UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIVANOVA, INC. and LIVANOVA USA, INC. ("LivaNova"),

Petitioner

v.

NEURO AND CARDIAC TECHNOLOGIES, LLC

Patent Owner

IPR2018-01709
U.S. Patent No. 7,076,307

PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §312 AND 37 C.F.R. §42.104

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PETITIONER'S EXHIBIT LIST

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Ex. 1001	U.S. Patent No. 7,076,307 to B. Boveja *et al*. ("the '307 patent")
Ex. 1002	Prosecution history of the '307 patent
Ex. 1003	Declaration of Dr. Richard T. Mihran
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Ex. 1005	Prosecution history of U.S. Patent Application No. 10/142,298 (application to which the '307 patent claims priority) ("CIP-Grandparent")
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Ex. 1007	U.S. Patent Publication No. 2003/0212440, publication corresponding to CIP-Parent application ("Parent Publication")
Ex. 1008	U.S. Patent No. 6,366,814 to B. Boveja *et al*. ("*Boveja-814*")
Ex. 1009	U.S. Patent No. 6,662,052 to A. Sarwal and B. Boveja ("*Sarwal-052*")
Ex. 1010	Ignacio Valencia MD et al., *Vagus nerve stimulation in pediatric epilepsy: a review*, Pediatric Neurology, Vol 25:5, pp. 368-376, November 2001 ("*Valencia*")
Ex. 1011	John G. Webster, *Design of Cardiac Pacemakers*, IEEE Press (1995) (selected pages) ("*Webster*")
Ex. 1012	U.S. Patent No. 5,304,206 to R. Baker *et al*. ("*Baker*")
Ex. 1013	U.S. Patent No. 6,442,432 to M. T. Lee ("*Lee*")
Ex. 1014	Declaration of Dr. Ingrid Hsieh-Yee Under 37 C.F.R. § 1.68
Ex. 1015	U.S. Patent Pub. No. 2005/0004622 to P. Cullen et al. ("*Cullen*")
Ex. 1016	U.S. Patent No. 6,381,496 to P. Meadows et al. ("*Meadows*")
Ex. 1017	U.S. Patent No. 6,760,626 to B. Boveja ("*Boveja-626*")
Ex. 1018	U.S. Patent No. 5,591,217 to F. Barreras ("*Barreras*")
Ex. 1019	U.S. Patent No. 6,449,512 to B. Boveja ("*Boveja-512*")
Ex. 1020	Brian Litt, *Evaluating Devices for Treating Epilepsy,* Epilepsia, 44(Supp. 7):30-37, 2003 ("*Litt*")

Ex. 1021	Max Schaldach, *Electrotherapy of the Heart: Technical Aspects in Cardiac Pacing*, (Springer-Verlag, 1992) ("*Schaldach*")
Ex. 1022	*Physician's Manual, NeuroCybernetic Prosthesis System, NCP® Pulse Generator, Models 100 and 101*, August 2002, (herein "*Cyberonics NCP 100/101 Physician's Manual*")
Ex. 1023	Mark H. Schoenfeld, *A Primer on Pacemaker Programmers*, PACE Vol. 16, October 1933 ("*Schoenfeld*")
Ex. 1024	Robert D. Gold et al., *Programmable Pacing Systems: The Medium and the Message*, PACE Vol. 5, September-October 1982 ("*Gold*")
Ex. 1025	Reese Terry et al., *An Implantable Neuocybernetic Prosthesis System*, *Epilelspia*, 31(Suppl. 2):S33-S37, 1990 ("*Terry*")
Ex. 1026	U.S. Patent No. 5,235,980 to A. Varrichio et al. ("*Varrichio*")
Ex. 1027	Jacob Zabara, *Peripheral Control of Hypersynchronous Discharge in Epilepsy*, Electroencephalography Clinical Neurophysiology, 61: 162, 1985 ("*Zabara Abstract*")
Ex. 1028	U.S. Patent No. 4,702,254 to J. Zabara ("*Zabara-254*")
Ex. 1029	U.S. Patent No. 4,867,164 to J. Zabara ("*Zabara-164*")
Ex. 1030	U.S. Patent No. 5,025,807 to J. Zabara ("*Zabara-807*")
Ex. 1031	Alicia Ault, *FDA approves first-ever epilepsy device*, The Lancet – Science and Medicine, Vol. 350, p. 268, July 26, 1997 ("*Ault*")
Ex. 1032	Edward J. Hammond et al., *Vagus Nerve Stimulation in Humans: Neurophysiological Studies and Electrophysiological Monitoring*, *Epilepsia*, 31 (Suppl. 2):S51-S59, 1990 ("*Hammond*")
Ex. 1033	U.S. Patent No. 5,299,569 to J. Wernicke et al. ("*Wernicke*")
Ex. 1034	M. Rise, *Review Article: Instrumentation for Neuromodulation*, Arch. Med. Res., 31, 237-247, 2000 ("*Rise*")
Ex. 1035	U.S. Patent No. 5,237,991 to R. Baker et al. ("*Baker-991*")
Ex. 1036	U.S. Patent No. 4,539,992 to R. Calfee et al. ("*Calfee*")
Ex. 1037	Ross Davis, *Artificial Organs*, 26(3):280-283, Blackwell Publishing, 2002 ("*Davis*")
Ex. 1038	Schwartz, *Chronic Carotid Sinus Nerve Stimulation in the Treatment of Essential Hypertension,* American Journal of Surgery, Vol. 114,

	July 1967 ("*Schwartz*")
Ex. 1039	ScienceDirect information on *Valencia*, copy of https://www.sciencedirect.com/science/article/pii/S0887899401003198 (as of September 10, 2018)
Ex. 1040	ScienceDirect information on *Rise*, copy of https://www.sciencedirect.com/science/article/pii/S0188440900000618 (as of September 10, 2018)
Ex. 1041	U.S. Patent No. 5,188,104 to J. Wernicke et al. ("*Wernicke-104*")
Ex. 1042	U.S. Patent No. 5,269,303 to J. Wernicke et al. ("*Wernicke-303*")
Ex. 1043	U.S. Patent No. 5,335,657 to R. Terry et al. ("*Terry-657*")
Ex. 1044	U.S. Patent No. 5,215,086 to R. Terry et al. ("*Terry-086*")
Ex. 1045	U.S. Patent No. 5,231,998 to J. Wernicke et al. ("*Wernicke-988*")
Ex. 1046	U.S. Patent No. 5,330,515 to P. Rutecki et al. ("*Rutecki*")
Ex. 1047	U.S. Patent No. 5,529,578 to Struble ("*Struble*")

Note that the following analysis may bold, underline and/or italicize quotations and add color or annotations to the Figs. from these exhibits for the sake of emphasis, unless otherwise indicated.

I. INTRODUCTION

The alleged inventions in U.S. 7,076,307 (the "'307 patent") are based on old, well-known teachings that pre-date the proper priority of the claims. The original examiner recognized this fact and originally rejected the challenged claims. Only after the applicants removed a primary reference as prior art were the claims allowed. However, as shown below, there is additional prior art not known to the examiner that renders the claims obvious for the reasons explained below.

The '307 patent relates generally to devices for delivering electrical stimulation to the body to treat various conditions. More specifically, the '307 patent describes purported improvements for stimulating the vagus nerve with an implantable pulse generator ("IPG") that can be programmed with default stimulation therapy programs that can later be modified via a programing system.

The '307 patent describes building-in "pre-packaged" default stimulation therapy programs into the IPG such that a patient may have limited control over changing the stimulation intensity by stepping between at least two of the default programs. The '307 patent describes the well-known technique of using an external magnet to modify the stimulation intensity of the IPG. In addition to use of pre-packaged programs built-in to the IPG, the '307 patent recognizes the need for custom programming to meet specific patient needs by permitting modification of the pre-packaged programs after implantation of the IPG in a patient. To

achieve the programming, the ’307 patent discloses use of a conventional external programming system permitting bi-directional communication between the IPG and a programmer.

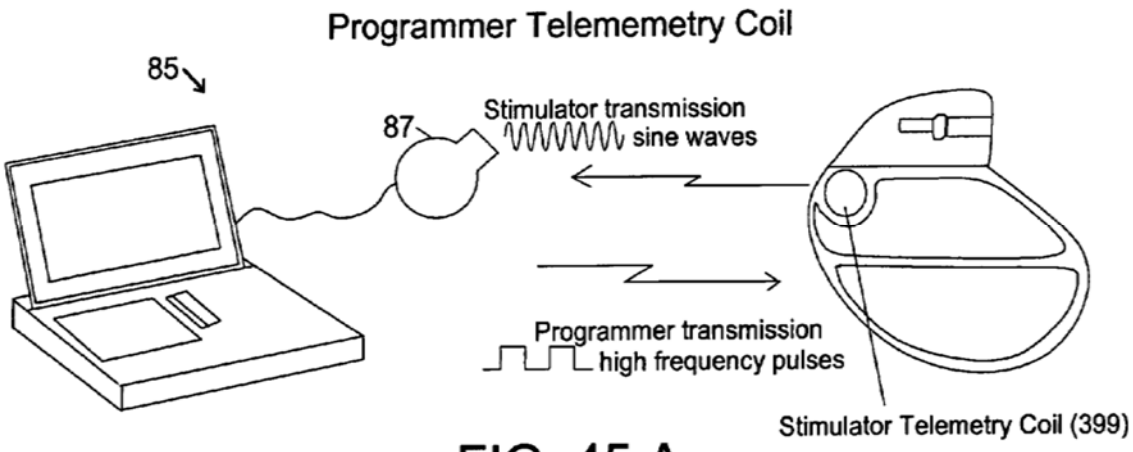

FIG. 45 A

Fig. 45A of the ’307 patent shows a programmer 85 with a programmer wand 87 communicating with an IPG via coil 399. The structural components of the ’307 patent are conventional components with the only alleged changes being the timing of when initial program parameters are loaded into memory of the IPG.

During prosecution, the examiner identified U.S. Patent No. 5,304,206 (“*Baker*”) as disclosing the standard structural features of an IPG along with at least one predetermined program stored in the memory of the IPG for vagal nerve therapy. To overcome the rejection, the applicants added the claim limitation that at least two predetermined “pre-packaged” therapy programs must be stored in the memory of the IPG and that the programmer utilizes “bi-directional inductive

telemetry" to communicate with the IPG. In response, the examiner rejected the amended claims based on an earlier issued patent, *Boveja-626*, disclosing "predetermined/pre-packaged" therapy programs. In response to the rejection, the applicants created a transfer agreement and filed a declaration alleging common ownership of *Boveja-626* at the time of the purported invention of the '307 patent, arguing this removes *Boveja-626* as prior art. After filing of the agreement, inventor declarations and arguments, the '307 patent was allowed.

What the examiner did not know is that there are other Boveja patents that disclose the same "predetermined/pre-packaged" default therapy programs and that these patents are prior art under 35 U.S.C. §102(b). For example, U.S. Patent No. 6,366,814 ("*Boveja-814*") issued April 2, 2002, more than one year before the application for the '307 patent was filed on May 8, 2004. Similar to the '307 patent, *Boveja-814* discloses the concept of utilizing a small set of "pre-packaged" therapy programs as default programs the patient can use to adjust stimulation without input from a physician and that those "pre-packaged" default programs may be later modified by a physician as needed to adjust stimulation applied to the vagus nerve.

In the same amendment, the applicants added the limitation that the programmer communicates with the IPG via "bi-directional inductive telemetry." As discussed further below and demonstrated by Dr. Mihran in his declaration, the

corresponding figure and written description in the '307 patent of a "programmer means" with bi-directional inductive telemetry appear to be copied from a 1995 textbook, referred to herein as *Webster*. *Webster* discloses a "programmer means" virtually identical to that disclosed in the '307 patent and was not cited during prosecution.

As explained further below, the combination of the conventional IPG components of *Baker* programmable through a conventional programmer like the one of *Webster* discloses the structural components of the claims. Moreover, *Baker* discloses that its IPG was programmed to give patients limited control of the implanted IPG to change stimulation intensity applied to the vagus nerve without physician intervention. *Baker* describes that the patient can adjust the stimulation therapy by using finger taps to transition the output of the IPG to higher or lower stimulation intensities, but *Baker* does not provide details on how such stimulation changes would be implemented in the device. *Boveja-814* discloses similar features of patient adjustable intensities for vagal nerve stimulation and expressly provides that the changes of intensity may be accomplished with the use of "predetermined/pre-packaged" therapy programs. The combination of *Baker*, together with *Boveja-814* suggesting the use of "predetermine/pre-packaged" therapy programs as a way to implement the patient controllable therapy settings of *Baker*, and *Webster* teaching details of how the programming system of *Baker* can

be implemented using inductive telemetry, discloses all of the features of the challenged claims of Ground 1.

With respect to Ground 2, the *Lee* reference is added to demonstrate that in addition to remote programming of the IPG through telephone connections, it was well known that such connections for remote programming can also be made via a wide area network.

Thus, Petitioner submits that there is a reasonable likelihood that Petitioner will prevail as to claims 1-8, 10-12, 18, 19-23, and 25-28 of the '307 patent. Accordingly, *inter partes* review of these claims is requested.

II. MANDATORY NOTICES

A. Real Party-in-Interest

Pursuant to 37 C.F.R. §42.8(b)(1), LivaNova, Inc. and LivaNova USA, Inc. (collectively "LivaNova" or "Petitioner") certifies that it is the real party-in-interest. Out of an abundance of caution, Petitioner further identifies LivaNova Plc, LIVN US HOLDCO Inc., LIVN UK 3 CO LIMITED, LIVN US LP, LIVN US 1 LLC, LIVN US 3 LLC, LivaNova Holdings USA, Inc., and Cyberonics Holding, LLC as real parties-in-interest for the IPR requested by this Petition. Petitioner notes that LivaNova Plc is a publicly traded entity with numerous affiliated entities, each of which agrees to be estopped under the provisions of 35 U.S.C. § 315 to the same extent that Petitioner is estopped.

B. Related Matters

Pursuant to 37 C.F.R. §42.8(b)(2), to the best knowledge of the Petitioner, the '307 patent is involved in the following case (which involves Petitioner as a named defendant):

- *Neuro and Cardiac Technologies, LLC v. LivaNova, Inc. and LivaNova USA, Inc.*, Case No. 2:18-cv-01517, Southern District of Texas.

C. Lead and Back-up Counsel and Service Information

Pursuant to 37 C.F.R. §42.8(b)(3), Petitioner identifies the following counsel (and a power of attorney accompanies this Petition).

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Please address all correspondence to lead and back-up counsel. Petitioner consents to electronic service.

III. GROUNDS FOR STANDING

Pursuant to 37 C.F.R. §42.104(a), Petitioner certifies that the '307 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the Challenges identified in this Petition.

IV. CLAIM CONSTRUCTION

A. Claim Interpretation in *Inter Partes* Review

1. General Principles

During *inter partes* review, claims of an unexpired patent are to be given their broadest reasonable interpretation consistent with the specification, unless the inventor, as a lexicographer, has set forth a special meaning for a term (referred to as "the BRI standard"). *See* 37 C.F.R. §42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144-45 (2016).

2. Means-plus-function Terms

Use of the term "means" in a claim results in the rebuttable presumption that the claim is expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof (i.e., is expressed in "means-plus-function" format), and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. *TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259 (Fed. Cir. 2008). The presumption

may be overcome if the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure. *Williamson v. Citrix Online*, 792 F.3d 1339, 1349 (Fed. Cir. 2015).

Construing a means-plus-function limitation includes two steps: (1) identifying the claimed function, and (2) identifying the corresponding structure in the specification (including identifying the specific portions of the specification where found) of the patent that performs the function. *Id*.at 1351.

B. "*providing programmer means for activating and/or programming said implanted pulse generator, wherein bi-directional inductive telemetry is used to exchange data with said implanted pulse generator*" (claim 1) / "*means for activating and/or programming said implantable pulse generator, wherein bi-directional inductive telemetry is used to exchange data with said implantable pulse generator*" (claim 18)

The use of the term "means" creates the rebuttable presumption that the claim term is expressed in means-plus-function format. Neither the term "programmer means" of claim 1 nor the "means" of claim 18 was understood by a person of ordinary skill in the art (POSITA) to have a sufficiently definite meaning as the name for structure, thus confirming that the terms are a means-plus-function terms. Ex. 1003, ¶ 40.

The function for both terms in question is activating and/or programming the claimed implanted pulse generator using bi-directional inductive telemetry to exchange data with said implanted pulse generator. *Id*.¶¶ 42, 49-50 and Ex. 1002, p.193 (In

prosecution applicants argued, "claims 1 and 21 [issued claim 18], as amended include programmer means 'wherein bi-directional inductive telemetry is used to exchange data with said implanted pulse generator.'").

To resolve the obviousness inquiry, it is not necessary in this case to exhaustively determine every structure that satisfies the function. Rather, it is only necessary to recognize that the structure presented for the "programmer 85" in Fig. 47 operable with special alignment circuit of programming head 87 shown in Figs. 45A and 48 of the '307 patent is one example of a structure that performs the stated function. Ex. 1003, ¶ 43-45, 52-52. The specification describes the "programmer 85" as "[t]he left half of FIG. 47" which "communicates programming and telemetry information with the IPG 391… The IPG 391 of this embodiment includes the capability of bi-directional communication." Ex. 1001, 26:13-27. Fig. 47 of the '307 patent is reproduced below, illustrating the "programmer 85 which communicates programming and telemetry information with the IPG 391," using "bi-directional communication":

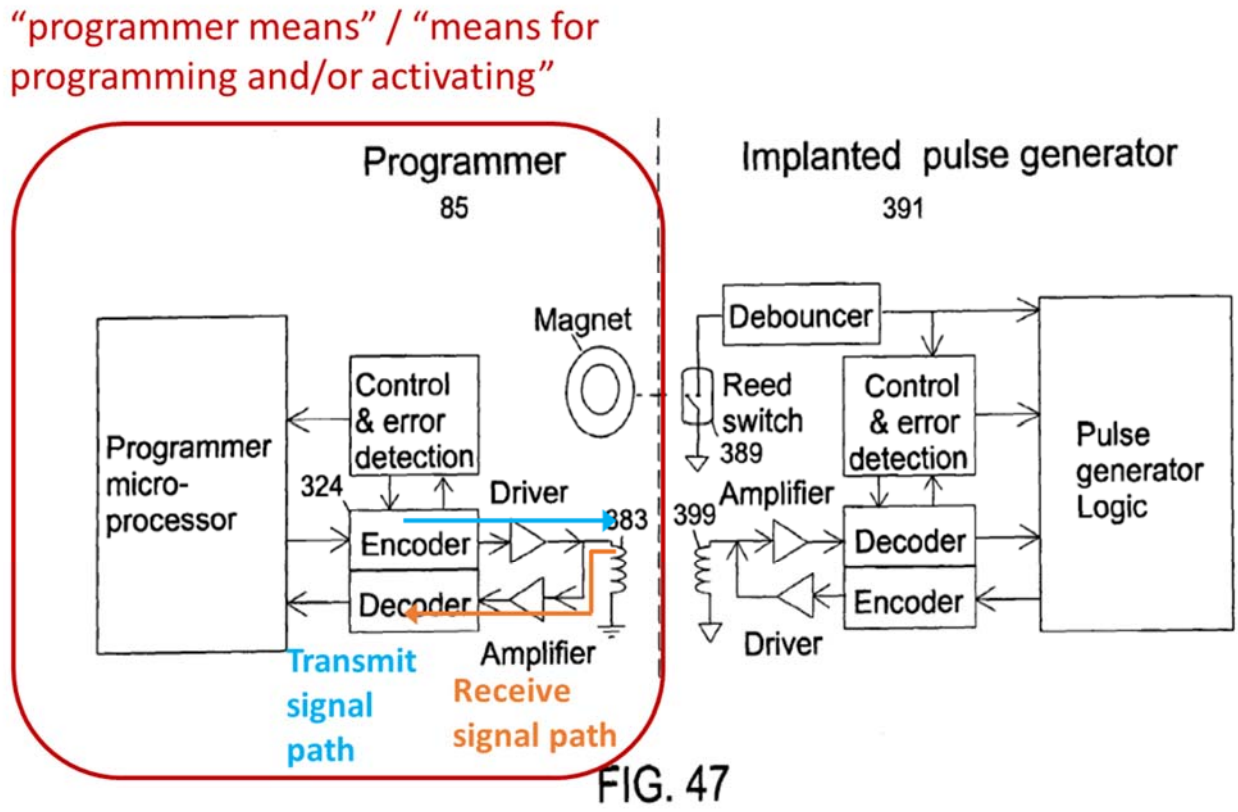


FIG. 47

Ex. 1001, Fig. 47 (annotated in color); Ex. 1003, ¶ 46

In addition, Fig. 48 illustrates circuitry that is part of the "programmer" 85 of Fig. 47. Ex. 1001, 26:55-59. Specific implementation details of the programmer 85 of Figs. 47 and 48 are provided in Figs. 49-52 of the '307 patent and the associated disclosure in the '307 patent at 26:60 to 28:23. Thus, the "programmer means"/ "means" of claims 1 and 18 also includes the NOR gate, amplifier, phase shift detector, and comparator to generate a program-enabled signal, configured as shown in Fig. 48. Ex. 1003, ¶ 51-53.

Thus, one structure corresponding to the function of the "programming means" is "programmer 85" in Fig. 47, which includes an encoder and driver for

transmitting to the IPG 391, and amplifier and decoder for receiving from the IPG 391, coils 383, magnet and microprocessor, and also includes at least the oscillator, set of coils, NOR gate, amplifier, phase shift detector, and comparator configured as shown in Fig. 48 and implementation details of Figs. 49-52 along with the related description. Ex. 1003, ¶¶ 39-54.

C. "*telemetry means for remote device interrogation and/or programming over a wide area network*" (claim 6)

The use of the term "means" in claim 6 creates the rebuttable presumption that the claim term is expressed in means-plus-function format. A POSITA would not have understood "*telemetry means*" to have a sufficiently definite meaning as the name for structure, thus confirming that the term is a means-plus-function term. Ex. 1003, ¶ 55. The stated function for this term is "*remote device interrogation and/or programming over a wide area network*."

Under the BRI standard and to the extent there is written description support, the claimed function is achieved in the '307 patent by an implanted pulse generator with telemetry means via an external programmer itself connected to a wide area network as discussed below. Ex. 1003, ¶ 57.

As described above, Fig. 47 discloses the structure for bi-directional telemetry between the programmer and IPG. Specifically, "[t]he sections of the IPG 391 associated with programming and telemetry are shown on the right half of FIG.

47." Ex. 1001, 26:17-19. The annotated red box in Fig. 47 below shows the telemetry components of the IPG. Ex. 1003, ¶ 58.

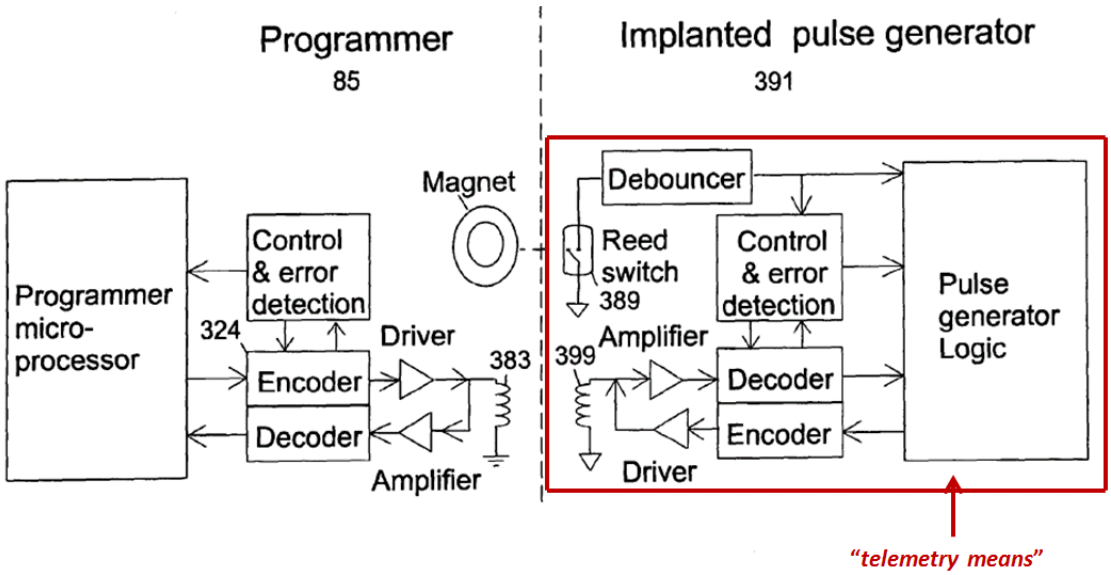


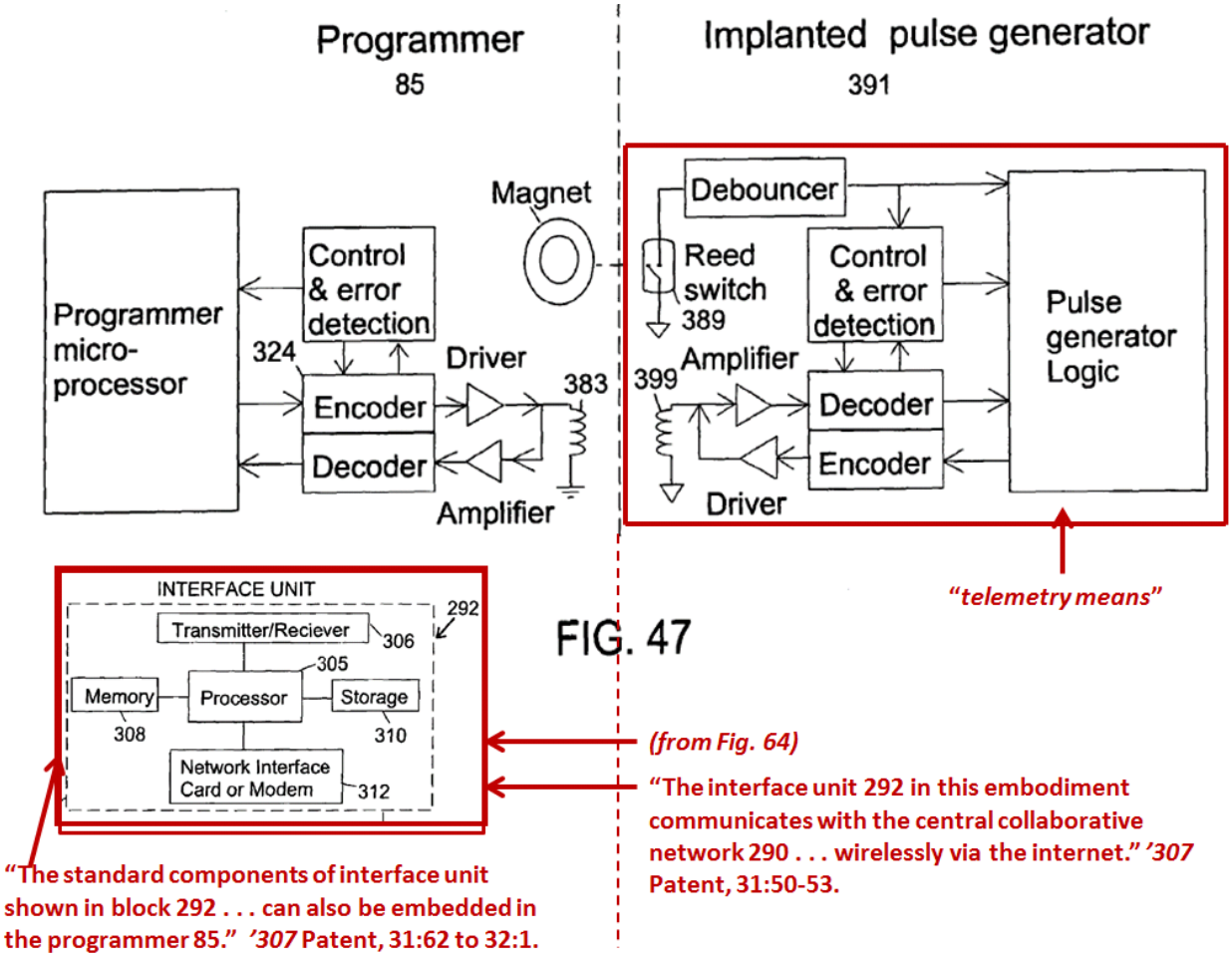
FIG. 47

Ex. 1001 (annotated in color); Ex. 1003, ¶ 58

Thus, one example structure in the '307 patent's specification for "*telemetry means*" is the "coil 399," the "amplifier," the "driver," the "decoder ," the "encoder," the "control & error detection," "debouncer," "reed switch 389" and the "pulse generator logic" in the IPG 391. *Id*., ¶ 60.

The specification also discloses that "[p]rogramming of the implantable pulse generator (IPG) is done via an external programmer 85." Ex. 1001, 20:52-53. According to the '307 patent, as illustrated below, programmer 85 may be modified to

include an interface device that communicates over a WAN ("wide area network"). Ex. 1003, ¶¶ 63-64.



Ex. 1001, Figs. 47, 64 (partial) (annotated in color); Ex. 1003, ¶ 61

The specification explains that device interrogation and/or programming may be performed ***remotely*** at a server, and then downloaded to the IPG. Ex. 1003, ¶ 66 (citing Ex. 1001, 30:40-43

Thus, the above-discussed example of the structure in the IPG for "*telemetry means*" (i.e. the "coil 399," the "amplifier," the "driver," the "decoder ," the "encoder," the "control & error detection," and the "pulse generator logic" in Fig. 47 of the '307 patent) performs the function of "remote device interrogation and/or programming over a wide area network," via the programmer 85 embedded with the interface unit 292. Ex. 1003, ¶¶ 55-68.

D. "*telemetry means to remotely control said predetermined program(s)*" (claim 21)

Again, a POSITA would not have understood the term "*telemetry means*" to have a sufficiently definite meaning as the name for structure, thus confirming that the term is a means-plus-function term. Ex. 1003, ¶ 69. The stated function for this term is to "*remotely control said predetermined program(s).*"

Under the BRI standard and to the extent there is written description support, the claimed function is achieved in the '307 patent by an implanted pulse generator via an external programmer connected to a remote device. *Id*., ¶ 71.

As described above, one example structure in the '307 patent's specification for "*telemetry means*" is the structure of Fig. 47 including the "coil 399," the "amplifier," the "driver," the "decoder ," the "encoder," the "control & error detection," "pulse generator logic," "reed switch," and "debouncer" in the IPG 391. *Id*., ¶¶ 72-74.

According to the specification of the '307 patent, the function of the "telemetry means" is performed in the IPG via the programmer 85 connected to a remote device, such as a physician's computer. Ex. 1001, 31:47-50; Ex. 1003, ¶ 77. The specification indicates that the programmer 85 may be connected to a remote computer giving the attending physician full control for activating and de-activating selected programs on the IPG.

Thus, the above-discussed example of the structure for "*telemetry means*" (i.e. the "coil 399," the "amplifier," the "driver," the "decoder ," the "encoder," the "control & error detection," and the "pulse generator logic" in Fig. 47 of the '307 patent) may perform the function "to remotely control said predetermined program(s)," via the programmer 85 of Fig. 47 connected to a remote device. *Id*., ¶¶ 69-82.

V. EFFECTIVE FILING DATE OF THE CHALLENGED CLAIMS

A. Legal Principles

A patent, such as the '307 patent, that issues from a continuation-in-part application may only claim the parent application's priority date if the parent's specification contains written description support for every element of a claim in question. *See In re Chu*, 66 F.3d 292, 297 (Fed.Cir.1995). The analysis is performed on a claim-by-claim basis. *Lucent Techs., Inc. v Gateway, Inc*., 543 F.3d 710, 718 (Fed. Cir. 2008).

A disclosure satisfies the written description requirement if it reasonably conveys to those skilled in the art that the inventor possessed the claimed subject matter as of the date in question. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (all limitations sufficiently described, not just obvious).

Furthermore, for means-plus-function claim terms, a parent application must disclose *each of* the corresponding structures disclosed in a continuation-in-part application for the patent to obtain the earlier filing date. *Automotive Techs. Int'l, Inc. v. Delphi Corp.*, 776 F. Supp. 2d 469, 492 (E.D. Mich. 2011)[1]. This means that parent/grandparent applications must disclose each of the means-plus-function structures from the'307 patent.

[1] The PTAB has acknowledged that there is not "a clear and binding resolution of [this] specific legal issue," deferring further consideration. *Medtronic, Inc., v Miazi Licensing Corp.*, IPR2018-00609, Decision to Institute, Paper No. 8, pp. 14-15 (Aug. 20, 2018). However, for reasons presented in *Automotive Techs.*, Petitioner asserts that the court reached the correct result.

B. Analysis

1. The priority documents do not support means-plus-function elements of claims 1 and 18

The claim element having the "programming means" of claim 1, and the claim element having the "means for" of claim 18 are both means-plus-function terms as discussed previously. As explained earlier, the function is "activating and/or programming the claimed implanted pulse generator using bi-directional inductive telemetry to exchange data with said implanted pulse generator." The structure corresponding to the claimed function is a "programmer" of Fig. 47 of the '307 patent, having an encoder and driver for transmission, an amplifier and decoder for reception, coils for bi-directional inductive telemetry, a microprocessor, and a magnet. The "programmer" also includes, from Fig. 48, the oscillator, NOR gate, the amplifier, the phase shift detector, the comparator, and coils, as configured therein. Ex. 1003, ¶ 86.

In order for the '307 patent to obtain the benefit of the filing date of parent Application No. 10/196,533 ("CIP Parent") or grandparent Application No. 10/142,298 ("CIP Grandparent") (collectively "Priority Applications"), the application in question must disclose each of the corresponding structures from the'307 patent associated with the means-plus-function terms, which means the Priority Applications must reasonably convey to a POSITA the structure described above. The Applicant added disclosure to the specification of the '307 patent as

compared to the Priority Applications. At a minimum, Figs. 34-65B (and associated description) were added to the '307 patent specification compared with the Priority Applications. Ex. 1003, ¶¶ 88-89.

For example, the disclosure of the "programmer 85" in Figs. 47 and 48 was added to the '307 patent specification compared to the Priority Applications. The Priority Applications do not disclose (thus neither reasonably convey) the structure of "programmer 85" in Figs. 47 and 48 of the '307 patent. In other words, the Priority Applications do not disclose a device having (1) an encoder and driver for transmission, an amplifier and decoder for reception, coils for bi-directional inductive telemetry, a microprocessor, and a magnet; and (2) the oscillator, NOR gate, amplifier phase shift detector, comparator and coils, configured as shown in Fig. 48. Ex. 1003, ¶ 89.

In addition, at least parts of the following documents were incorporated by reference into CIP Parent: App. No. 09/837,565 (now U.S. Patent No. 6,662,052 ("*Sarwal-052*")) and U.S. Patent No. 6,366,814 ("*Boveja-814*"). *See* Ex. 1006, pp. 23-24.

Neither of *Boveja-814* nor *Sarwal-052* discloses the structure of the "programmer" 85 of Fig. 47, including the circuit of Fig. 48 of the '307 patent. In fact, there was no "programming" of an IPG disclosed because the implantable devices of those references were passive (e.g., contained no memory). Ex. 1003, ¶ 92. For example, the Applicant admitted as much for *Sarwal-052* during the

prosecution history, stating: "The implantable circuitry of Sarwal et al. '052, and Boveja '359 comprises only passive components." Ex. 1002, p. 193.

In summary, the priority documents (CIP Parent, CIP Grandparent, *Boveja-814*, and *Sarwal-052*) do not provide adequate written description support for the means-plus-function claim elements of claims 1 and 18. Ex. 1003, ¶ 93.

2. The priority documents do not support "at least two predetermined/prepackaged programs" stored in an IPG

Claim 1 recites: "at least two predetermined/pre-packaged programs of neuromodulation therapy stored in memory of said implantable pulse generator." Claim 18 similarly recites: "at least two predetermined/pre-packaged programs of stimulation therapy stored in said memory to control said electrical pulses emitted by said implantable pulse generator." There is no written description support for either of these two claim elements in the priority documents. Ex. 1003, ¶¶ 94-104.

The CIP Parent never uses the term "prepackaged." The CIP Parent discloses at most "pre-determined" programs in an external pulse generator of Figure 25. *See* Ex. 1006, p. 23. Turning to Fig. 34, the CIP Parent describes two modes of operation of the implanted device once it is charged: a "DEMAND" mode and an "AUTO" mode. Programming of the values to be used in the implanted device is performed by programmer unit 250 communicating

information to memory 214 of the internal pulse generator. *See* Ex. 1006, pp. 29-30.

The "DEMAND" mode does not satisfy the claim limitation in question because the "ON" and "OFF" times are controlled by the user, so these times are not "stored in memory of said implantable pulse generator" (as required by claims 1 and 18). Ex. 1003, ¶ 99. In addition, there is no disclosure of "two predetermined/prepackaged programs" for use in AUTO mode. For example, there is no mention or discussion of any way to determine which of more than one program would have been used in AUTO mode. *Id*. Rather, CIP Parent discloses that "the digital programming information is captured by memory 214," and "[i]n the automatic mode (AUTO), the implanted stimulator turns ON and OFF automatically according to the programmed values for the ON and OFF times." Ex. 1006, p. 31.

The CIP Grandparent has even less disclosure than CIP Parent and also does not disclose the structure of '307 patent Figure 47 or "pre-packaged" programs stored in IPG memory. Ex. 1003, ¶ 100.

Next the documents incorporated by reference into the CIP Parent are analyzed. *Sarwal-052* does not disclose "two programs" stored in memory of an IPG, much less two "predetermined/prepackaged programs" as claimed in claims 1 and 18. The Applicant admitted as much during prosecution of the '307 patent. Ex. 1002, p. 193. ("There is simply no disclosure or even a suggestion in the Sarwal

'052 … to have a microprocessor, memory, and power - source in the implantable components.") Thus, the implantable devices of *Sarwal-052* were not even capable of storing any programs, much less the claimed "at least two predetermined/prepackaged programs" in an IPG. Ex. 1003, ¶¶ 101-102.

Boveja-814 discloses a passive implantable device in Fig. 11, which is incapable of storing any programs for the reasons given above by the Applicant in the prosecution history of the '307 patent. Ex. 1003, ¶ 103.

3. Summary

In summary, the disclosures of the priority documents do not provide adequate written description for at least two claim elements of independent claims 1 and 18. Accordingly, the challenged claims of the '307 patent (claims 1 and 18 and claims depending therefrom) are not entitled to an earlier filing date than the filing date of the '307 patent. As a result, the earliest effective date of the challenged claims is May 8, 2004. Ex. 1003, ¶¶ 104-107.

VI. LEVEL OF ORDINARY SKILL IN THE ART

The level of ordinary skill in the art may be reflected by the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Here, a POSITA at the time of the earliest priority date of May 8, 2004 would have had a bachelor's degree in electrical engineering, biomedical engineering, or similar field, and two to three years of experience in devices and systems utilized for

neuro- and/or neuromuscular stimulation, or equivalent. Furthermore, a person with more technical education but less experience could also meet the relevant standard for POSITAs. Dr. Richard T. Mihran, whose declaration this Petition cites, was at least a POSITA as of the priority date. Ex. 1003, ¶¶ 108-113.

VII. SUMMARY OF '307 PATENT PROSECUTION HISTORY

The application leading to issuance of the '307 patent was filed on May 8, 2004 and assigned serial number 10/841,995. As explained above, the claims of the '307 patent are not supported by the earlier filed CIP Parent and CIP Grandparent applications.

In an Office Action dated November 1, 2005, the Examiner rejected the initially filed claims under 35 U.S.C. § 102(b) as being anticipated by U.S. 5,304,206 to Baker ("*Baker*") (referred to in prosecution history as "Baker '206"). Ex. 1002 at 166-168. The Examiner asserted that *Baker* disclosed "a microprocessor based programmable pulse generator 10 implanted in the body of a patient 30, and a lead 22 in electrical contact with the implantable pulse generator 10 and further comprising stimulating electrodes 25 adapted to be in contact with the vagus nerve 27 upon activation of a predetermined program." *Id*. at 167.

The Applicant submitted an Amendment and Response dated December 7, 2005, which amended independent claim 1 (with similar amendments to independent claim 21(issued claim 18)) as set forth below.

1 (currently amended): A method of providing electrical pulses to a vagus nerve(s) of a patient for treating or alleviating the symptoms of at least one of neurological, neuropsychiatric, and obesity disorders, comprising the steps of:

[a)] providing a microprocessor based implanted pulse generator[;], wherein said pulse generator comprises ~~at least one predetermined program to deliver said electrical pulses~~ microprocessor, circuitry, memory, and power source;

providing at least two predetermined/pre-packaged programs of said neuromodulation therapy stored in memory of said implantable pulse generator, wherein said predetermined/pre-packaged programs define neuromodulation parameters of pulse amplitude, pulse-width, pulse frequency, on-time and off-time;

[b)] providing an implanted lead in electrical contact with said implanted pulse generator; wherein said implanted lead comprising at least one electrode adapted to be in contact with said vagus nerve(s);

[c)] providing programmer means for activating and/or programming said implanted pulse generator, wherein bi-directional inductive telemetry is used to exchange data with said implanted pulse generator; and

[d)] selectively choosing between at least two predetermined/pre-packaged program and activating said selected program ~~activating said at least one predetermined program to emit said predetermined pulses to said vagus nerve(s)~~.

Id. at 184.

As shown above, among other changes, the applicant deleted "at least one predetermined program to deliver said electrical pulses" and added the limitation of "at least two predetermined/pre-packaged programs of said neuromodulation therapy stored in memory of the implantable pulse generator."

While recognizing that *Baker* provides the patient with the ability to manually adjust the stimulation signals, the applicant stated: "the finger tapping or the 'bracelet' would be using only for patient activated situations such as epilepsy where either an 'aura' occurs or there is vigorous repetitive motion such as during a seizure." Id. at 195. As discussed further below, the Applicant's characterization of *Baker* is not accurate, as *Baker* does not limit the patient's selection of stimulation levels to particular times or events. Moreover, *Baker* does not require tuning with synchronization/desynchronization feedback. Ex. 1003, ¶¶ 118-122.

Still further in the response, the Applicant argued "[i]n contrast, Applicant's invention is based on providing therapy for depression, and other neuropsychiatric and neurologic disorders with predetermined/pre-packaged programs." Ex. 1002, p. 195 (emphasis in original). The applicant continued to stress that the claims are directed to "predetermined/pre-packaged programs" and that "[t]here is simply no disclosure or even a suggestion in the prior art teaching to have predetermined/pre-packaged programs as in the Applicant's disclosure." *Id*., 196.

Despite Applicant's assertion that the use of "predetermined/pre-packaged programs" did not exist in the prior art, the Examiner located U.S. 6,760,626 to Boveja ("*Boveja-626*") which discloses the use of a limited number of predetermined/pre-packaged programs as default stimulation programs that may be selected by the patient. The Examiner utilized the *Boveja-626* patent and its

disclosure of predetermined/prepackaged programs to reject the claims under 35 USC §§102(e) and 103 in the Office Action of January 23, 2006. *Id*. at 232-236.

In a response filed March 16, 2006, Applicant argued that the *Boveja-626* patent is not prior art to the '307 patent and cannot be properly combined with other references in the rejection. *Id*. at 258-259. Specifically, the inventors submitted declarations that they were obligated to assign the concepts of the '307 patent to a future entity that would also hold the rights to the *Boveja-626* patent. *Id*. at 270-271. The Applicant submitted an assignment to the new entity and filed a terminal disclaimer linking the term of the '307 patent to the term of the *Boveja-626* patent. *Id*. at 273. Ex. 1003, ¶¶ 123-125.

On April 14, 2006, a Notice of Allowance issued in response to the communication of March 16, 2006. Ex. 1002 at 301.

VIII. TECHNOLOGY OVERVIEW

The '307 patent relates to a specific application of nerve stimulation referred to as Vagus Nerve Stimulation (VNS). VNS is a subset of a more general class of therapy known as neuromodulation, which encompasses a broad array of therapies utilizing electrical stimulation to treat a variety of medical conditions. In addition to VNS, such therapies include spinal cord stimulation (SCS); deep brain stimulation (DBS); peripheral nerve stimulation (PNS) and various forms of

transcutaneous electrical nerve stimulation (e.g., TENS); among others. Ex. 1003, ¶ 245.

VNS technology development occurred in parallel with these and other neuromodulation modalities, and thus a POSITA involved with vagus nerve stimulation systems would have been aware of this larger body of prior art. Moreover, the underlying technology of implantable pulse generators (IPGs) and non-invasive programming systems evolved from a yet-larger technological foundation provided by the early development and extensive clinical use of cardiac pacemaker systems, which began in the 1960s. *Id*., ¶¶ 253-265 (citing Ex. 1012, 1035-1038, 1047). Thus, a POSITA involved with VNS systems was also keenly aware of the body of prior art associated with cardiac pacemaker IPGs and programming systems and would commonly draw upon these closely-related pacemaker system technologies to apply to VNS and other neuromodulation systems. *Id*., ¶¶ 250-252.

IPGs used for VNS are physically and functionally similar to a traditional programmable pacemaker and typically deliver stimuli to the left vagus nerve bundle via bipolar electrodes disposed within a flexible helical structure and surgically placed on the vagal nerve. Stimulation of the left vagus nerve for the treatment of epilepsy is preferred to limit the adverse side effects that can be generated when the right vagus nerve is stimulated. Ex. 1003, ¶¶ 249, 266. This is

illustrated, for example in Figure 1 of the 1990 publication, Ex. 1025, reproduced below. Ex. 1003, ¶ 249.

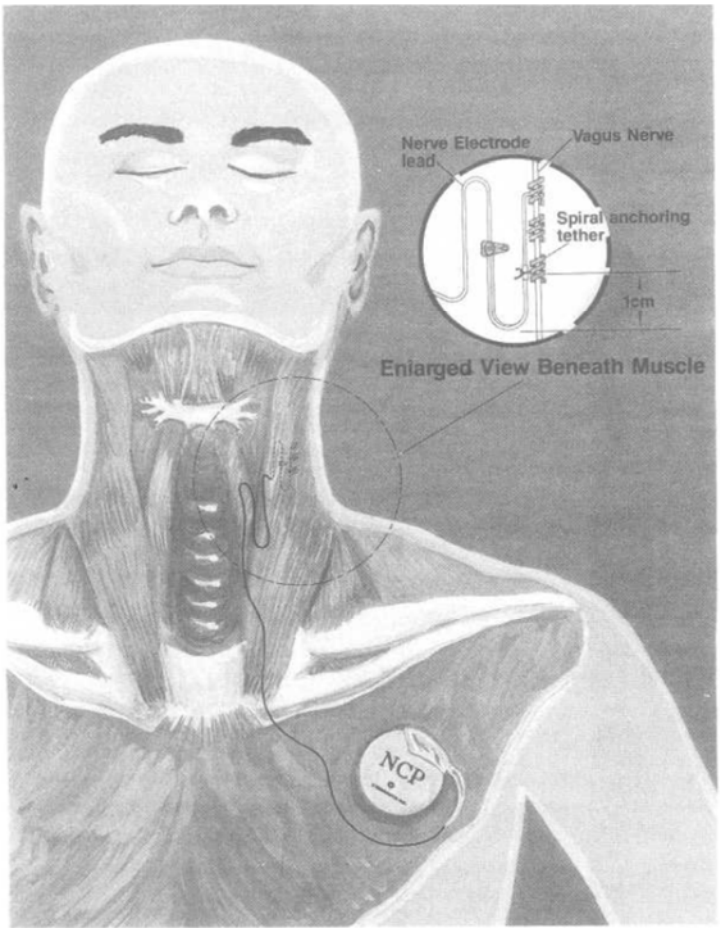


FIG. 1. Implant detail of neurocybernetic prosthesis.

Ex. 1025, Figure 1, NCP and Helical Electrode

The reference to NCP refers to a system, known as the implantable neurocybernetic system, or NCP, offered commercially by Cyberonics after it received FDA approval in 1997. Ex. 1003, ¶ 247. Cyberonics merged with Sorin in 2015 to become LivaNova.

In addition to commercial products, the Cyberonics VNS technology was described in patents and publications dating back to the late 1980s. Similar devices

and systems were also being investigated for VNS to treat an array of neurological, psychiatric and other indications, such as depression, dementia, obesity, and endocrine disorders, well before 2004. *Id*., ¶ 248 (citing numerous exhibits).

In utilizing early IPGs based on pacemaker technology, it was recognized that they had a relatively short battery life. Battery technology available for implantation continued to advance along with a reduction in size and power consumption of both memory and processors. POSITAs in the field were aware of improvements in long-term battery effectiveness and readily adopted such technology. For example, Cyberonics continued to improve its commercially available neurostimulator devices with the launch of the Model 101 IPG described in a journal article from 2001, with the new model described as having a battery life that usually ranges "from 10 to 12 years at low stimulation settings." Ex. 1010, p. 3; Ex. 1003, ¶ 300.

IX. OVERVIEW OF THE '307 PATENT

The '307 patent discloses "[a] method and system for neuromodulating vagus nerve(s) to provide therapy for neurological and neuropsychiatric disorders [that] comprises implantable and external components," and identifies the field of the invention as "relat[ing] to neuromodulation, more specifically neuromodulation of vagus nerve with pulsed electrical stimulation, to provide therapy for neurological and neuropsychiatric disorders. Ex. 1001, Abstract, 1:24-27. In

particular, the '307 patent discloses that "[t]he pulsed electrical stimulation to vagus nerve(s) is used for disorders such as epilepsy, depression, anxiety disorders, neurogenic pain, compulsive eating disorders, obesity, dementia including Alzheimer's disease, and migraines." *Id*., Abstract.

The '307 patent lists a variety of known systems to deliver "pulsed electrical stimulation to vagus nerve(s)." *Id*. As explained by Dr. Mihran, all of these embodiments were known in the art of neuromodulation well before May 8, 2004. *See* Ex. 1003, ¶¶ 129-131, 139, 153-154, 162-163, 171-172.

The '307 patent discloses that "programs consist of specific parameters and each unique program will be stored sequentially in long-term memory." Ex. 1001, 14:66-15:1. These parameters, "which can be individually programmed, include variables such as pulse amplitude, pulse width, frequency of stimulation, stimulation on-time, and stimulation off-time." *Id*., 15:23-51. An example of the range of values suggested for these parameters is provided in Table 2, reproduced below:

TABLE 2

Electrical parameter range delivered to the nerve

PARAMER	RANGE
Pulse Amplitude	0.1 Volt–10 Volts
Pulse width	20 μS–5 mSec.
Frequency	5 Hz–200 Hz
On-time	10 Secs–24 hours
Off-time	10 Secs–24 hours

These stimulation pulse parameters and their suggested ranges were known for a variety of neuromodulation applications, including VNS, well prior to the purported invention. Ex. 1003, ¶ 138. The '307 patent further discloses that groups of these parameters may be arranged as "predetermined" programs to provide default initial settings some of which can be built into the IPG as "pre-packaged" programs. The values in the pre-packaged programs may later be modified after implantation using a programming wand to perform "custom" programming of the IPG.

However, the use of both "predetermined/pre-packaged" programs and "custom" programming of stimulation pulse parameters was well-known prior to May 8, 2004. *Id*., ¶ 140-146 (citing *Boveja-814* and *Meadows*).

As Dr. Mihran explains in his declaration, after reviewing the '307 patent, he believed that portions of the '307 patent figures and written description derived from the work of others. Ex. 1003, ¶ 132. Dr. Mihran utilized searching techniques, similar those used to evaluate student submissions for plagiarism, to identify the source of the reproduced material. *Id.*

While not exhaustive of all areas that may come from other sources, it appears likely that at least Figs. 30, 35, 36, 37B, 38A, 38B, 41, 45A, 46A-53, 55 and 64 of the '307 patent, along with the associated written description, were reproduced from other sources. *See* Ex. 1003, ¶¶ 152-154, 172-223, 241.

Of particular importance are those specific embodiments in the '307 patent that arguably support the challenged claims – for example, programming of the IPG is described at col. 25:60–28:30, in conjunction with Figures 45-52. Each of the independent claims was amended during prosecution to contain a programmer "means," "wherein bi-directional inductive telemetry is used to exchange data with said implanted pulse generator." Sources of material for the '307 patent specification are highlighted below.

A. Bi-Directional Inductive Telemetry – Same as *Webster*

To support the claimed "bi-directional inductive telemetry" aspects of the "programmer means" claimed in the '307 patent, the specification presents a series of drawings at Figures 47-53 along with extensive accompanying description spanning 26:13–28:30. Dr. Mihran recognized that this disclosure is strikingly and substantively similar to Chapter 12 of the well-known textbook, "Design of Cardiac Pacemakers," edited by J.G Webster. ("*Webster*") (Ex. 1011). Ex. 1003, ¶¶ 203-230 (*see* figure-for-figure comparison).

For example, Figure 47 of the '307 patent is reproduced below in juxtaposition with Figure 12.1 of *Webster*:

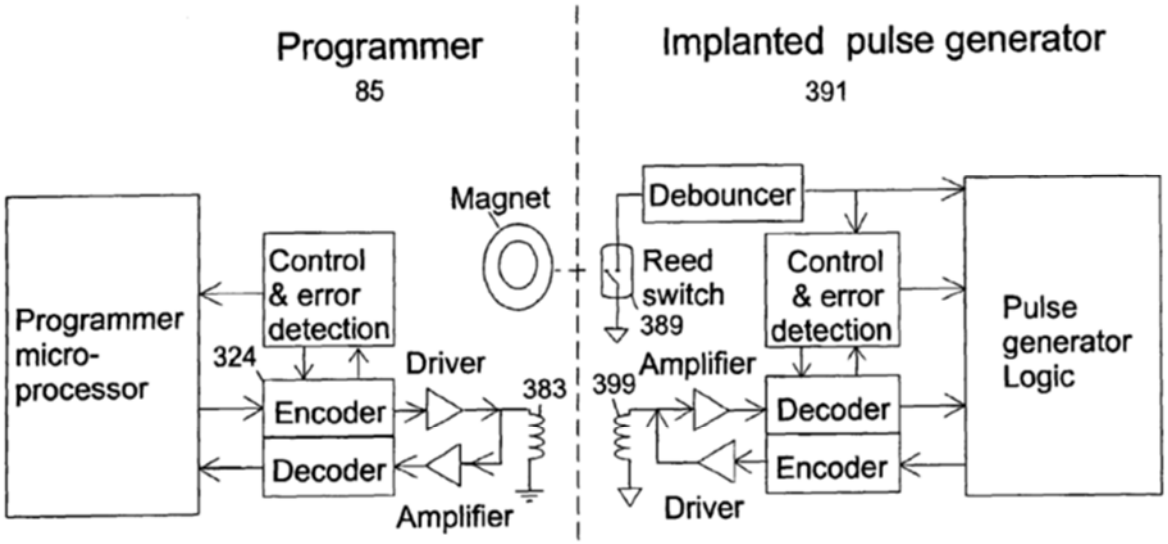


FIG. 47

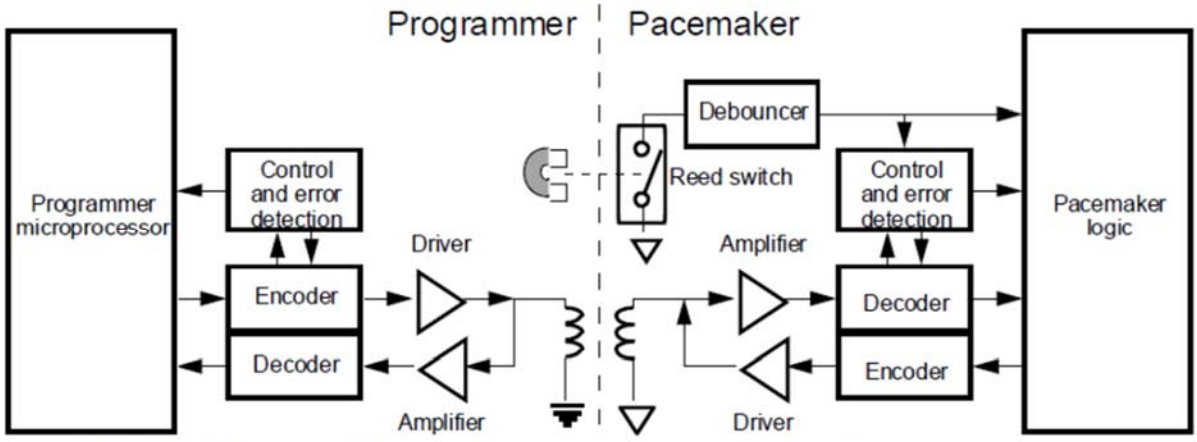


Figure 12.1 Block diagram of pacemaker programming and telemetry interface.

Ex. 1001, Fig. 47 (top) and Ex. 1011, Fig. 12.1 (bottom)

As can be seen in the figures above, other than the substitution of the word "pulse generator" in Fig. 47 of the '307 patent for "pacemaker" of Fig. 12.1 of *Webster*, these figures are substantively identical. Ex. 1003, ¶¶ 209-210. Notably,

Figs. 47-52 of the '307 patent help define the means-plus-function terms of claims 1 and 18.

B. Telecommunications Module – Same as *Lee*

Dr. Mihran also identified the apparent source of the figures and text disclosing the telecommunications module. As an example, Fig. 64 of the '307 patent depicts how "the external stimulator 42 and/or the programmer 85 may also be networked to a central collaboration computer 286 as well as other devices such as a remote computer 294, PDA 502, phone 141, physician computer 143," and is reproduced below.

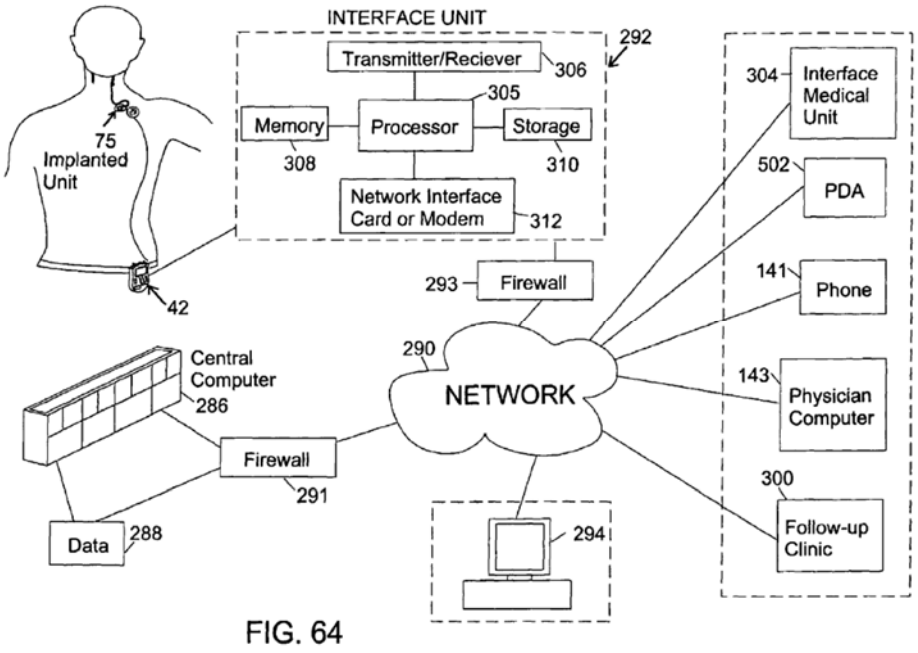


FIG. 64

Ex. 1001, Fig. 64

As shown in Figs. 1 and 2 of U.S. Patent No. 6,442,432 to Lee ("Lee"), Fig. 64 of the '307 patent (above) substantially mirrors Figure 1 of *Lee* (reproduced below). Ex. 1003, ¶¶ 241-244.

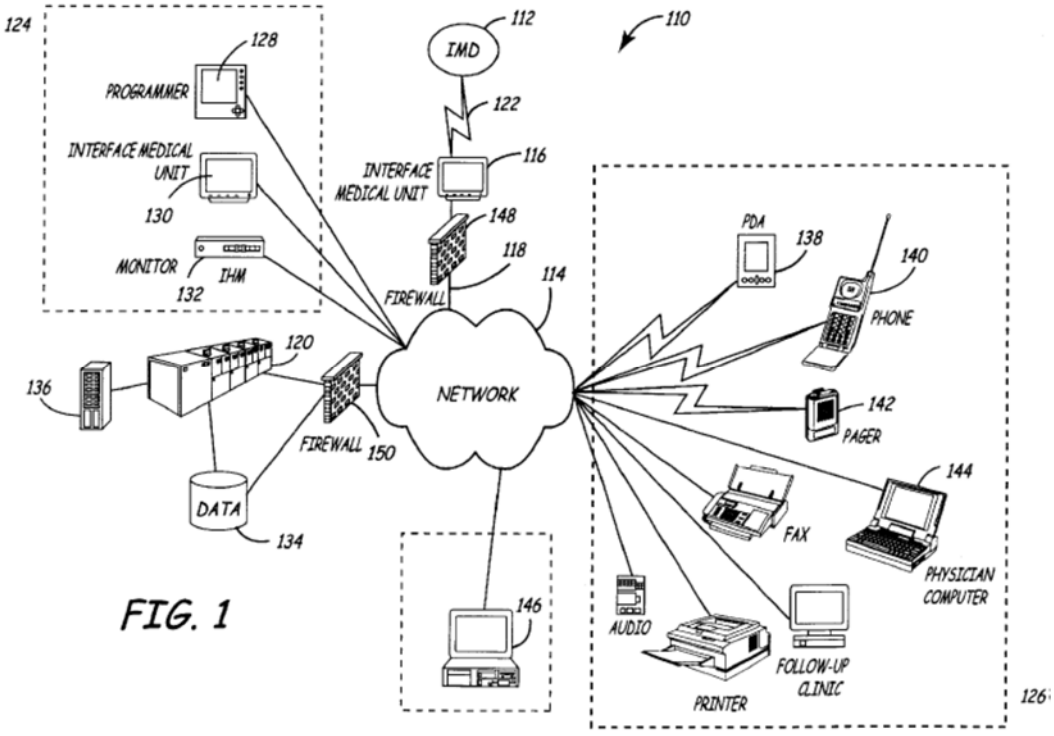
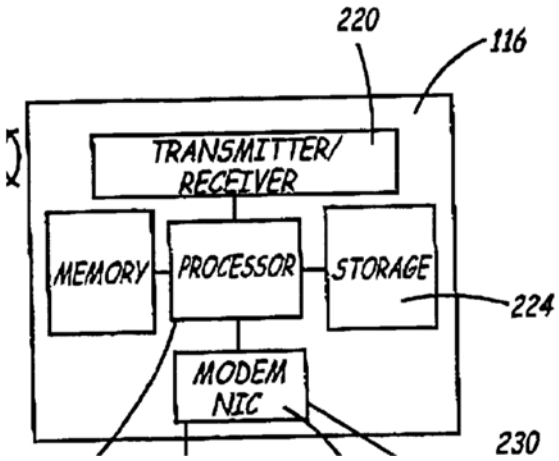


FIG. 1

Ex. 1013, Fig. 1

Further, the interface unit 292 of the '307 patent (in Fig. 64 above) is similar to the interface unit 116 of Fig. 2 of *Lee* (below).



X. REQUESTED RELIEF

Petitioner asks that the Board review the accompanying prior art and analysis, institute a trial for *inter partes* review of the challenged claims and cancel those claims as unpatentable.

XI. IDENTIFICATION OF CHALLENGE

A. Challenged Claims and Statutory Grounds

This Petition challenges claims 1-8, 10-12, 18-23, and 25-28 of the '307 patent on the following grounds.

Grounds	Claim(s)	Basis
Ground 1	1-5, 7, 8, 10-12, 18-23, and 25-28	35 U.S.C. §103 over the combination of *Baker*, *Boveja-814*, and *Webster*
Ground 2	6	35 U.S.C. §103 over the combination of *Baker*, *Boveja-814*, *Webster* and *Lee*

B. Status as Prior Art

As shown herein, the earliest effective filing date of the '307 patent is May 8, 2004. *Baker* is a U.S. patent issued on April 19, 1994, *Boveja-814* is a U.S. patent issued on April 2, 2002; and *Lee* is a U.S. patent issued on August 27, 2002, making each prior art under 35 U.S.C. § 102(b).

Webster (Ex. 1011) is a textbook that was publicly available no later than April 27, 1996 and is therefore prior art under 35 U.S.C. § 102(b). For example, based on Library of Congress (LC) bibliographic records, LC records of receiving and cataloging *Webster*, and the LC date stamp on an actual copy of *Webster*, *Webster* was available for access such that persons of ordinary skill could have located and accessed *Webster* in the LC no later than April 27, 1996. Ex. 1014, ¶¶ 17-22, 32. (In addition, based on records of cataloging in the Naval Academy Nimitz Library (NAL) and based on NAL markings on an actual copy of the textbook containing a copy of *Webster*, a copy of *Webster* was available for access such that persons of ordinary skill could have located and accessed *Webster* in the NAL no later than February 6, 1997. *Id*., ¶¶ 25-32.)

Secondary references *Rise* and *Valencia* are journal articles published more than one year before May 8, 2004, making these references prior art under 35 U.S.C. § 102(b). *See* Ex. 1003, ¶ 296, n. 12 and ¶ 300, n. 13 (citing Exs. 1039 and 1040).

C. Challenges Not Redundant of Prosecution

The present grounds of unpatentability are not redundant of the prosecution of the '307 patent. Specifically, while *Baker* was applied during prosecution, the other references, *Boveja-814*, *Webster* and *Lee*, were not part of the file history. Further, the disclosure of *Boveja-814* contradicts the applicant's assertion "[t]here is simply no disclosure or even a suggestion in the prior art teaching to have predetermined/pre-packaged programs as in the Applicant's disclosure." Ex. 1002 at 196.

XII. IDENTIFICATION OF HOW THE CLAIMS ARE UNPATENTABLE

A. Ground 1: Claims 1-5, 7, 8, 10-12, 18-23, and 25-28 are unpatentable under 35 U.S.C. §103(a) over the combination of *Baker, Boveja-814,* and *Webster*

1. Summary of *Baker*

Baker's IPG allows the stimulation parameters of pulse amplitude, frequency, and delay to be programmed using coded sequences of taps, as well as to provide for manual activation and inactivation of stimulation using additional coded sequences. The idea is not to replace external programming of these and other stimulation parameters, but rather to provide "patient[s] … with a ***limited amount of control*** over the operation of the device, to an extent determined to be appropriate for the particular patient by the attending physician." Ex. 1012, 3:54-57; Ex. 1003, ¶ 279.

Baker contemplates that parameters other than amplitude, frequency, and delay are programmable. For example, the logic and control section of the IPG "controls the ***programmable*** functions of the device, such as current or voltage, frequency, pulse width, on-time and off-time of the output pulses generated by the genrator [*sic*]." Ex. 1012, 1:66 to 2:2.

Baker discloses an external programmer for programming the IPG as including a "programming wand" and "computer" "for adjustment of parameters." *Id*., 2:55-61. The external programmer comprising computer 35 coupled to programming wand 33 is depicted in Figure 2 of *Baker* and permits bi-directional communication between the implanted pulse generator and the external programmer. *Id*., 2:11-20.

In an embodiment, *Baker* discloses circuitry that responds to a patient physically tapping the IPG to select output parameters (e.g., pulse amplitude and pulse frequency) for the IPG. For example, *Baker* explains:

> "Another embodiment includes programming the device to ***recognize a particular coded pattern or sequence of the taps*** so that, for example, ***if the device is currently in its stimulating state*** the coded sequence may be used to deactivate (turn off) the device or ***to increase or decrease the output pulse amplitude and/or frequency***."

Id., 3:44-49. Thus, the device is pre-programmed to correlate a number of taps to changes in pulse amplitude and/or frequency. Ex. 1003, ¶¶ 279-285.

2. Summary of *Boveja-814*

Boveja-814 describes storing "pre-determined" and "pre-packaged" programs having the same parameters as *Baker* in the memory of an external stimulation that may be used for VNS and just like *Baker*, give the patient limited control to adjust stimulation. For example, *Boveja-814* discloses:

> "The external stimulator containing ***limited number of predetermined programs packaged into the stimulator***, giving the patient or caretaker a way to adjust the therapy within confined limits, or turn the device off. The ***pre-packaged programs contain unique combination of pulse amplitude, pulse width, frequency of stimulation, and on-off time***."

Ex. 1008, Abstract; Ex. 1003, ¶ 286.

Boveja-814 teaches any number of programs (e.g., up to 60) stored in an external stimulator. Ex. 1008, 14:14-24. *Boveja-814* recognizes the ease and convenience of having a subset of pre-packaged programs out of "millions of different [possible] combinations" pre-selected for the patient. *Id*., 8:38-46. *Boveja-814* further explains that the programs are stored in memory of the stimulator. *Id*., 15:44-51. *Boveja-814* also provides examples of the different types of therapies provided by different predetermined/pre-packaged programs:

The following are examples of least aggressive therapy.
Program #1:
1.0 mA current output, 0.2 msec pulse width, 15 Hz frequency, 15 sec ON time-1.0 min OFF time, in repeating cycles.
Program #2:
1.5 mA current output, 0.3 msec pulse width, 20 Hz frequency, 20 sec ON time-2.0 min OFF time, in repeating cycles.
The following are examples of intermediate level of therapy.
Program #5:
2.0 mA current output, 0.2 msec pulse width, 25 Hz frequency, 20 sec ON time-1.0 min OFF time, in repeating cycles.
Program #6:
2.0 mA current output, 0.25 msec pulse width, 25 Hz frequency, 30 sec ON time-1.0 min OFF time, in repeating cycles.
The following are examples of most aggressive therapy.
Program #8:
2.5 mA current output, 0.3 msec pulse width, 30 Hz frequency, 40 sec ON time-1.5 min OFF time, in repeating cycles.
Program #9:
3.0 mA current output, 0.4 msec pulse width, 30 Hz frequency, 30 sec ON time-1.0 min OFF time, in repeating cycles.

Id., 14:39-67; Ex. 1003, ¶ 287.

As pointed out by *Boveja-814*, using an RF-coupled external stimulator was an alternative to a fully-implantable pulse generator with internal power source (as used in *Baker*). *See* Ex. 1008, 9:66-10:5. Storing parameter values in the external stimulator of *Boveja-814* was an alternative to storing them in an implantable device, such as in *Baker*. These commonly employed alternatives had well-known trade-offs as discussed further herein. Ex. 1003, ¶ 288.

3. Reasons to Combine *Baker* and *Boveja-814*

As discussed above, *Baker* teaches that parameters are programmed into the memory of an implantable pulse generator, and teaches the utility of providing the patient with a limited number of different stimulation outputs from which the patient can select using coded sequences of taps. Ex. 1003, ¶ 289. *Baker* does not expressly disclose the initial parameter values a patient may select or when they are stored in memory, so a POSITA would look to other references such as *Boveja-814* for such implementation details. *Id.*

It was well known that stimulation systems may be implemented as fully implanted IPGs, as disclosed in *Baker*, or alternatively, as RF-coupled transmitter/receivers, as is disclosed in *Boveja-814.* The considerations involved in making this design choice were well-known to those of ordinary skill in the art, and the methods used for combining elements of these systems would be predictable. Thus, implementing program storage as disclosed in *Boveja-814* in IPG memory such as *Baker* represents an obvious design choice, as the trade-offs between different types of stimulator systems were well-known in the art of neuromodulation long before the earliest priority date of the ’307 patent. These engineering trade-offs are summarized below. Ex. 1003, ¶ 290.

i. Energy demands of the neuromodulation v. patient convenience

As discussed herein, neural stimulators configured as both fully implantable

IPGs such as disclosed in *Baker* and external pulse generators ("EPG") such as disclosed in *Boveja-814* have been known for decades, and each of these types of systems have been applied to a wide variety of applications in the neuromodulation field, including VNS. While the requisite technology to build and use IPGs capable of delivering pulses at high average power levels has long been available, the battery technology for long periods was still developing in the late 1990's. Ex. 1003, ¶ 291.

As recognized in *Boveja-814*, "battery drain is typically much higher for nerve stimulation applications than for cardiac pacemakers." Ex. 1008, 10:4-5. *Boveja-814* recognizes several advantages to EPG systems. *Id*., 10:15-52 (including less implanted hardware, easier to implant and remove implanted device, implanted device power not limited by on-board power source). Ex. 1003, ¶¶ 292-293. At the same time, it was widely understood that systems, such as *Boveja-814*, were relatively burdensome on patients, and the bulky external components that the patient was required to carry or wear to receive therapy placed restrictions on certain activities. (*see e.g. Boveja-814* Fig. 4 and 11:47-50 showing wearing of stimulator). *Baker* itself recognized similar benefits of "no need to carry a magnet or other obtrusive device." Ex. 1012, 7:7-18; Ex. 1003, ¶ 297. None of the advantages of *Boveja-814*'s EPG mimics or overcomes the advantage to the patient of not needing an expensive and burdensome external device for external stimulation and storage of corresponding program parameters. Rather, the choice between external power and storage of corresponding program parameters and

internal power and storage of corresponding program parameters represents basic engineering tradeoffs. Ex. 1003, ¶ 294.

The understanding of the trade-offs between externally-powered and internally-powered pulse generators is reflected not only in *Baker* and *Boveja-814* but also throughout the prior art. *See id*., ¶¶ 295-300 (discussing Exs. 1010, 1015, 1022, 1034). For example, *Cullen* explains the disadvantage to a patient of using an external stimulator (coupled to a type of IPG known as a spinal cord stimulator (SCS)) to store various sets of programming parameters. Ex. 1015, ¶¶ [0012]-[0013]. *Cullen* therefore discloses a solution as "a system, method, and implantable pulse generator (IPG) device that stores, on the implantable device, two or more stimulus programs, preferably as prescribed by a doctor." *Id*., ¶ [0021]. Another reference also discusses the well-known tradeoffs between fully implantable neurostimulators, such as that disclosed in *Baker*, and EPGs such as that disclosed in *Boveja-814,* and further articulates the well-known design choice based upon the relative power drain that a particular application or patient may present. Ex. 1034, p. 3 ("RF neurostimulators provide an economically viable alternative when stimulation parameters result in high energy consumption. ***However, RF systems require the patient to deal with the external transmitter components for receiving therapy***.") The prior art also recognized that advances in electronics were leading to sufficient battery life in implantable neurostimulators (e.g., 10 to 12 years at low stimulation settings and up to five years with higher settings). Ex. 1003, ¶ 300

(citing Ex. 1010).

Furthermore, there were no operational or technical hurdles that needed to be overcome to implement the additional memory requirements for storing a small amount of additional data on the IPG itself of *Baker* to hold more than one stimulation program in memory, as taught in *Boveja-814*. *Id.* Moreover, the storing of predetermined parameter values and that those initially stored parameters can later be modified was known in the art, including from at least *Boveja-814*. Ex. 1003, ¶ 301 (also citing Ex. 1010, p. 4).

Therefore, a POSITA would have looked to *Boveja-814* to teach how various initial stimulation parameters may be stored on a device, such as *Baker*'s IPG, to achieve the predictable result of *Baker*'s patient selection of differing levels of stimulation, yielding the benefit of sparing a patient from having to carry/wear an external stimulator. Additional reasons for combining *Baker* and *Boveja-814* are presented in the analysis of claims. *Id*., ¶ 302.

4. Summary of *Webster*

Webster, a textbook, describes and illustrates a "programmer—an external device which communicates programming and telemetry information with the pacemaker." Ex. 1011, Chapter 12, Section 12.1.1, p. 33. Figure 12.1 of *Webster* is reproduced below.

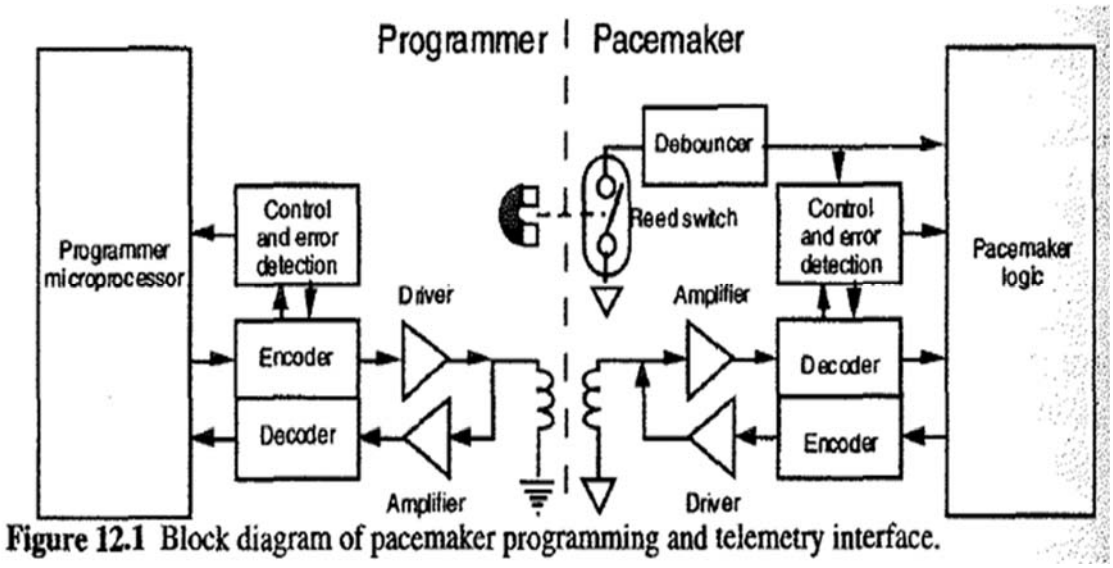


Figure 12.1 Block diagram of pacemaker programming and telemetry interface.

Webster describes how the external programmer communicates "programming and telemetry information with the pacemaker . . . electromagnetically through a set of coils," *Webster*, Chapter 12, Section 12.1.1, p. 33. The "programmer" on the left side of *Webster*'s Figure 12.1 is virtually identical to the embodiment of "programmer 85" in Fig. 47 of the '307 patent. Ex. 1003, ¶¶ 303-305.

5. Reasons to Combine *Baker* and *Webster*

Programming systems for non-invasively modifying the operational parameters of and receiving status and diagnostic data from implanted medical devices were well-known to POSITAs. While *Baker* does not present specific implementation details of the computer or programming wand disclosed in the specification and depicted in Figure 2, a POSITA seeking to design or build *Baker*'s system would be motivated to specify those implementation details, based on known programming systems used with

implanted medical devices such as IPGs. Ex. 1003, ¶¶ 306-311.

Webster is an example that presents details on how to implement a programmer for programming an IPG, and thus a person of ordinary skill in the art would readily recognize the applicability to *Baker*. *Webster*'s "programmer" includes the functionality of *Baker*'s programming wand combined with external computer. *Id*., ¶ 312.

While the programming system disclosed in *Webster* is described in the context of a bi-directional telemetry of an IPG used for stimulating cardiac tissue, i.e. a pacemaker, IPGs used for VNS are physically and functionally very similar to a traditional programmable pacemaker, and in each case, external programmers are used to modify programmable stimulation parameters in the IPG and receive status and diagnostic information from the IPG. *Id*., ¶ 313.

A POSITA involved with VNS systems would have also been keenly aware of the extensive body of prior art associated with cardiac pacemaker IPGs and programming systems, such as disclosed in *Webster,* and would draw upon these closely-related pacemaker system technologies to apply to aspects of VNS, and other neuromodulation systems. *Id*., ¶ 314.

This awareness of the cross-applicability of pacemaker technology with neural stimulators targeting a wide range of neural tissues and conditions is reflected in many patent and academic references from the field of implantable

stimulation devices. Ex. 1003, ¶¶ 315-330 (citing Exs. 1020, 1035-1038). For example, U.S. Patent No. 5,529,578 (Ex. 1047) explains that:

> "The class of implantable medical devices now includes not only pacemakers, but also implantable cardioverters, defibrillators, neural stimulators, and drug administering devices…
>
> As the functional sophistication and complexity of implantable medical devices has increased over the years, it has become increasingly more important for such devices to be equipped with a telemetry system for enabling them to communicate with an external unit."

Ex. 1047, 1:14-30. Another example explains that "[t]ypically [implantable medical] devices are programmable so that they may be adapted to provide the specific treatment" required by a patient," and "[e]xamples are nerve stimulators and cardiac pacemakers." Ex. 1035 (U.S. Patent No. 5,237,991), 1:14-33.

These observations reflect the understanding of those of ordinary skill in the art that the programming and telemetry technologies that had been developed for pacemakers are readily applicable to IPGs used for nerve stimulation, including the IPG of *Baker* utilized for vagus nerve stimulation. Thus, a person of ordinary skill in the art would have been motivated to apply the teachings of *Webster* for implementation details of the bi-directional telemetry function disclosed in *Baker* for programming and monitoring the VNS IPG. *Id*., ¶¶ 330.

6. Claim 1

[1.0] ***A method of providing electrical pulses to a vagus nerve(s) of a patient for treating or alleviating the symptoms of at least one of neurological, neuropsychiatric, and obesity disorders[2], comprising the steps of***

Baker discloses [1.0].

Baker teaches an apparatus and method for treating a disorder by delivering an "electrical waveform" (example "*electrical pulses*") to a "vagus nerve." *Baker*, Abstract. The disorders treatable by the apparatus and techniques of *Baker* include psychiatric and neurological disorders. Ex. 1012, 1:6, Ex. 1003, ¶¶ 332-333.

Baker makes clear that the electrical waveform is delivered to the vagus nerve in the form of pulses. Ex. 1012, 1:66-2:2.

In summary, *Baker* discloses a method of providing electrical pulses to a vagus nerve(s) of a patient for treating or alleviating the symptoms of a psychiatric or neurological disorder, thus disclosing all the features of [1.0]. Ex. 1003, ¶¶ 331-336.

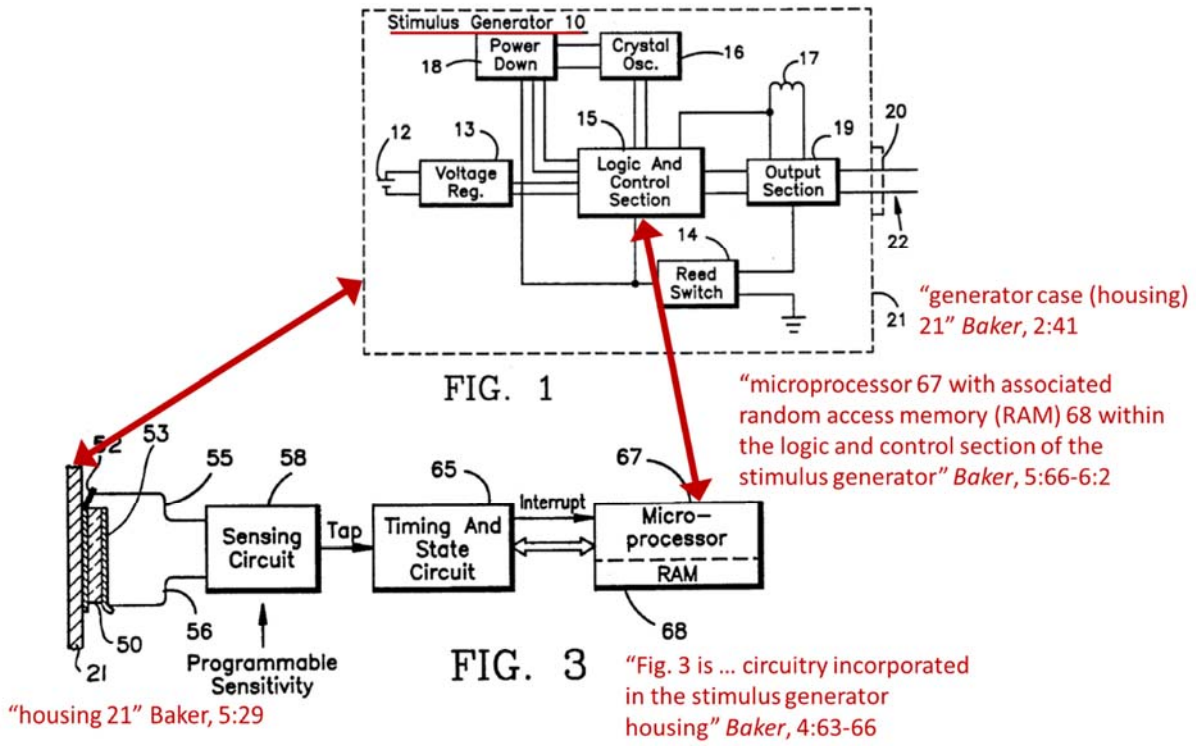
[1.1] ***providing a microprocessor based implanted pulse generator, wherein said pulse generator comprises microprocessor, circuitry, memory, and power source***

Baker discloses all the features of claim element [1.1].

---

[2] The specification does not support a conjunctive reading requiring treatment for all listed conditions. Ex. 1003, p. 179, n. 14.

Baker presents circuitry of an implanted/implantable pulse generator (IPG) in Figure 1. Ex. 1012, 1:46-48 and 4:57-59. More detailed circuitry is presented in Figures 3 and 4. Figures 1 and 3 are combined below according to the description in *Baker*:

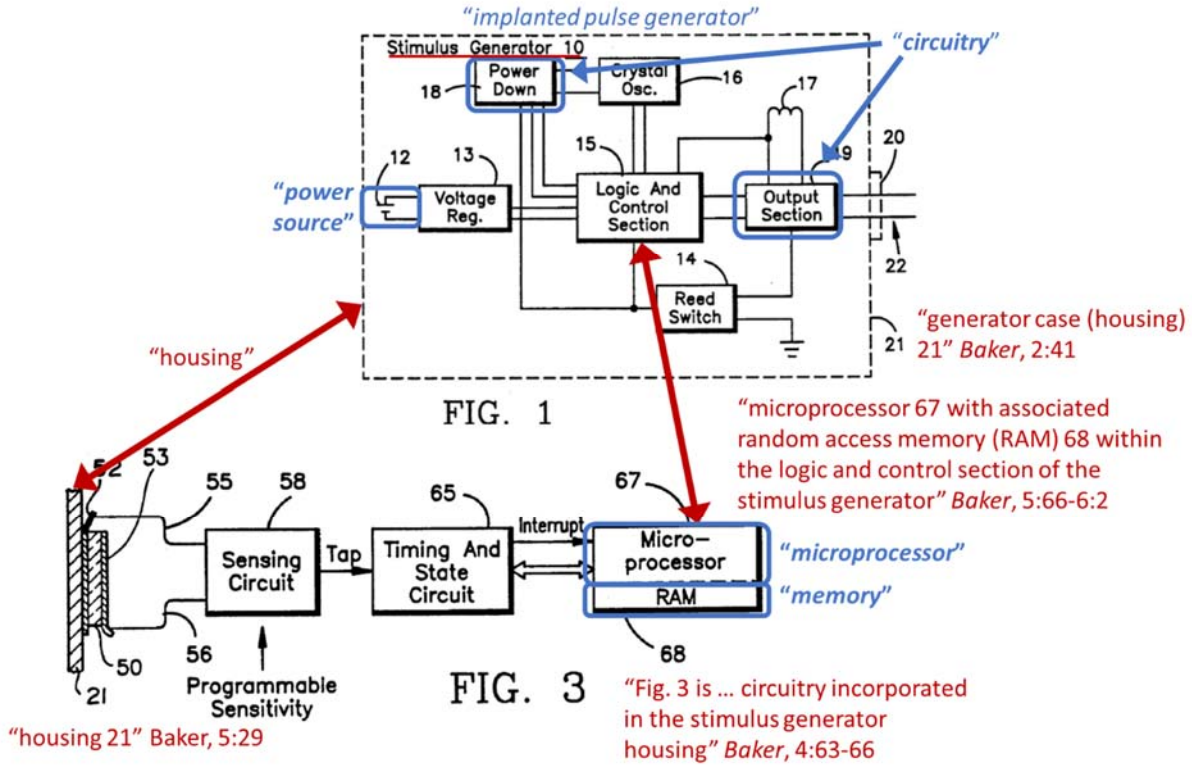


Figs. 1 and 3 (annotated in color); Ex. 1003, ¶ 342

Baker describes a variety of circuitry in the implanted pulse generator of Fig. 1, including a "power down circuit 18" and "output circuit 19." Id., 2:21-43. *Baker* further discloses that its IPG has an example of the claimed "*power source*," as a "battery 12." *Id*., 1:62-64. *Baker* describes the "logic and control section" of the IPG, such as the "logic and control section 15" of Fig. 1, as having a microprocessor and associated memory: "Circuit 65 also receives commands from

the microprocessor 67 with associated random access memory (RAM) 68 within the logic and control section of the stimulus generator." *Id*., 5:66-6:2.

In summary, *Baker* discloses all the features of claim element [1.1], as illustrated below (*see* Ex. 1003, ¶¶ 337-348):



Figs. 1 and 3 (*Baker* quotes in red; claim elements in blue); Ex. 1003, ¶ 347

[1.2] ***providing at least two predetermined/pre-packaged programs of neuromodulation therapy stored in memory of said implantable pulse generator, wherein said predetermined/pre-packaged programs define neuromodulation parameters of pulse amplitude, pulse-width, pulse frequency, on-time and off-time***

Baker combined with *Boveja-814* renders obvious [1.2].

Baker discloses that its IPG stores neuromodulation parameters in memory:

> "The regulator smoothes the battery output and supplies power to logic and control section 15, which includes a microprocessor and controls the ***programmable functions of the device, such as current or voltage, frequency, pulse width, on-time and off-time of the output pulses generated by the generator*** [*sic*]."

Ex. 1012, 1:64-2:2.

As discussed previously, the "logic and control section 15" of *Baker* includes not only a microprocessor but also a memory. *Id*., 5:66-6:2. A POSITA would have understood that the memory is where the "programmable functions, such as current or voltage, frequency, pulse width, on-time and off-time of the output pulses" would have been stored. Ex. 1003, ¶ 352.

One objective of *Baker* was to provide a simple mechanism for the patient to change the parameters of the IPG output. Ex. 1012, 3:6-20, 44-48. *Baker* discloses circuitry that responds to a patient physically tapping the IPG to activate or program parameters (e.g., pulse amplitude and pulse frequency) for applied electrical pulses. For example, *Baker* explains:

> "Another embodiment includes programming the device to ***recognize a particular coded pattern or sequence of the taps*** so that, for example, ***if the device is currently in its stimulating state*** the coded sequence may be used to deactivate (turn off) the device or to ***increase or decrease the output pulse amplitude and/or frequency***."

Id., 3:44-49. Thus, the device is pre-programmed to correlate a number of taps to a change in pulse amplitude and/or frequency. Ex. 1003, ¶¶ 353-354.

Baker describes providing limits on the amount of control given to the patient. Ex. 1012, 3:54-58 (describes providing "the patient…with a limited amount of control of the operation of the device").

Referring to Figures 3 and 4, *Baker* further explains an embodiment for allowing a patient to modify pulse frequency or pulse amplitude in limited ways, using "predetermined"/"set" increments (implying that those increments programmed on the IPG prior to implantation). Ex. 1012, 6:55-7:2. While this embodiment is described in terms of "reprogramming" the device, it was obvious to a POSITA that the parameters were already stored on the device and are simply being selected for activation. Ex. 1003, ¶¶ 355-357.

For example, *Baker* subsequently teaches that the "implanted device" is readily "controlled…by the patient by application of sequences of light taps on the skin overlying the implanted device." Further, *Baker* teaches "the implanted device is readily programmed to recognize different coded patterns or sequences of taps by the patient… to increase or decrease the intensity and/or frequency of the stimulation." Ex. 1012, 7:3-18. Thus, *Baker* teaches that "predetermined" or "set" adjustments to pulse amplitude and/or frequency were pre-programmed into the device corresponding to the number of taps applied by a patient to select the combination of pulse amplitude and frequency (while on-time, off-time, and pulse width were already set). Ex. 1003, ¶¶ 358-359.

Baker does not describe the specific implementation of how the IPG was programmed to permit changes in pulse amplitude and/or pulse frequency after implantation based on taps by the patient. A first possibility was that a microprocessor or other circuitry could have performed arithmetic on the programmed values of frequency and/or amplitude using "predetermined" or "set" increments. A second possibility was that a limited set of options was stored, and the options were retrieved from memory depending on the tap sequence. A POSITA would have recognized that there are natural trade-offs between these two design choices. The first possibility uses less memory but more power than the second possibility. Ex. 1003, ¶¶ 360-363.

Given the lack of implementation details in *Baker*, a POSITA would have been motivated to look to related prior art for design choices in storing different stimulation parameters in memory prior to implantation. *Id*., ¶ 364. One such reference is *Boveja-814*, which describes storing "pre-determined" and "pre-packaged" programs in an external stimulator, having the same parameters identified in *Baker*. For example, *Boveja-814* discloses:

> "The external stimulator containing ***limited number of predetermined programs packaged into the stimulator***, giving the patient or caretaker a way to adjust the therapy within confined limits, or turn the device off. The ***pre-packaged programs contain unique combination of pulse amplitude, pulse width, frequency of stimulation, and on-off time***."

Ex. 1008, Abstract (emphasis added).

That *Boveja-814* teaches that the "programs" are stored in an external stimulator (coupled to an implanted device) does not signal to a POSITA that the teachings of *Boveja-814* are inapplicable. *Baker* already teaches that parameters are programmed into an implantable pulse generator. On the other hand, while *Boveja-814* states an advantage is that the "hardware components implanted in the body are much less," leading to various benefits (*Boveja-814*, 10:15-26), as explained in Section XII.A.3, *Baker* trades the benefits of the use of *Boveja-814*'s external device for selecting parameters for the benefit of patient convenience. Ex. 1003, ¶¶ 364-365.

Therefore, a POSITA would have looked to *Boveja-814* for implementation details of how various stimulation parameters may be stored on a stimulation device prior to implantation, such as *Baker*'s IPG, for later activation by a patient to adjust stimulation. *Id*.

Boveja-814 specifically recognizes the benefit and convenience of having a subset of pre-packaged programs out of "millions of different [possible] combinations." *Id*., 8:38-46; Ex. 1003, ¶ 366.

Boveja-814 explains that the pre-packaged programs are stored in memory. *Id*., 15:44-51. *Boveja-814* also provides examples of the different types of therapies provided by different predetermined/pre-packaged programs, as different

combinations of pulse amplitude, pulse width, frequency, on time, and off time. Id., 14:39-67. Below is one example:

> Program #1:
> 1.0 mA current output, 0.2 msec pulse width, 15 Hz frequency, 15 sec ON time-1.0 min OFF time, in repeating cycles.

Id., 14:40-43.

To the extent not obvious in view of *Baker* and basic engineering principles of providing increased flexibility to vary parameters, *Boveja-814* discloses that not only pulse amplitude and/or frequency may be varied, but also pulse-width, on-time and off-time (although the claim does not require that more than one parameter be varied). Ex. 1003, ¶¶ 367-368.

To be clear, in view of *Boveja-814*, *Baker*'s IPG having a memory requires no modification to store parameters. *Baker* already discloses storing at least one set of the claimed parameters as well as providing a patient a way to change certain parameters (e.g., by "predetermined" or "set" amounts) according to the number of taps (which would not have been unlimited), therefore limiting the number of potential combinations of parameters. Implementing one design option, *Boveja-814* confirms that these different parameters would be stored in the memory of a stimulation device, such as the memory of the IPG of *Baker,* by explicitly disclosing the storage of different sets of parameters in a stimulation device. Ex. 1003, ¶ 369.

Thus, *Baker*'s teaching of storing stimulation parameters in IPG memory and techniques for modifying the IPG output with limited patient control, further in view of *Boveja-814*'s teaching of storing two or more sets of "predetermined/pre-packaged" programs having the parameters (pulse amplitude, pulse-width, pulse frequency, on-time and off-time) on a stimulator device renders obvious [1.2]. *Id*., ¶¶ 375-376.

[1.3] ***providing an implanted lead in electrical contact with said implanted pulse generator; wherein said implanted lead comprising at least one electrode adapted to be in contact with said vagus nerve(s)***

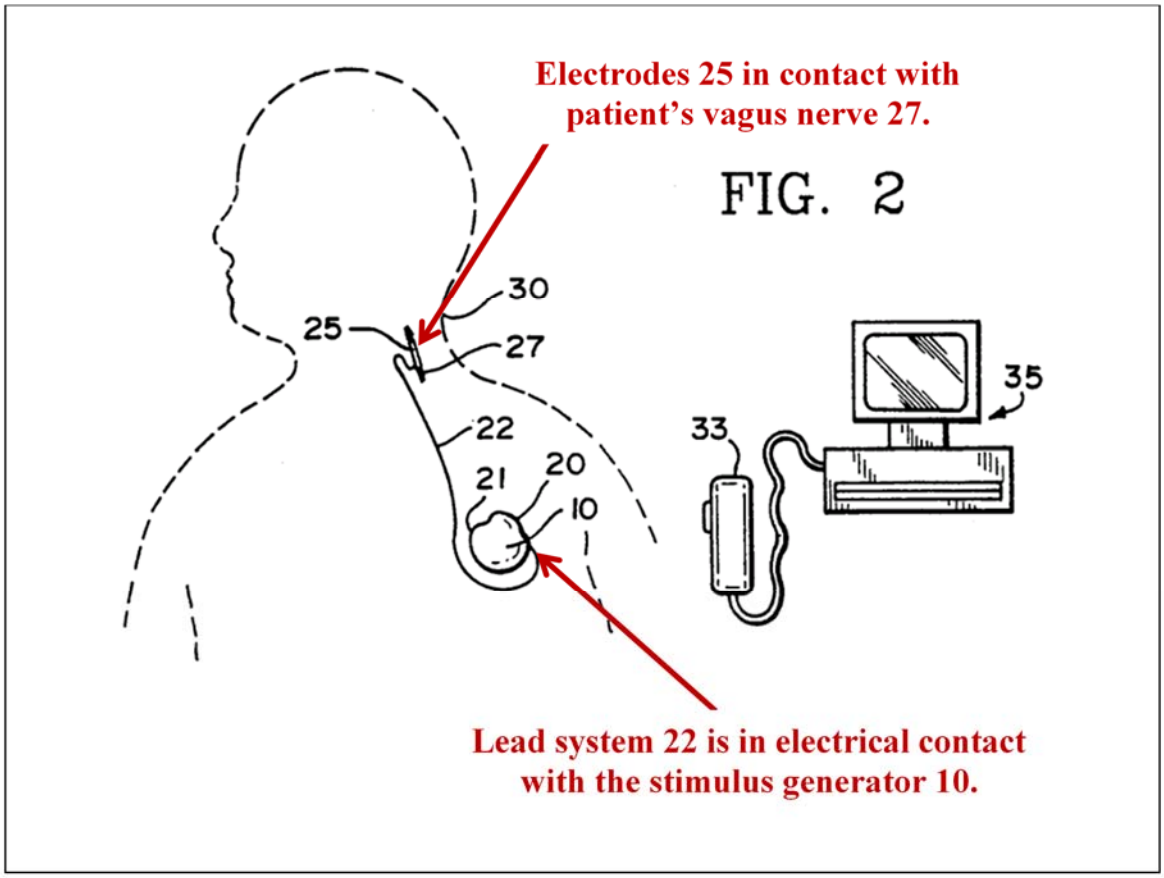
Baker discloses [1.3].

In *Baker*, the neurostimulator

> "includes implantable stimulating electrodes 25 together with a lead system 22 for applying the output signal of the stimulus generator to a selected nerve such as the patient's vagus nerve 27."

Ex. 1012, 1:51-55.

In Fig. 2 of *Baker*, the lead system 22 is shown with implantable stimulating electrodes 25 that are in contact with the patient's vagus nerve 27 and the implanted stimulus generator 10.



Ex. 1012, Fig. 2 (annotated in color); Ex. 1003, ¶ 379

Thus, *Baker* teaches the elements of [1.3]. Ex. 1003, ¶¶ 377-380.

[1.4] ***providing programmer means for activating and/or programming said implanted pulse generator, wherein bi-directional inductive telemetry is used to exchange data with said implanted pulse generator***

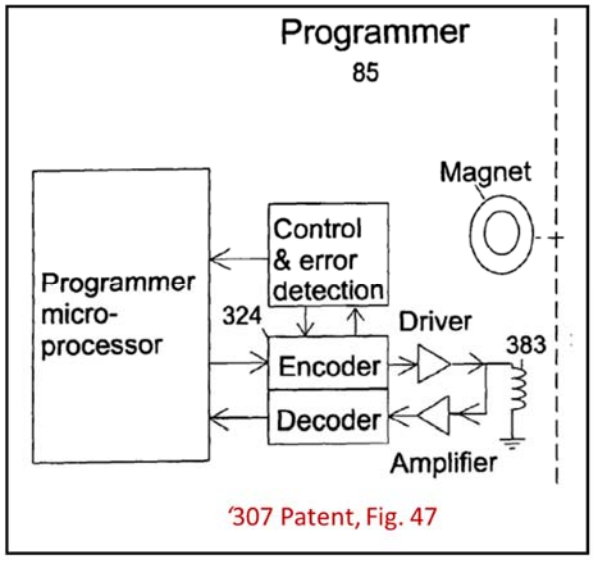
Webster discloses [1.4].

Specifically, the "programmer" of *Webster*'s Figure 12.1, including the "[p]rogramming head positioning circuit in Figure 12.4, along with the accompanying description of these elements and associated details in Figures 12.5-12.9 is an example "programmer means…" as construed herein. As explained by Dr. Mihran, Figures 12.1, 12.4-12.9 and the accompanying text were substantially

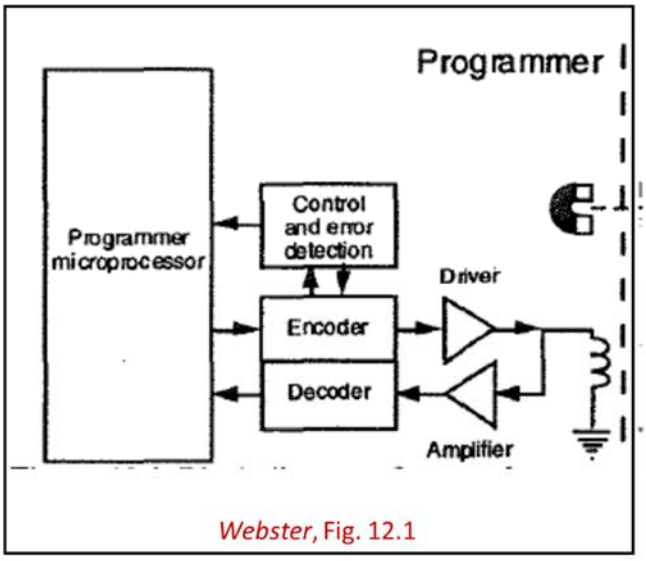
copied into the '307 patent as Figs. 47-52 and the accompanying text, which is also the disclosure of the claimed "means" in [1.4]. Thus, as explained by Dr. Mihran, *Webster* discloses virtually the identical "programmer means for activating and/or programming" as disclosed in the '307 patent. Ex. 1003, ¶¶ 382-388.

Webster describes how the external programmer communicates "programming and telemetry information with the pacemaker . . . electromagnetically through a set of coils," Ex. 1011, Chapter 12, Section 12.1.1, p. 33. Further, *Webster* teaches that the use of coils was beneficial to "permit the pacemaker to transmit information out of the device, [which is] useful for verifying parameters." *Id*., Chapter 12, p. 33. *Webster*'s description is consistent with the teaching of bi-directional communication (i.e., communication to and from the implanted device) in *Baker*: "[c]omponents external to the patient's body include a programming wand 33 for telemetry of parameter changes to the stimulus generator and monitoring signals from the generator." Ex. 1012, 1:55-58; *see also* 2:10-20; Ex. 1003, ¶ 383.

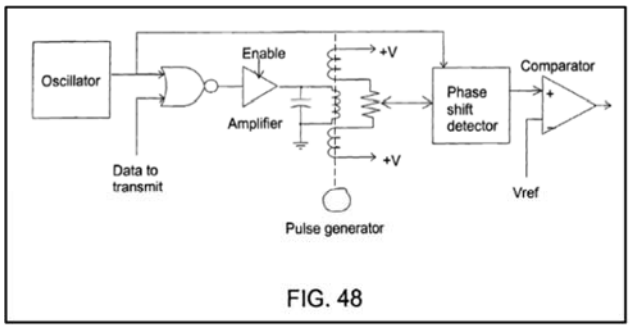
Webster's programming circuitry in Figures 12.1 ("programmer") and 12.4 ("[p]rogrammer head positioning circuit," *Webster*, Figure 12.4, caption) are compared against the programming circuitry in Figures 47 ("programmer") and 48 ("programmer head positioning circuit," '307 patent, 10:13) of the '307 patent below, illustrating that the '307 patent is essentially identical to *Webster*. Ex. 1003, ¶ 386, 388.



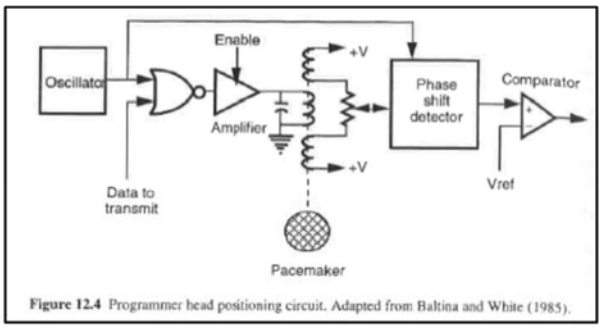
'307 Patent, Fig. 47



Webster, Fig. 12.1



'307 Patent, Fig. 48



Webster, Fig. 12.4

The physical phenomenon underlying the communication between the coils in *Webster*'s devices was known to be induction. Ex. 1003, ¶ 384. Thus, the use of *Webster*'s coils for bi-directional communication with an implanted device (such as disclosed in both *Baker* and *Webster*) uses coupling on the basis of mutual inductance, thereby disclosing "*bi-directional inductive telemetry*" as claimed. *Id*., ¶ 385.

Thus, *Webster*'s disclosure of "programmer" in Figs. 12.1 and 12.4-12.9 and accompanying description is an example of the "means" of [1.4]. Ex. 1003, ¶ 389.

[1.5] ***selectively choosing between at least two predetermined/pre-packaged program and activating said selected program.***

Baker combined with *Boveja-814* renders obvious [1.5].

As discussed in the analysis of [1.2], *Baker* teaches that:

> "Another embodiment includes ***programming the device to recognize a particular coded pattern or sequence of the taps*** so that, for example, ***if the device is currently in its stimulating state*** the coded sequence may be used to deactivate (turn off) the device or ***to increase or decrease the output pulse amplitude and/or frequency***."

Ex. 1012, 3:44-49. Thus, *Baker* discloses selectively choosing and activating different IPG outputs.

As explained in [1.2], *Baker* combined with *Boveja-814* renders obvious two predetermined/pre-packaged programs stored in memory of an IPG. Given the storage in memory of the IPG, a natural consequence is that *Baker*'s "coded pattern or sequence of taps" that changes pulse amplitude and/or frequency selects one of the set of parameters in a "program" defining the "*pulse amplitude, pulse-width, pulse frequency, on-time and off-time*" to be used. Ex. 1003, ¶ 393.

A stimulus generator that is configured to recognize a particular "number of taps" (*Baker*, 6:38-41) as a selection of new parameter values, would use the number of taps to select or activate different predetermined/pre-packaged "programs" that define the parameter values. Thus, *Baker*, in view of the teachings of *Boveja-814*, suggests selectively choosing between at least two predetermined/pre-packaged programs

and activating the selected program, rendering obvious [1.5]. Ex. 1003, ¶¶ 390-395.

7. Claim 2

The method of claim 1,

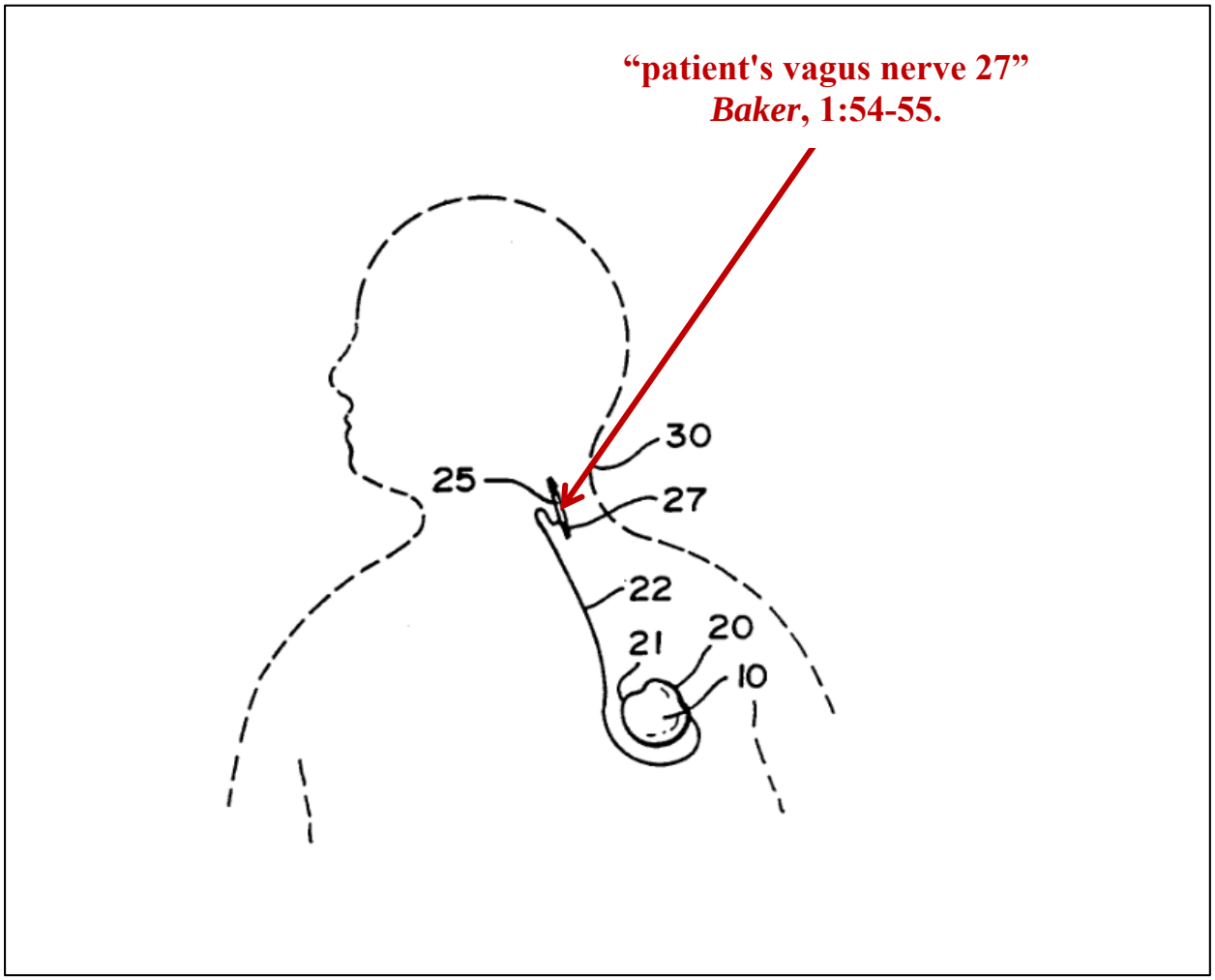
[2.0] ***wherein said electric pulses are provided to said vagus nerve(s) to provide neuromodulation therapy for at least one of epilepsy, involuntary movement disorders including Parkinson's disease, depression, anxiety disorders, neurogenic/psychogenic pain, obsessive compulsive disorders, obesity, dementia including Alzheimer's disease, and migraines.***

As previously discussed for [1.0], *Baker* teaches a method of providing electrical pulses to a vagus nerve of a patient suffering from epilepsy to treat epileptic seizures. Ex. 1012, 4:39-48. Thus, *Baker*'s electrical pulses are used to treat epilepsy, thereby teaching the additional features of [2.0]. Ex. 1003, ¶¶ 396-397.

8. Claim 3

The method of claim 1,

[3.0] ***wherein said vagus nerve(s) further comprises at least one of the left vagus nerve, right vagus nerve, and branches of said left vagus nerve and right vagus nerve.***



As shown above in FIG. 2 of *Baker*, the vagus nerve that is shown is the left vagus nerve, as evidenced by the direction of the patient's head in Figure 2. Thus, *Baker* discloses [3.0]. Ex. 1003, ¶¶ 398-399.

9. Claim 4

The method of claim 1,

[4.0] ***wherein said electric pulses are supplied to said vagus nerve(s) at any point along the length of said vagus nerve(s)***

Baker discloses "applying the output signal of the stimulus generator [electrical pulses] to a selected nerve such as the patient's vagus nerve 27" and thus discloses [4.0]. Ex. 1003, ¶¶ 400-401.

10. Claim 5

The method of claim 1,

[5.0] ***wherein said at least two predetermined/pre-packaged programs can be modified.***

Boveja-814 discloses that the "the pre-packaged programs can be **modified** with a programming station connected to the pulse generator with a RS232-C serial connection." Ex. 1008, 11:17-20.

The teaching of modifying or reprogramming parameters is consistent with the teachings of *Baker*, which teaches modifying parameters. Ex. 1012, 2:11-20 (discussing the implantable device receiving signals from an external programmer for "parameter changes" and being "reprogrammed"). Ex. 1003, ¶ 404.

Thus, modifying "pre-packaged programs," according to *Boveja-814*, teaches [5.0]. *Id*., ¶¶ 402-405.

11. Claim 7

***The method of claim 1*,**

[7.0] wherein said at least one predetermined program:

a) comprises at least one variable components from a group consisting of pulse amplitude, pulse width, pulse frequency, ON-time, and OFF-time sequences, and

b) controls said variable component of said electric pulses.

As discussed above in [5.0], *Boveja-814* teaches that the parameters of predetermined programs can be modified. Ex. 1008, 15:7-29. The parameters included in the various predetermined/pre-packaged programs of *Boveja-814* "contain unique combination of pulse amplitude, pulse width, frequency of stimulation, and on-off time." Ex. 1008, Abstract.

Thus, *Boveja-814*'s teaching of "chang[ing]" the "parameters for various stimulation programs" (as shown previously, *Boveja-814*'s parameters are pulse amplitude, pulse width, frequency of stimulation, and on-off time), discloses that at least one of the parameters is variable, thereby disclosing [7.0]. Ex. 1003, ¶¶ 406-408.

12. Claim 8

The method of claim 1,

[8.0] ***wherein said implanted pulse generator is activated or programmed with an external programmer.***

Baker discloses that its IPG is programmed with a system that includes an external "programming wand 33" and computer, the combination of which is an example "*external programmer*." Accordingly, *Baker* discloses [8.0]. Ex. 1012, 1:55-61; *see also* Ex. 1003, ¶¶ 409-411.

13. Claim 10

The method of claim 1,

[10.0] ***wherein said implanted lead comprises a lead body with insulation selected from the group consisting of polyurethane, silicone, and silicone with polytetrafluoroethylene.***

Boveja-814 discloses that a lead body is made out of insulation materials selected from a group consisting of "silicone," "polyurethane," and "silicone with polytetrafluoroethylene (PTFE)."

Table of lead-receiver design variables

Proximal End						Distal End
Circuitry and Return electrode	Lead body-Lumens	Lead body-Insulation materials	Lead-Coating	Conductor (connecting proximal and distal ends)	Electrode-Material	Electrode-Type
Bipolar	Single	Polyurethane	Lubricious (PVP)	Alloy of Nickel-Cobalt	Pure Platinum	Standard ball electrode
Unipolar	Double	Silicone	Antimicrobial		Platinum-Iridium (Pt/Ir) alloy	Hydrogel electrode
	Triple	Silicone with Polytetrafluoroethylene (PTFE)	Anti-inflammatory		Pt/Ir coated with Titanium Nitride	Spiral electrode
	Coaxial				Carbon	Steroid eluting Fiber electrode

Ex. 1008, 17:3-27. Therefore, *Boveja-814* discloses [10.0]. Ex. 1003, ¶¶ 412-415.

Reasons to Combine *Baker* and *Boveja-814:* As explained in the analysis of [1.4], *Baker* discloses an "implanted lead." However, *Baker* does not specify the materials or structure of the implanted lead. A POSITA desiring to build an implantable device would have been motivated to study other implantable stimulation devices to determine the materials and structure to use for the implanted lead. *Boveja-814* provides an example. *Id*., ¶ 416.

14. Claim 11

The method of claim 1,

[11.0] ***wherein said at least one electrode of said implanted lead comprises a material selected from the group consisting of platinum, platinum/iridium alloy, platinum/iridium alloy coated with titanium nitride, and carbons.***

Boveja-814 discloses that an electrode may be selected from a group consisting of platinum, a platinum/iridium alloy, a platinum/iridium alloy coated with titanium nitride, and carbons:

Table of lead-receiver design variables

Proximal End						Distal End
Circuitry and Return electrode	Lead body-Lumens	Lead body-Insulation materials	Lead-Coating	Conductor (connecting proximal and distal ends)	Electrode-Material	Electrode-Type
Bipolar	Single	Polyurethane	Lubricious (PVP)	Alloy of Nickel-Cobalt	Pure Platinum	Standard ball electrode
Unipolar	Double	Silicone	Antimicrobial		Platinum-Iridium (Pt/Ir) alloy	Hydrogel electrode
	Triple	Silicone with Polytetrafluoroethylene (PTFE)	Anti-inflammatory		Pt/Ir coated with Titanium Nitride	Spiral electrode
	Coaxial				Carbon	Steroid eluting Fiber electrode

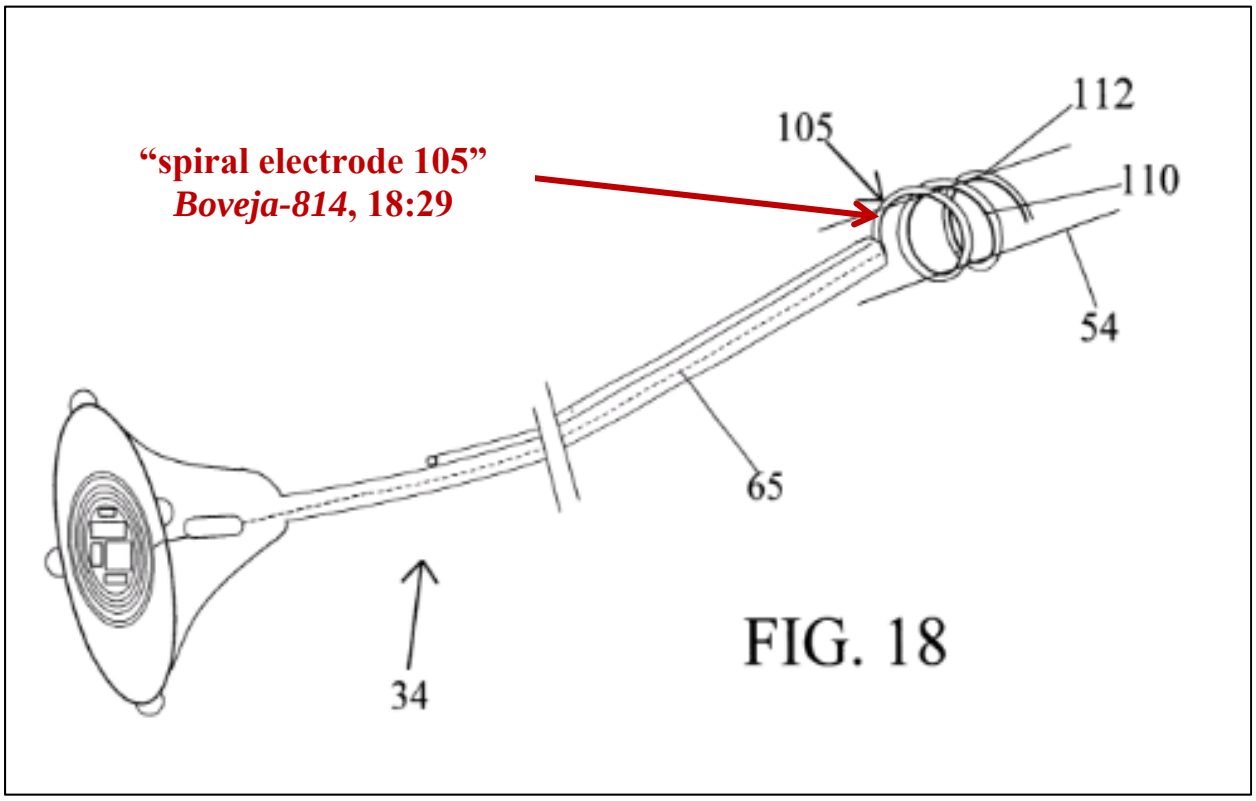
Ex. 1008, 17:3-27. Therefore, *Boveja-814* discloses [11.0]. Further, the reasons to combine *Baker* and *Boveja-814* are the same as for [10.0] (*see* [10.0]). Ex. 1003, ¶¶ 417-421.

15. Claim 12

The method of claim 1,

[12.0] ***wherein said at least one electrode is from a group consisting of spiral electrodes, cuff electrodes, steroid eluting electrodes, wrap-around electrodes, and hydrogel electrodes.***

Boveja-814 discloses a variety of types of electrodes, including hydrogel, wrap-around, spiral, and steroid eluting. Ex. 1008, 12:21-34, Figs. 15, 17, 18, 20-22. For example, "FIG. 18 is a diagram of a lead-receiver with a spiral electrode" and annotated:



Thus, *Boveja-814* discloses [12.0]. Furthermore, the reasons to combine *Baker* and *Boveja-814* are the same as for [10.0] (*see* [10.0]). Ex. 1003, ¶¶ 422-427.

16. Claim 18

[18.0] ***A system for providing electrical pulses to a vagus nerve(s) of a patient for treating or alleviating the symptoms of at least one of neurological, neuropsychiatric, and obesity disorders[3], comprising:***

Baker discloses a system for providing electrical pulses to a vagus nerve. For example, *Baker* discloses different views of an "implantable neurostimulator" in Figs. 1 and 2, and a "programmer" external to the patient's body. *See*, *e.g.*, Ex. 1012, 1:37-45, 4:57-59 and Figs. 1-2.

Baker's system is for treating a disorder by delivering an "electrical waveform" (example "*electrical pulses*") to a "vagus nerve." *Id.*, Abstract. The disorders treatable by *Baker*'s system include "***psychiatric or neurological disorders*** **by application of modulating electrical signals to a selected nerve** or nerves of the patient." *Id.*, 1:6-11.

Thus, *Baker* discloses all the features of [18.0]. Ex. 1003, ¶¶ 428-432.

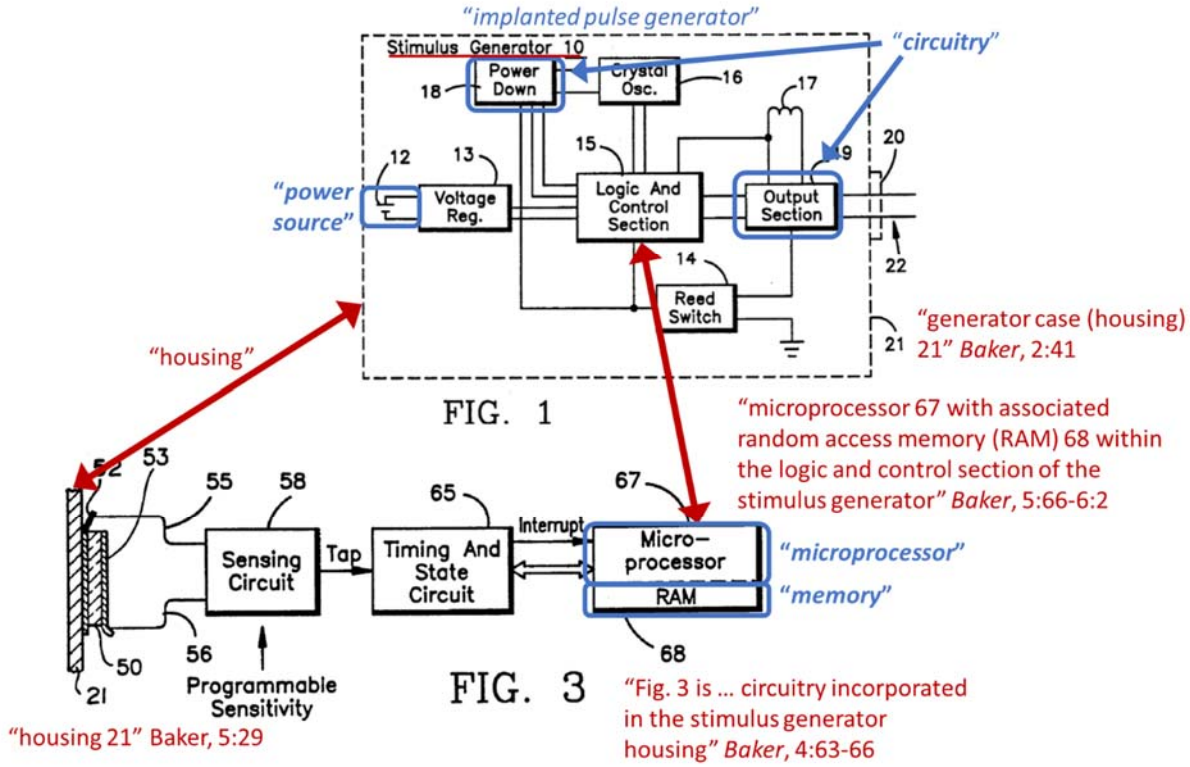
[18.1] ***an implantable pulse generator comprising microprocessor, circuitry, memory, and power source***

According to the analysis of claim element [1.1], *Baker* discloses "*providing a microprocessor based implanted pulse generator, wherein said pulse generator*

[3] The specification does not support a conjunctive reading requiring treatment for all listed conditions. Ex. 1003, p. 224, n. 18.

comprises microprocessor, circuitry, memory, and power source." The "implanted pulse generator" having "*microprocessor, circuitry, memory, and power source*" as described in the analysis of [1.1] also discloses [18.1] for the same reasons.

For example, *Baker* discloses all the features of claim element [18.1], as illustrated below (figure taken from the analysis of [1.1]):



Figs. 1 and 3 of *Baker* (quotes from *Baker* in red; claim elements in blue); Ex. 1003, ¶ 435

[18.2] ***at least two predetermined/pre-packaged programs of stimulation therapy stored in said memory to control said electrical pulses emitted by said implantable pulse generator, wherein said predetermined/pre-packaged programs define neuromodulation parameters of pulse amplitude, pulse-width, pulse frequency, on-time and off-time***

Claim element [18.2] is substantially similar to [1.2]. Note that the "neuromodulation therapy" in [1.2] is an example of "stimulation therapy" of [18.2]. Thus, the entirety of claim element [1.2] is within [18.2]. The "neuromodulation parameters" are parameters for controlling electrical pulses. Thus, for the same reasons as presented in claim element [1.2], *Baker* combined with Boveja-814 renders obvious [18.2]. Ex. 1003, ¶ 437.

[18.3] ***an implantable lead in electrical contact with said implantable pulse generator, wherein said lead comprising at least one electrode adapted to be in contact with said vagus nerve(s)***

Claim element [18.3] is substantively the same as [1.3], except that [1.3] is the step of "providing" the "implantable lead" of claim [18.3]. Thus, for the same reasons as presented in claim element [1.3], *Baker* discloses [18.3]. Ex. 1003, ¶ 438.

[18.4] ***means for activating and/or programming said implantable pulse generator, wherein bi-directional inductive telemetry is used to exchange data with said implantable pulse generator.***

The claim construction for [18.4] is identical to [1.4]. Thus, for the same reasons as presented in claim element [1.4], *Webster* discloses all the features of claim element [18.4]. *Id*., ¶ 439.

17. Claim 19

The system of claim 18,

[19.0] ***wherein said vagus nerve(s) further comprises at least one of a left vagus nerve, right vagus nerve, and branches of said left vagus nerve and right vagus nerve.***

Element [19.0] is identical to [3.0]. Therefore, according to the analysis of [3.0], *Baker* discloses [19.0]. Ex. 1003, ¶ 440.

18. Claim 20

The system of claim 18,

[20.0] ***wherein said electric pulses are supplied to said vagus nerve(s) anywhere along the length of said vagus nerve(s)***

Element [20.0] is identical to [4.0]. Therefore, according to the analysis of [4.0], *Baker* discloses [20.0]. Ex. 1003, ¶ 441.

19. Claim 21

The system of claim 18,

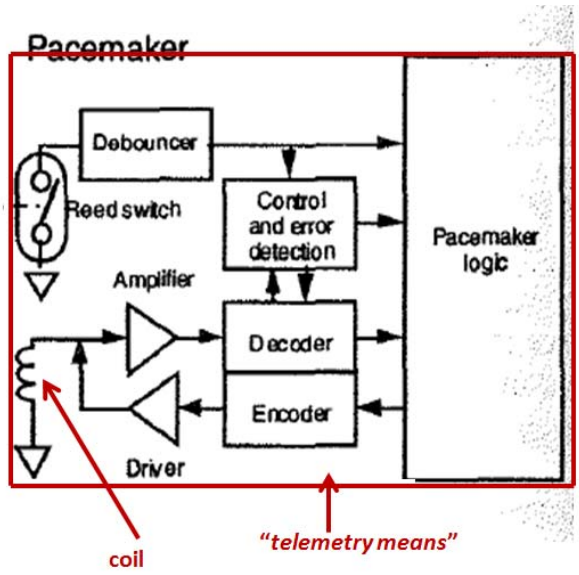
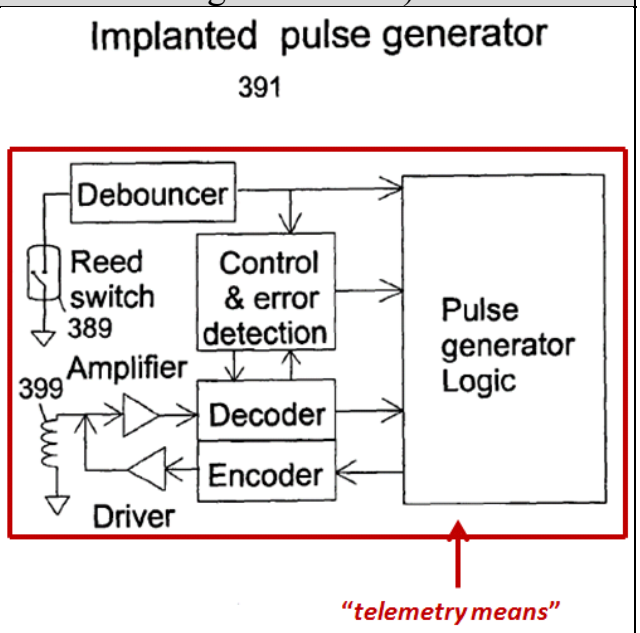
[21.0] ***wherein said pulse generator may further comprise a telemetry means to remotely control said predetermined program(s).***

Baker combined with *Boveja-814* and *Webster* render obvious [21.0].

First, as explained above for [1.4] and [18.4], *Webster's* programmer is an example of the "*programmer means"* of [18.4].

Second, *Webster* discloses the structure of the claimed "*telemetry means*." Just like the '307 patent, the "telemetry means" of *Webster*, within the red box in annotated figure 12.1 below, includes the following components: "coil," the "amplifier," the

"driver," the "decoder," the "encoder," the "control & error detection," "debouncer," "reed switch," and the "pacemaker logic." Ex. 1003, ¶¶ 444-446.

***Webster*, Portion of Fig. 12.1** ("telemetry means" in an implanted medical device)	***'307 Patent*, Portion of Fig. 64** ("telemetry means" in implantable pulse generator 391)
	

Although *Webster's* "telemetry means" resides in a pacemaker, as previously discussed, it was well-known that such features of a pacemaker would be implemented in a neurostimulator device, such as an implantable pulse generator. *See* Section VIII.

Third, there are reasons why *Webster*'s "telemetry means" would have been incorporated into *Baker*'s IPG as described in [1.1] and [18.1]. *Baker* presents a high-level schematic in its Fig. 1, and also explains that the "[b]uilt-in antenna 17" enables bi-directional communication between the IPG and external electronics. Ex. 1012, 2:11-

20. However, *Baker* does not present the specific circuitry for achieving that bi-directional communication. Further, as explained in the analysis of [1.4] and [18.4], *Webster* discloses the "*means for activating and/or programming*" the claimed "*implantable pulse generator*." Therefore, a POSITA would have used *Webster*'s "telemetry means" in *Baker*'s IPG to more completely define the circuitry for bi-directional inductive telemetry with the external programmer (especially using the circuitry that is specifically designed to work with *Webster*'s "means for activating and/or programming"). Ex. 1003, ¶¶ 447-448.

Fourth, *Webster* in view of *Boveja-814* discloses the claimed function. *Webster* discloses that "telemetry and programming enable the physician to monitor the patient and provide changes to the operational parameters of the pacemaker." Ex. 1011, Chapter 12, p. 44. *Webster* further discloses that "[i]nstead of making an office visit for a check-up, a patient may save time and money by using a telephone link from home" to connect via modem in the programmer to a "physician's computer via local or long-distance telephone." *Id*., Chapter 12, p. 43.

Webster explains that the physician could remotely control parameters via a telephonic link established through a computer modem in the programmer to (i.e. a direct dial-up connection). *Webster* explicitly describes the straightforward modification to its "programming unit" by replacing "entry and display hardware" with "a computer modem" to achieve the benefit of saving a patient "time and money." *Id.*

Turning to *Boveja-814*, as discussed above for [1.2], *Boveja-814* discloses predetermined programs, as discussed above for [18.2], and a programmer for controlling such programs. For example, *Boveja-814* discloses the "ability to reprogram and even redesign existing programs previously installed as predetermined programs." Ex. 1008, 16:10-16. For example, "the health care provider [may] select stimulation programs of choice. [ ] This allows the authorized user to create, modify and select for execution, programs to use for a particular time period." *Id*.

Selecting a predetermined program for execution for a particular time period is equivalent to ***activating the predetermined program*** for the particular time period and then ***deactivating the predetermined program*** after the particular time period has expired. Ex. 1003, ¶ 452.

Further, the benefit of the remote control of the programming unit taught by *Webster* (to save a patient time and money) applies equally to permit the remote control of *Boveja-814's* "predetermined programs," e.g., allowing a physician to remotely select a predetermined program "for a particular time period." *Id*., ¶ 453.

In summary, applying *Webster*'s teachings to the combined *Baker*/*Boveja-814/Webster* system of claim 18 yields the structure of *Webster*'s "*telemetry means*" in *Baker*'s IPG and the remote control of *Webster*'s programmer (modified to include *Webster*'s modem) to yield the function (and benefit) of "*remotely control[ling] said predetermined program(s)*," via the modified programmer. Ex. 1003, ¶¶ 442-454.

20. Claim 22

The system of claim 18,

[22.0] ***wherein said at least one predetermined program:***

a) comprises at least one variable components from a group consisting of pulse amplitude, pulse width, pulse frequency, ON-time, and OFF-time sequences, and

b) controls said variable component of said electric pulses.

Element [22.0] is identical to [7.0]. Therefore, according to the analysis of [7.0], *Boveja-814* discloses [22.0]. *Id*., ¶ 455.

21. Claim 23

The system of claim 18,

[23.0] ***wherein said pulse generator implanted in the patient is programmed with an external programmer.***

As shown in the analysis of [8.0], *Baker* discloses [23.0]. Ex. 1003, ¶ 456.

22. Claim 25

The system of claim 18,

[25.0] ***wherein said implanted lead comprises a lead body with insulation selected from the group consisting of polyurethane, silicone and silicone with polytetrafluoroethylene.***

As shown in the analysis of [10.0], *Boveja-814* discloses [25.0]. *Id*., ¶ 457.

23. Claim 26

The system of claim 18,

[26.0] ***wherein said at least one electrode comprises a material selected from the group consisting of platinum, platinum/iridium alloy, platinum/iridium alloy coated with titanium nitride, and carbon.***

Element [26.0] is substantively the same as [11.0]. Therefore, according to the analysis of [11.0], *Boveja-814* discloses [26.0]. Ex. 1003, ¶ 458.

24. Claim 27

The system of claim 18,

[27.0] ***wherein said at least one electrode consists from a group comprising, spiral electrodes, cuff electrodes, steroid eluting electrodes, wrap-around electrodes, and hydrogel electrodes.***

Element [27.0] is substantively the same as [12.0]. Therefore, according to the analysis of [12.0], *Boveja-814* discloses [27.0]. *Id*., ¶ 459.

25. Claim 28

The system of claim 18,

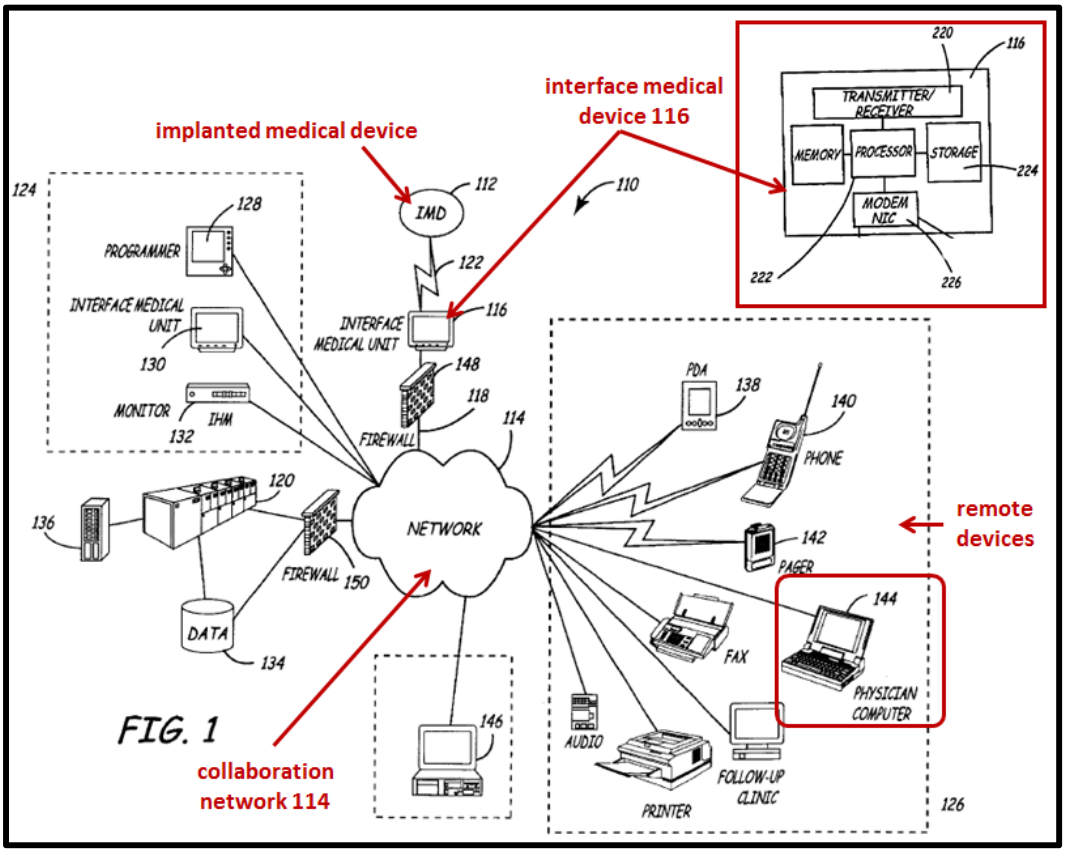
[28.0] ***wherein said electric pulses are provided to said vagus nerve(s) to provide neuromodulation therapy for at least one of epilepsy, Parkinson's disease, depression, anxiety disorders, neurogenic/psychogenic pain, obsessive compulsive disorders, obesity, dementia including Alzheimer's disease, and migraines.***

Element [28.0] is substantively the same as [2.0]. Therefore, according to the analysis of [2.0], *Baker* discloses [28.0]. *Id*., ¶ 460.

B. Ground 2: – Claim 6 is unpatentable under 35 U.S.C. § 103 over the combination of *Baker*, *Boveja-814* and *Webster* further in view of *Lee*

1. Summary of *Lee*

As shown below in Fig. 1, annotated to show the network interface device 116 of Fig. 2, *Lee* discloses devices and systems that permit remote physicians to interface with remote implanted medical devices ("IMD") through a network.



Ex. 1013, FIG. 1 (annotated in color, including interface 116 of Fig. 2); Ex 1003, ¶ 476

As explained by *Lee*, "[t]he interface medical device 116 may also communicate with a central collaborative network 114 via modem, LAN, WAN,

wireless or infrared means according to network connection 118." Ex. 1013, 10:52-53. *Lee*'s interface unit 116 is strikingly similar to the '307 patent's interface unit 292. Ex 1003, ¶ 474.

2. Claim 6

[6.0] ***The method of claim 1,***

See analysis of claim 1.

[6.1] ***wherein said implanted pulse generator may further comprise a telemetry means for remote device interrogation and/or programming over a wide area network.***

Webster alone discloses [6.1]. In addition or alternatively, *Webster* combined with *Lee* renders obvious [6.1].

First, as explained above for [1.4], *Webster's* programmer is an example of the "*programmer means"* of [1.4].

Second, as explained in [21.1] the *Baker's* IPG is modified to include the "telemetry means" of *Webster*." Ex 1003, ¶¶ 464-466.

Third, as explained in [21.1] there are reasons why *Webster*'s "telemetry means" would have been incorporated into *Baker*'s IPG. *Id*., ¶ 467.

Fourth, *Webster* discloses the claimed function of using the implanted device's telemetry means for remote interrogation or programming. In addition or alternatively, *Webster* in view of *Lee* discloses the claimed function. *Webster* explains "changes" to "parameters" by programming: "telemetry and programming enable the physician to

monitor the patient and provide changes to the operational parameters of the pacemaker." Ex. 1011, Chapter 12, p. 44. *Webster* also discloses that "[a]ll of the parameters that can be programmed can also be read back, or **interrogated**." *Id*., p. 41.

Webster teaches a physician remotely interacting with *Webster's* implanted medical device through a computer modem in the programmer to allow communications over a long-distance telephone connection. *Id*., Chapter 12, p. 43. Thus, *Webster* discloses the claimed function of remote implanted device interrogation and/or programming over a wide area network (e.g., the long-distance telephone network) to achieve the benefit of saving a patient "time and money." Ex 1003, ¶¶ 469-470.

In addition or alternatively, *Webster* in view of *Lee* discloses the claimed function. *Webster* teaches to replace "entry and display hardware" of the external programming unit with a "modem," but *Webster* does not present a schematic of an example of such an external programmer. A POSITA seeking to build *Webster*'s programmer with a modem would be motivated to determine such a schematic as part of the design process. *Lee* presents at least one such example. *Id*., ¶¶ 471-472.

As demonstrated above in annotated Fig. 1 of *Lee* above, *Lee* discloses that a "networked interface medical device 116 may communicate with the [implanted medical device] 112 via, e.g., radio frequency." *Id*., 10:41-51. As explained by *Lee*, "**[t]he interface medical device 116 may also communicate with a central**

collaborative network 114 via modem, LAN, **WAN**." *Id*., 10:52-53; Ex 1003, ¶¶ 472-473.

In summary, the programmer of *Webster* is modified with the modem of *Webster* (to achieve the benefit of saving a patient "time and money") together with circuitry for communication in the programmer further specified by the interface medical device 116 of *Lee*. The structure of the implanted medical device "telemetry means" disclosed in *Webster* is an example of the "*telemetry means*" as claimed and performs the function of "*remote device interrogation and/or programming over a wide area network*," via this modified programmer of *Webster*. *Id*., ¶¶ 474-479.

C. CONCLUSION

For the reasons detailed above, *inter partes* review of claims 1-8, 10-12, 18-23, and 25-28 is requested.

Dated: September 13, 2018

Respectfully submitted,

By /J. Andrew Lowes/
J. Andrew Lowes
Registration No.: 40,706
Customer No. 27683
Attorney Docket No. 57348.3
Lead Counsel for Petitioner

XI. CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. §42.24, the undersigned attorney for the Petitioner Ericsson, declares that the argument section of this Petition (Sections I, III–X) has a total of 13,745 words according to the word count tool in Microsoft Word™.

/J. Andrew Lowes/
J. Andrew Lowes
Registration No. 40,706
Lead Counsel for Petitioner

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of: Boveja	§	Petition for *Inter Partes* Review
	§	
U.S. Patent No. 7,076,307	§	Attorney Docket No.: 57348.3
	§	
Issued: July 11, 2006	§	Customer No.: 27683
	§	
Title: METHOD AND SYSTEM FOR MODULATING THE VAGUS NERVE (10TH CRANIAL NERVE) WITH ELECTRICAL PULSES USING IMPLANTED AND EXTERNAL COMPONENTS, TO PROVIDE THERAPY NEUROLOGICAL AND NEUROPSYCHIATRIC DISORDERS	§	Petitioners: LivaNova, Inc. and LivaNova USA, Inc.

CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. §42.205, that service was made on the Patent Owner as detailed below.

Date of service September 13, 2018

Manner of service FEDERAL EXPRESS

Documents served Petition for *Inter Partes* Review Under 35 U.S.C. §312 and 37 C.F.R. §42.104; Petitioner's Exhibit List; Certificate of Word Count; Exhibits: Ex. 1001 through Ex. 1047.

Persons served	Birinder R. Boveja & Angely Widhany 4350 S. 116th Street Greenfield WI 53228
Courtesy Service	Via Email: andrew@nbafirm.com; and ema@nbafirm.com

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