of sympathetic nervous system

modulation therapy, and that understanding was confirmed by Cyberonics, he would not have pursued those rights from LivaNova for over a decade. Moreover, he would not have been willing to pay [REDACTED]. *See generally* Exs. M, N. This is nonsensical and is further evidence that DiLorenzo's interpretation of the License Grant should be rejected.

2. The Plain Language of the Agreement Confirms DiLorenzo's Intent; DiLorenzo's Ignores It

The plain grammatical reading of the License Grant reflects the parties' intent only to grant back to DiLorenzo a license in the field of treating obesity and metabolic disorders.

As DiLorenzo states, the word "for" can be used "as a function word to indicate purpose." Resp. at 12; Ex. 3 to Abramson Decl. But it can also be used to mean "being or constituting." Ex. 3 to Abramson Decl. The full clause states:

devices and methods *for* sympathetic nervous system modulation therapy and *for* neuromodulation therapy *for* treating obesity and other metabolic disorders

The phrase "*for* treating obesity and other metabolic disorders" describes the purpose for which those treatments are used, whereas "*for* sympathetic nervous system modulation therapy" and "*for* neuromodulation therapy" are both types of therapies and describe the types of therapy the license constitutes. In other words, it is more logical for the purpose of the license grant to modify both types of therapies that make up the License Grant rather than only to provide the purpose for one type of therapy. Moreover, to read "*for* sympathetic nervous system modulation" therapy without applying the "obesity and other metabolic disorders" modifier would mean LivaNova's predecessor-in-interest granted to DiLorenzo "sympathetic nervous system modulation therapy" *for any purpose*, which contradicts the agreement and every other agreement between the parties which kept all epilepsy-related rights with LivaNova, as discussed above.

DiLorenzo relies on Washington’s “last antecedent rule” in support of its position. Resp. at 12-13. Putting aside that this rule relates to statutory, and not contract, interpretation, more recent case law explains that “[t]he rule of the last antecedent can be overcome by other indicia of meaning.” *Matter of Marriage of Cardwell*, 479 P.3d 1188, 1192 (Ct. App. Wa. 2021) (internal quotations and citations omitted). The Supreme Court of Washington has chosen to ignore the rule when following it would lead to an “interpretation contrary to the reading of the whole statute and the policies behind the statute.” *Id.* As the court pointed out, “[s]ince the English speaking universe employs commas arbitrarily and whimsically, a court should not divine legislative intent on the thin reed of the placement of a comma,” or in this case, the lack of a comma.

Cardwell provides a helpful parallel to this case. In *Cardwell*, the court was interpreting a statute that contained the clause “[i]s based on a change of residence of the parent with whom the child does not reside the majority of the time or an involuntary change in work schedule by a parent which makes the residential schedule in the parenting plan impractical to follow.” *Id.* at 1191. The court was required to determine whether the clause “which makes the residential schedule in the parenting plan impractical to follow” was intended to modify just “an involuntary change in work schedule by a parent” or also “a change of residence of the parent with home the child does not reside the majority of the time.” *Id.* Considering the practical effect of adopting the interpretation and the legislative intent, the court determined that the last clause modified both of the first clauses despite the last antecedent rule and the lack of a comma. *Id.* at 1192-93. For the reasons discussed above, the same outcome is warranted here.

3. The Court Should Ignore DiLorenzo’s Self-Serving Declaration and Questionable Exhibits

The Court should ignore the litigation-driven explanation of changes to an alleged previous version of the Agreement in Dr. DiLorenzo’s declaration and exhibits 1 and 2 thereto. With respect

to the declaration, “[a] conclusory, self-serving affidavit, lacking detailed facts and any supporting evidence, is insufficient to create a genuine issue of material fact.” *F.T.C. v. Publ’g Clearing House, Inc.*, 104 F.3d 1168, 1171 (9th Cir. 1997), *as amended* (Apr. 11, 1997) (citing *Hansen v. United States*, 7 F.3d 137, 138 (9th Cir. 1993)). Dr. DiLorenzo points to no corroborating evidence relating to these documents, such as a description of how these versions came into existence or with whom they were exchanged. *Central Flyway Air, Inc. v. Grey Ghost Int’l, LLC*, No. 3:20-CV-05506-BJR, 2022 WL 4534402, at *7 (W.D. Wa. Sept. 28, 2022) (granting summary judgment of breach of contract claim where the plaintiff’s only evidence was a self-serving declaration with no corroborating evidence “that the alleged agreement existed, or indicating any circumstances under which it came into being.”). Notably, DiLorenzo has never produced these documents or raised this alleged explanation in the twenty years of correspondence between the parties or even in the past six months when litigation counsel specifically asked whether DiLorenzo had any documents supporting his position.² See Ex. O, pg. 2; Ex. P, pg. 1. Dr. DiLorenzo’s eleventh-hour declaration should be given no weight in the Court’s analysis.

With respect to exhibits 1 and 2 to Dr. DiLorenzo’s declaration, Dr. DiLorenzo states that Exhibit 1 is a “true and correct copy of a draft of a license agreement, dated January 25, 2005.” Dkt. 33-5, ¶ 3. Dr. DiLorenzo then states that Exhibit 2 is a “true and correct copy of a draft of the license agreement from on or around March 2005. This draft shows that I made edits to the definition of the Field of Use *in tracked changes*.” *Id.*, ¶ 4 (emphasis added). However, when reviewing Exhibit 1 and Exhibit 2, it is clear that Exhibit 2 is *not* a redline to Exhibit 1. For example, in Exhibit 1, the title of the first numbered paragraph is “Intellectual Property Transfer.”

² Even if Dr. DiLorenzo were to provide further “corroborating evidence” at this late stage, it could not change the outcome, given the wealth of evidence discussed above in Sections II.B.1 and II.B.2.

But in Exhibit 2, it is titled “License Grant,” and that change is *not shown in redline*, nor is the first numbered paragraph of Exhibit 1.³

Whether Exhibit 2 is actually a redline to Exhibit 1 is illustrative of a larger point, which is that these drafts lack context and have no evidentiary value. Dr. DiLorezo did not produce all iterations of the Agreement, nor did he produce any correspondence associated with the Agreement or his changes thereto. It is just as likely Dr. DiLorenzo made these clarifications to ensure that “for treating obesity and metabolic disorders” properly modified both clauses, as that is consistent with the plain language of the agreement and the nearly twenty-year history between the parties. DiLorenzo has produced no evidence corroborating Dr. DiLorenzo’s explanation of the change in the language of the agreement. What is probative is the actual language in the Agreement and the course of dealing between the parties, both of which support LivaNova’s interpretation of the License Grant.

What is abundantly clear from all the agreements and correspondence (and not disputed by DiLorenzo) is that the parties’ *never* expressed an intent to divide the fields of use along the lines of “sympathetic” and “parasympathetic” nervous system modulation therapy for treating epilepsy. Only now, nearly twenty years later and in the context of litigation, has DiLorenzo raised this interpretation of the License Grant. DiLorenzo’s interpretation, which is contradicted by the language of the License Grant, the prior agreements between the parties, and the course of dealing between Dr. DiLorenzo and LivaNova, is only supported by Dr. DiLorenzo’s self-serving and unsupported affidavit. It should not be adopted.

³ LivaNova requested the native versions of these documents. DiLorenzo declined to produce them. *See generally* Ex. Q.

C. The '880 Patent Is Owned by LivaNova, Despite That DiLorenzo Failed to Execute an Assignment to LivaNova

LivaNova owns the '880 patent, even if Dr. DiLorenzo did not execute a formal assignment of the '880 patent to LivaNova, as required. Recording an assignment in the patent office “is not a determination by the Office of the validity of the document or the effect that document has on the title to an application, a patent, or a registration.” 37 C.F.R. § 3.54. DiLorenzo does not dispute that every agreement between the parties requires Dr. DiLorenzo to disclose and execute an assignment to BioNeuronics for any invention relating to BioNeuronics’ business. Ex. A § 2(b); Ex. B §§ 2(b), 2(c); Ex. D, § 4(b); Ex. E, pg. 1; Ex. F, §§ 7.3, 8.2. These assignments were codified in the “Assignment to Neurobionics Corporation” in which Dr. DiLorenzo assigned “all inventions, original works of authorship, developments, improvements, trade secrets, patents, patent applications, and other intellectual property, including clinical and preclinical data, related to the Company’s business of neurodiagnostics and/or neuromodulation.” Ex. C. As DiLorenzo’s response explains, “neuromodulation” is the broadest category in this field, and generally means “delivery of a stimulus to the nervous system.” Resp. at 4. As DiLorenzo argues, the claims of the '880 patent relate to “sympathetic nervous system modulation therapy,” which is a subset of neuromodulation. Resp. at 20, 4. Thus, the '880 patent falls under this assignment. The exception contained in § 6 of the Agreement does not apply. Section § 6 of the Agreement only grants DiLorenzo the right to prosecute continuing patent applications in the Field of Use, which, as explained above, does not include epilepsy treatment. Because, according to DiLorenzo, the '880 patent relates to a system and method for epilepsy treatment (Dkt. 1, ¶¶ 1, 2, 43-52), it was assigned to LivaNova’s predecessor-in-interest. Thus, LivaNova is the owner of the '880 patent.

DiLorenzo argues it disclosed the '880 patent to LivaNova’s predecessor-in-interest and cites a letter in response to that disclosure in support. However, DiLorenzo does not cite any

evidence that the application that led to the '880 patent was actually included in Dr. DiLorenzo's alleged correspondence. Further, the parties' course of dealings over the past twenty years establishes that Dr. DiLorenzo was not trying to read any of the patents against LivaNova's products, so to say DiLorenzo's Complaint was a shock to LivaNova is an understatement. Moreover, as the letter points out, "[i]t is always difficult, of course, to know whether a pending patent claim will actually be granted in that form when the patent issues. Claims can be amended or canceled during prosecution based on many factors, including unpatentability over prior art." However, the letter is clear that "[a]ny patent application containing claims falling under any one of the three clauses of the definition of Company Inventions and Works are the property of BioNeuronics Corporation and should be assigned back to the company." Dkt. 33-9, pg. 2. Simply because Dr. DiLorenzo failed to execute a formal assignment in the patent office (as the parties' agreements required him to do) after the patent issued does not mean that LivaNova is not the rightful owner of the '880 patent.

III. CONCLUSION

DiLorenzo lacks standing to bring this suit against LivaNova because DiLorenzo failed to join LivaNova as a plaintiff and because DiLorenzo does not have rights to the Asserted Patents in the field of epilepsy treatment. DiLorenzo's Complaint should be dismissed with prejudice.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned attorney hereby certifies that on November 16, 2023, a true and correct copy of the foregoing document was served via electronic mail on all counsel of record.

/s/ Benjamin C. Elacqua

Benjamin C. Elacqua