

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA**

DILORENZO BIOMEDICAL, LLC,)	
)	
Plaintiff,)	
– against –)	No.
)	
MEDTRONIC, INC.,)	JURY TRIAL DEMANDED
)	
Defendant.)	
)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff DiLorenzo Biomedical, LLC (“Plaintiff”), for its complaint against Defendant Medtronic, Inc. (“Defendant” or “Medtronic”), alleges as follows:

INTRODUCTION

1. Plaintiff owns numerous patents in the field of neural stimulation, including without limitation closed loop neural sensing and modulation and related control systems for determining treatment parameters and delivering treatment. Plaintiff’s pioneering work has been cited in hundreds of other patents later filed by leading medical device companies, including dozens of citations in patents filed by Medtronic. This Complaint accuses Medtronic of infringing at least two of Plaintiff’s patents, in various Medtronic product lines related to implants for spinal cord stimulation (SCS), for treating otherwise intractable chronic back pain.

THE PARTIES

2. Plaintiff DiLorenzo Biomedical, LLC is a Washington limited liability company with a business address at P.O. Box 1626, Loma Linda, California 92354-1626.

3. Defendant Medtronic, Inc. is a Minnesota corporation with a place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

JURISDICTION AND VENUE

4. 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.*

5. This Court has personal jurisdiction over Defendant because it is incorporated and principally operates in this District.

6. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b) because Defendant is incorporated in this District.

PATENTS-IN-SUIT

7. This action concerns U.S. Patent Nos. 6,366,813 (“’813 patent”) and 8,781,597 (“’597 patent”) (together, the “Asserted Patents”), attached hereto as Exhibits A and B respectively and incorporated by reference.

8. The ’813 patent was duly and legally issued on April 2, 2002 and expired on June 25, 2019.

9. The ’597 patent was duly and legally issued on July 15, 2014 and expired on February 23, 2022.

10. Plaintiff is the record owner of each of the Asserted Patents and owns all rights in each of them, including without limitation all rights to recover for past infringement thereof.

11. Prior to the Asserted Patents, electrical neurostimulation to treat disease required a set stimulus or periodic adjustment or re-programming by means external to the patient. The Asserted 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 has provided great advantages in fields practiced in by Medtronic, including SCS.

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

COUNT I: INFRINGEMENT OF THE '813 PATENT
BY MEDTRONIC SPINAL CORD STIMULATION PRODUCTS

13. Plaintiff repeats and realleges the averments of paragraphs 1-12 above as if fully set forth at length herein.

14. Defendant has directly infringed the '813 patent under 35 U.S.C. § 271(a) by making, using, selling, and offering to sell systems in accordance with one or more claims thereof, in the United States, during the term of the '813 patent.

15. For example, with reference to claim 1 of the '813 patent, Defendant has manufactured, marketed, and sold in the U.S., spinal cord stimulation products, including without limitation, the Medtronic RestoreSensor™, Intellis™, and Vanta™ spinal cord

stimulators, and other Medtronic products and/or related components (“Accused Products”), which apply neural modulation to the spinal cord to treat chronic back pain. The operation of the Accused Products is reflected in Medtronic patents such as U.S. Patent No. 11,672,989 (Medtronic ’989 patent”), which has been marked by Medtronic on its spinal cord stimulation devices. Other evidence includes clinician programming manuals and other documents available at https://manuals.medtronic.com/manuals/main/en_US/home/index.

16. The Accused Products share the feature that they each comprise a signal conditioning circuit, for conditioning signals input from sensors. See for example blocks 34 and 41 in the Medtronic ’989 patent:

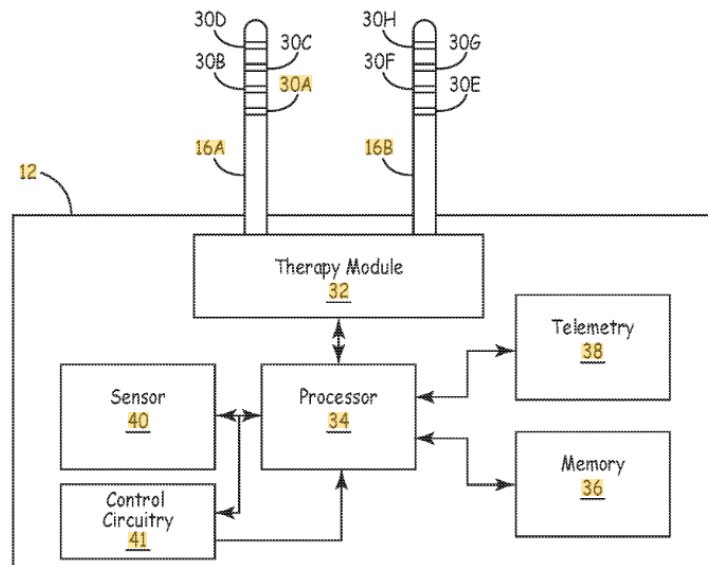


FIG. 2

17. In each case, the Accused Products incorporate sensor arrays (e.g., block 40), including sensors such as accelerometers, pressure transducers, and gyroscopes, in electronic communication with the signal conditioning circuit, which processes the raw signals

provided by the sensors to determine information such as activity levels and velocity along one or more accelerometer axes, for use in detecting a posture state, *e.g.*, '989 patent, 8:49-58.

18. Each Accused Product further comprises a signal processor (*e.g.*, block 40) in electronic communication with the signal conditioning circuit that performs disease state estimation. For example, disease state may depend on the posture of the patient, which is estimated based on inputs from accelerometer, pressure transducer, or gyroscopic sensors, which may further include dwell time in certain posture states.

19. Each Accused Product further comprises a control circuit in electronic communication with the signal processor (*e.g.*, blocks 34 and 32).

20. Each Accused Product further comprises an output stage circuit in electronic communication with the control circuit (*e.g.*, '989 patent, 8:13-33).

21. Each Accused Product further comprises a stimulating electrode array in communication with the output stage circuit (*e.g.*, blocks 16A, 16B).

22. Defendant has committed the above alleged acts of infringement during the term of the '813 patent and during the six-year limitations period prior hereto.

23. Pursuant to 35 U.S.C. § 284, Plaintiff is entitled to not less than a reasonable royalty for the use made by Defendant 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 '597 PATENT
BY MEDTRONIC SPINAL CORD STIMULATION PRODUCTS**

24. Plaintiff repeats and realleges the averments of paragraphs 1-23 above as if fully set forth at length herein.

25. Defendant has directly infringed the '597 patent under 35 U.S.C. § 271(a) by at least making, using, selling, and offering to sell systems in accordance with one or more claims thereof, in the United States, during the respective terms thereof.

26. For example, with regard to at least claim 1 of the '597 patent, the Accused Products have been made, used, offered for sale, and sold by Medtronic together with external wireless telemetry and communication devices, *e.g.*,



<https://www.medtronic.com/us-en/healthcare-professionals/products/neurological/spinal-cord-stimulation-systems/vanta-pc-neurostimulator.html>.

27. Further with respect to at least claim 1 of the '597 patent, the Accused Products sold with components as in par. 26 likewise constitute systems for modulating a patient's neurological disease state.

28. As alleged in par. 17 above, the Accused Products as in par. 26 comprise one or more sensors that sense at least one signal that comprises a characteristic that is indicative of a neurological disease state (postural conditions and/or changes indicative of chronic back pain due to physical pressure and/or abrasion on nerves).

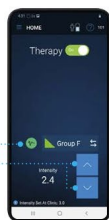
29. As alleged in pars. 18-19 above, the Accused Products as in par. 26 comprise a signal processing assembly in communication with the one or more sensors that processes the at least one signal using a disease state processor to estimate the neurological disease state. This functionality further includes adjusting a parameter of a therapy to the patient as a function of the estimated neurological disease state, as shown, for example, in the following Medtronic publication:

Closed-loop technology

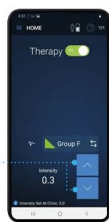
Closed-loop technology personalizes treatment based on your body signals.

If your active programmed group is a closed-loop (Neuro Sense) group (with green triangle icon), the neurostimulator can adjust your stimulation by sensing signals from your body.

You can also adjust the settings with the up and down arrows if needed.



If you want to increase or decrease the intensity back to the original clinic setting displayed on the patient programmer, use the arrows on the bottom of the screen.



AdaptiveStim™ technology

AdaptiveStim™ technology is another option that might be programmed for you.

It would be programmed in a different group than closed-loop technology and is based on body positions.

If AdaptiveStim™ is enabled in your therapy group, you'll see a spine icon.

Tap that icon if you want to turn AdaptiveStim™ on or off.

AdaptiveStim™ can recognize seven different body positions.



If you want to change your pain therapy intensity for one of the seven positions with AdaptiveStim™, get in that position and adjust the therapy to your comfort.

The next time you return to this position, the AdaptiveStim™ feature will remember and **automatically adjust**.

<https://www.medtronic.com/uk-en/patients/treatments-therapies/spinal-cord-stimulation-chronic-pain/resources.html>.

30. As alleged in par. 21 above, the Accused Products as in par. 26 comprise a treatment assembly in communication with the signal processing assembly, wherein said treatment assembly delivers the therapy to a nervous system component of the patient.

31. The handheld unit, tablet, communicator, and telemetry devices of the Accused Products as in par. 26, alone or in combination, comprise a patient interface module that communicates with a patient the estimated disease state. As recited in claim 1 of the '597 patent, the patient interface module is in communication with the signal processing assembly (implanted in the patient's body), and external to the patient's body.

32. Defendant committed the above alleged acts of infringement during the term of the '597 patent and during the six-year limitations period prior hereto.

33. Pursuant to 35 U.S.C. § 284, Plaintiff is entitled to not less than a reasonable royalty for the use made by Defendant under the Asserted Patents, in an amount subject to proof at trial, together with interest and costs as fixed by the Court.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury on all issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests an entry of judgment in its favor and against Defendant as follows:

- i. Declaring that Defendant has infringed one or more claims of United States Patent Nos. 6,366,813 and 8,781,597;
- ii. Awarding to Plaintiff the damages arising out of said infringement;
- iii. Awarding attorneys' fees, costs, or other damages pursuant to 35 U.S.C. §§ 284 or 285 or as otherwise permitted by law, against Defendant;
- iv. Awarding costs in this action to Plaintiff; and
- v. For such other and further relief as the Court may deem just and proper.

Dated: October 31, 2024

By: *s/Todd S. Werner*

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