UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP., Petitioner,

v.

BOSTON SCIENTIFIC NEUROMODULATION CORP., Patent Owner.

Case No. IPR2019-01216 U.S. Patent No. 7,177,690

Petition for *Inter Partes* Review of U.S. Patent No. 7,177,690

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I. INTRODUCTION

Petitioner Nevro Corp. ("Nevro"/"Petitioner") requests *inter partes* review (IPR) of Claims 1-10, 23, and 32-38 ("challenged claims") of U.S. Patent No. 7,177,690 ("'690 patent"), which, pursuant to the USPTO's records, is assigned to Boston Scientific Neuromodulation Corp. ("BSNC"/"Patent Owner").

The challenged claims are directed toward a method and system that has (1) an implantable medical device with a rechargeable battery, and (2) an external device that receives battery information from the implanted device. <u>Barreras</u> discloses a similar system—*i.e.*, an implantable stimulator system with a rechargeable battery and an external device that interacts with the implantable system. The Patent Office allowed the challenged claims over the cited prior art, including <u>Barreras</u>, because, according to the Examiner, the cited prior art did not teach an implanted medical device that stores battery information that can later be retrieved to indicate the rechargeable battery's status.

Storing and using battery information to monitor battery status, however, was a fundamental technique for determining battery health and was well-known before the claimed priority date of the '690 patent. For example, <u>Kaib</u>, which was filed more than a year before the '690 patent's claimed priority date and was not considered during prosecution of the '690 patent, teaches a technique for monitoring a rechargeable battery in a medical device using the same battery information as the '690 patent. Accordingly, the '690 patent merely takes a known battery monitoring technique and applies it to a rechargeable battery in an implanted device. For the reasons set forth below, the challenged claims should be found unpatentable and cancelled.

II. COMPLIANCE WITH IPR REQUIREMENTS

A. Certification of Standing (37 C.F.R. §42.104(a))

Nevro certifies that the '690 patent is available for IPR and Nevro is not barred or estopped from requesting an IPR of the challenged claims on the grounds identified below. Neither Nevro nor any of its privies has filed a civil action challenging the validity of any claim of the '690 patent. This petition is timely filed within one year of the service of BSNC's complaint alleging infringement of the '690 patent. *See* Ex. 1010.

B. Mandatory Notices (37 C.F.R. §42.8)

1. <u>Real Party-in-Interest</u>

Nevro Corp. is the real party-in-interest for this petition.

2. <u>Related Proceedings</u>

The '690 patent is related to the following U.S. Patent Nos.:

- No. 6,052,624; No. 6,393,325;
- No. 6,516,227; No. 6,587,724;
- No. 6,609,320; No. 6,895,280;

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- No. 6,909,917; No. 7,496,404;
- No. 7,555,346; No. 7,742,821;
- No. 7,769,462; No. 7,801,615;
- No. 7,930,030; No. 8,121,701;
- No. 8,265,762; No. 8,401,658;
- No. 8,401,661; No. 8,706,254;
- No. 8,805,524; No. 8,918,174;
- No. 9,020,603 No. 9,050,473;
- No. 9,244,898; No. 9,492,672;
- No. 9,782,596; and No. 9,907,957.

Related U.S. Patent No. 6,895,280 was involved in IPR2017-01811,

IPR2017-01812, and IPR2017-01920. IPR2017-01920 was consolidated into IPR2017-01812. The Board's Final Written Decision on IPR2017-01812 is currently on appeal to the Federal Circuit. *See Boston Sci. Neuromodulation Corp. v. Nevro Corp.*, Lead Appeal No. 19-1582 (Fed. Cir.).

The '690 patent is at issue in the following district court case: *Boston Sci. Corp. v. Nevro Corp.*, Case No. 1-18-cv-00644 (D. Del.).

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C. Fees

The Director is authorized to charge any fees due during this proceeding to Deposit Account No. 50-1597.

D. Service on Patent Owner

Pursuant to 37 C.F.R. § 42.105(a) and the Certificate of Service, the petition and exhibits have been served on the correspondence of record for the '690 patent.

III. IDENTIFICATION OF CHALLENGED CLAIMS

Claims 1-10, 23, and 32-38 of the '690 patent are unpatentable as follows:

Ground 1. Claims 1-3, 5, 8-10, 32-34, and 37-38 are unpatentable under 35 U.S.C. § 103 as obvious over <u>Barreras</u> (Ex. 1005) in view of <u>Kaib</u> (Ex. 1006).

- **Ground 2.** Claim 23 is unpatentable under 35 U.S.C. § 103 as being obvious over <u>Barreras</u> (Ex. 1005) alone.
- Ground 3. Claims 9-10 are unpatentable under 35 U.S.C. § 103 as obvious over <u>Barreras</u> (Ex. 1005) in view of <u>Kaib</u> (Ex. 1006), in further view of <u>Schulman</u> (Ex. 1022).
- Ground 4. Claim 4 is unpatentable under 35 U.S.C. § 103 as obvious over <u>Barreras</u> and <u>Kaib</u>, in further view of <u>Munshi</u> (Ex. 1007)
- **Ground 5.** Claims 6-7 and 35-36 are unpatentable under 35 U.S.C. § 103 as obvious over <u>Barreras</u> and <u>Kaib</u>, in further view of <u>Bowman</u> (Ex. 1008)

The above references are prior art to the '690 patent as explained in sections VI.A.1, VI.A.2, VI.D.1, and VI.E.1 below. Nevro's challenges are further

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supported by the testimony of Mr. Ben Pless, an expert in implantable medical device systems with over 30 years of experience. Ex. 1003, ¶¶2-8.

<u>Barreras</u> (Ex. 1005) was at issue during the prosecution of the '690 patent. Patent Owner amended the claims to include limitations to overcome the cited prior art, including <u>Barreras</u>. Neither <u>Kaib</u> (Ex. 1006), <u>Munshi</u> (Ex. 1007), nor <u>Bowman</u> (Ex. 1008) were at issue during the prosecution of the '690 patent. Moreover, the Patent Office did not consider the expert testimony provided by Mr. Pless about the state of the art and how the prior art renders the challenged claims obvious. Thus, Petitioner has not advanced "the same or substantially the same prior art or arguments previously were presented to the Office."

IV. THE '690 PATENT

A. Prevailing Industry Trends Before the '690 Patent

1. <u>Battery Information</u>

Storing and using battery information to monitor battery status was a fundamental technique that was well-known before July 1999—the claimed¹ priority date of the '690 patent. Ex. 1003, ¶30-34. Indeed, in 1995-1996, several battery industry leaders, including Duracell and Intel, collaborated to form

¹ Petitioner assumes for the purposes of this petition that the '690 patent is entitled to its claimed priority date of July 1999 for this proceeding. *See* §IV.C below.

specifications (collectively, the "SBS specifications") describing how "smart" batteries would communicate charging and status information. Ex. 1012; Ex. 1009, 1; Ex. 1011, 1. The SBS specifications explained its applicability to various battery-powered devices including laptops, cellular telephones, and medical devices. Ex. 1009, 1; Ex. 1011, 5 ("For example, a medical device with a stricter temperature limits than the Smart Battery's self-contained charging algorithm, may use a Host controlled charger that factors in the battery's reported temperature into its charging algorithm."); Ex. 1003, ¶31. The SBS specifications also encompass different batteries types, such as Lithium Ion batteries. Ex. 1009, 22.

These SBS specifications explain that battery-powered devices should monitor, store, and send battery information to another user device (*e.g.*, a charger). Ex. 1009, 1 ("This specification defines the information that the Smart Battery supplies its user."); Ex. 1011, 6; Ex. 1003, ¶32; *see also* Ex. 1009, pp. 2, 4. Such information would include, for example, the remaining time a device will be able to operate (Ex. 1009, 9), the predicted remaining time that a battery needs to be fully charged (*id.*, 13), the predicted remaining battery capacity expressed as a percentage (*id.*, 16), and the number of times a battery has been charged (*id.*, 20). Ex. 1003, ¶32. The SBS specifications explain that, by sending this battery information, the user is advantageously provided "with accurate state of charge information ... [and] an accurate prediction of the remaining operating time" for "power management and charge control..." Ex. 1009, 3. Another document explains the benefits of implementing the SBS specification in battery-powered devices: it "increases battery life because it decreases the number of recharge cycles needed" and "reduces development costs and time." Ex. 1013; Ex. 1003, ¶33.

The SBS specifications were publicly available before July 1999, the priority date of the '690 patent. Exs. 1012, 1014-1015, 1017-1019; Ex. 1003, ¶¶30, 34. For example, the SBS specifications and corresponding documentation were located on the SBS forum website at least as early as June 1998. Exs. 1014-1015, 1017-1019; Ex. 1003, ¶¶34, 205-210.

2. <u>Medical Device Alarms</u>

Before July 1999, it was well-known that medical devices could use different types of and multiple alarms to alert a patient about an event. Ex. 1003, ¶¶35-36. For example, U.S. Patent 5,646,912 to Cousin describes various types of alarms that could be used in a medical device application: audible alarm, vibrating alarm, flashing indicators, etc. Ex. 1016, 6:48-52, 11:60-63; Ex. 1003, ¶35. Specifically, Cousin discloses a wrist-watch and a "digital beeper" that each use both a vibrating alarm and textual display to alert a patient of when to take specific medication. Ex. 1016, Fig. 5, 8:15-18, 11:53-12:8; Ex. 1003, ¶35. In another embodiment, Cousin further discloses that audible alarms may be used in conjunction with visual indicators for visually-impaired patients. Ex. 1016, 13:24-30. Barreras confirms that using multiple alarms to alert a patient was well known. Ex. 1005, 4:57-61 (using audible and vibrating alarms to alert a patient about low battery status); Ex. 1003, ¶36. Accordingly, it was well-known to use multiple, different types of alarms (*e.g.*, a vibrating alarm, audible alarm, and/or textual display) to alert a patient about an event (*e.g.*, time to take medication, battery status) before the claimed priority date of the '690 patent. Ex. 1003, ¶¶35-36.

B. Overview of the '690 Patent

The '690 patent is directed toward an "implantable medical device" that uses status indicators to indicate the status of a replenishable power source (*e.g.*, a rechargeable battery). Ex. 1001, 1:10-14. Specifically, the '690 patent discloses an implantable medical device system having three devices: (1) an implanted device, (2) an external programmer, and (3) a portable charger. *Id.*, 1:10-14, 6:32-37, Fig. 1; Ex. 1003, ¶37.

The implanted device is an implantable pulse generator ("IPG") 100, which is shown in Figure 4A below:



Id., Fig. 4A, 6:37-39, 14:55-58; Ex. 1003, ¶38.

The implantable pulse generator has a microprocessor 160, memory 162, and replenishable power source 180 (*e.g.*, rechargeable battery). *See* Ex. 1001, Fig. 1, 19:6-12. Different examples of information regarding the IPG's rechargeable battery are monitored by the system, such as the level of charge, the number of times the battery has been recharged, and the rate of charge. *Id.*, 4:5-24, 35:55-61. That battery charging and battery status information is then stored in memory 162 until the implantable pulse generator 100 is interrogated by an external programmer. *Id.*, 35:53-55; Ex. 1003, ¶39.

The IPG monitors and telemeters the status of its replenishable power source (e.g., how much charge is left) each time a communication link is established with the external programmer 202. Ex. 1001, 15:60-66. After receiving the IPG's battery status, the external programmer can "alert or inform a patient or clinician" *Id.*, 2:54-58. For example, the external programmer may alert the user that the implanted battery needs to be re-charged or inform the user of the number of times the battery has been recharged. *Id.*, 4:16-24. The external programmer may alert or inform the user in different ways, including a text description displayed on the external programmer (*id.*, 4:15-21), or an audible and/or vibrating alarm on the programmer (*id.*, 3:41-43). Ex. 1003, ¶40.

C. Prosecution History, Effective Filing Date, and Exemplary Claims

The '690 patent was filed on January 31, 2003, and claims priority to a provisional application filed on July 27, 1999. Ex. 1001, Face. For purposes of this Petition only, Nevro has assumed that the priority date of the '690 patent is July 27, 1999.

During prosecution, the examiner rejected several claims as being anticipated by <u>Barreras</u> et al. (Ex. 1005). Although those claims were amended and eventually allowed over <u>Barreras</u> (*Id.*), the examiner did not consider <u>Kaib</u> (Ex. 1006), <u>Munshi</u> (Ex. 1007), or <u>Bowman</u> (Ex. 1008) before allowing the '690 patent. Ex. 1003, ¶¶42-44.

The examiner initially rejected independent claims 17 (issued claim 11) and 36 (issued claim 16) and dependent claims 8, 38, and 39 (issued claims 4, 18, and 19, respectively) as being anticipated by U.S. Patent No. 5,733,313 to <u>Barreras</u> et al. (Ex. 1005). Ex. 1002, 35-36, 280-281, 371-374; Ex. 1003, ¶43. Several other claims were rejected as being anticipated by U.S. Patent No. 5,591,217 to <u>Barreras</u> et al. ("Barreras '217"). *Id.*, 279. The examiner also rejected claim 37 as being obvious over <u>Barreras</u> (Ex. 1005) in view of <u>Barreras</u> '217. For the remaining dependent claims, the examiner indicated that they contained allowable subject matter. Ex. 1002, 282, 371, 374-75. Those dependent claims required that sound emanating from a medical device be selected from "tones, pattern of sounds, music and speech" and/or that the status indicator be an "electrical signal delivered through [an] electrode array" Ex. 1002, 282, 371-72, 374-75.

Patent Owner responded that neither Barreras reference disclosed "*interrogating the medical device with an external programmer to upload battery status data.*" *Id.*, 272. Patent Owner also added these dependent claim limitations into the independent claims (*id.*, 255-56, 371), cancelled the objected-to dependent claims, and later added new claims with similar limitations (*id.*, 223-26, 259-61). Several claims were rejected again in view of different art. *Id.*, 240-42. Patent Owner then amended claims and added new claims requiring the battery charging information or battery status data be stored in a memory in the implanted device. *Id.*, 254, 217-25. The Patent Office later issued a Notice of Allowance after Patent Owner overcame these rejections. *Id.*, 25-28; Ex. 1003, ¶44.

Claims 1 and 33 are illustrative of the challenged system and method claims, shown below:

1. An implantable medical device system having a replenishable power source comprising:

an implantable medical device, the device having a housing which contains processing circuitry; and

an external programmer that may be placed in telecommunicative contact with the implantable medical device; and

means for recording battery charging information, which may be recalled later,

wherein the external programmer includes a status indicator for indicating the status of the replenishable power source within the implantable medical device.

33. A method for detecting and indicating the status of a rechargeable battery contained within an implanted medical device, the device having a memory storage for storing battery status data, the method comprising:

(a) implanting the medical device;

13 Petition for *Inter Partes* Review (b) interrogating the medical device with an external programmer to upload battery status data stored in memory storage, wherein the battery status data includes the last time the battery was charged, duration of the last charge, and number of times charging has been performed; and

(c) indicating the battery status with a status indicator included on the external programmer.

Ex. 1001, 49:59-50:3; 52:45-57.

D. Person of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSA") in the field of the '690 patent in July 1999 would have had at least (1) a bachelor's degree in electrical or biomedical engineering, or equivalent coursework, and (2) at least one year of experience researching and developing implantable medical devices. Ex. 1003, ¶49; *see also id.*, ¶¶50-51.

V. CLAIM CONSTRUCTION

The claims of the '690 patent should be given their "ordinary and customary meaning ... as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b); 83 Fed. Reg. 51358 (Oct. 11, 2018). Nevro is unaware of any "prior claim construction determination" related to the '690 patent. *See* 37 C.F.R. § 42.100(b).

A. Means for Recording Battery Charging Information

Claim 1 recites a "means for recording battery charging information," which is presumed to be a means-plus-function limitation because it uses the term "means for" along with a recited function "recording battery charging information." 37 C.F.R. § 42.104 (b)(3) requires that Nevro identify in the 690 patent the corresponding structure for "means for recording battery charging" information." The '690 patent specification discloses "IPG memory 162 or other memory" for storing battery charging information until it is recalled by the HHP. Ex. 1001, 35:53-55. Accordingly, the claimed "means for recording battery *charging information*" has a corresponding structure of a computer memory to perform the claimed function of "recording battery charging information." Ex. 1003, ¶§53-55. Dependent claim 5 confirms that this is the correct corresponding structure. Ex. 1001, 50:12-19 ("[W]herein the means for recording [battery] charging information is a memory storage contained within the implantable device").

B. Means for Non-Invasively Recharging

Claim 9 recites a "*means for non-invasively recharging the replenishable power source through the skin.*" This limitation is presumed to be a means-plusfunction limitation because it uses the term "*means for*" along with a recited function "*non-invasively recharging the replenishable power source through the* *skin.*" Nevro identifies the corresponding structure in the '690 patent for performing the recited function as an external power source (Ex. 1001, Fig. 9, 277), power amplifier (*id.*, Fig. 9, 275), an external coil (*id.*, Fig. 9, 279), and an internal coil (*id.*, Fig. 9, 680). *Id.*, 41:56-61. Ex. 1003, ¶56-60.

The '690 patent describes that energy from external battery 277 is transcutaneously transferred to implanted rechargeable power source 180 using a power amplifier 275. Ex. 1001, 41:49-53. The '690 patent further discloses that the charging station sends alternating energy to coil 279 (located outside the patient) through the patient's skin such that it is received by another coil 680 and then used to charge the implanted battery 180, as shown in Figure 9A below:



Id., Fig. 9A (annotated), 41:56-61; Ex. 1003, ¶¶57-58.

Accordingly, the components required to recharge the implanted devices battery are the external power source 277, power amplifier 275, and coils 279 and 680. Thus, the corresponding structure for a "*means for non-invasively recharging the replenishable power source through the skin*" is a power source, power amplifier, and two coils placed inside and outside the patient. Ex. 1003, ¶59. Moreover, dependent claim 10 confirms that this is the proper corresponding structure. Ex. 1001, 50:35-41 ("The system of claim 9, wherein the means for noninvasively recharging the replenishable power source is transcutaneous, RF power

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transmissions using a primary, implanted coil connected to the IPG and a secondary, external coil connected to an external recharger, wherein the primary and secondary coils are placed over each other to effect RF power transmission."); Ex. 1003, ¶60.

VI. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Claims 1-3, 5, 8-10, 32-34, and 37-38 Are Obvious Over <u>Barreras</u> (Ex. 1005) in view of <u>Kaib</u> (Ex. 1006)

1. <u>Barreras (Ex. 1005)</u>

U.S. Patent No. 5,733,313 to <u>Barreras</u> (Ex. 1005) ("Barreras") is prior art to the '690 patent under 35 U.S.C. § 102(b) because it issued in March 1998—over one year before the '690 patent's July 1999 claimed priority date. <u>Barreras</u> is directed to an "implantable, electrically operated medical device system" (*e.g.*, a tissue stimulator system) that includes "an implanted radio frequency (RF) receiving unit (receiver)" with a "back-up rechargeable power supply" and "an external RF transmitting unit (transmitter)." Ex. 1005, Abstract; *see also id.*, Figs. 1, 4, 7:20-51. Figure 1 (below) of <u>Barreras</u> shows a system with an "implanted receiver unit configured for an implantable, rechargeable tissue stimulator system." *Id.*, 7:6-9. Receiver 14 is surgically implanted beneath a patient's skin 16, shown in Figure 1 below:



Ex. 1005, Fig. 1, 7:33-47; Ex. 1003, ¶66.

Receiver 14 is connected to electrodes 21-24 that provide stimulation therapy to a target tissue. Ex. 1005, 7:37-47. To power these electrodes, receiver 14 uses different power sources including RF coupled energy and/or rechargeable power source 44. *Id.*, 8:1-4. When needed, receiver 14 alerts the patient when the power source is nearing depletion and needs to be recharged. *Id.*, 4:55-61. To do so, <u>Barreras</u>' system uses one or more of three alarms: (1) a vibrating alarm in the implanted receiver 14, (2) an audible tone generating within receiver 14, and/or (3) a specific message shown in the transmitter display 32 combined with a specific audible tone. *Id.*; Ex. 1003, ¶67. Recharging power source 44 involves the transmitter sending RF energy to the receiver using coils 64 and 60 to power the implanted medical device and/or recharge its back-up power supply. *Id.*, 8:35-43. Upon sensing that the implanted battery is fully charged, <u>Barreras</u>' receiver telemeters a termination command to the transmitter to stop RF energy transmission thereby preventing the implanted battery from overcharging and preserving the transmitter's battery supply. Ex. 1005, 6:15-20; *see also* Ex. 1003, ¶68.

2. <u>Kaib (Ex. 1006)</u>

U.S. Patent No. 5,929,601 (Ex. 1006) ("Kaib") is prior art to the '690 patent under 35 U.S.C. § 102(e) because it issued from an application that was filed in December 1997—before the '690 patent's July 1999 claimed priority date. <u>Kaib</u> "relates to methods and apparatus for the maintenance and management of the batteries of ... portable medical devices." Ex. 1006, 1:8-11. Specifically, <u>Kaib</u> discloses a system "designed to constantly monitor and comprehensively inform the patient of the ... condition of [a] device battery." *Id.*, 1:55-59. The medical device in <u>Kaib</u>'s system is a monitor-defibrillator worn by the patient. *Id.*, 1:59-61. <u>Kaib</u>'s monitor-defibrillator uses a processor and corresponding data storage to monitor battery information to check the condition of a rechargeable battery 18. *Id.*, Fig. 1, 4:1-8; Ex. 1003, ¶69.

Kaib explains that problems may occur if the batteries in a medical device are "at less than full capacity or are worn out or are accidently taken off their chargers so that the batteries are nonfunctional." Ex. 1006, 1:36-40. To solve these problems, Kaib's system monitors and stores various examples of information about the monitor-defibrillator's rechargeable battery, including for example, the "useful energy remaining [in] the battery" (*id.*, 4:11-13), the number of charging cycles performed (*id.* 9:44-48), the start and completion times of battery operations (id., 16:47-53), the length of charge/discharge cycles (id., 16:47-53). The battery information is then reported to the user. As one example, the user is notified of an "available device operating time" representing the remaining time a battery can operate the device before needing to be recharged. Id., 4:18-21, 5:26-48. The user may also be notified that the battery has been recharged too many times thereby exceeding the expiration criteria. Id., 9:41-44; Ex. 1003, ¶70.

<u>Kaib</u> further explains that there is a need in the "portable medical electronic device industry to implement a comprehensive way of informing the patient, as precisely as possible... [of] the status of the device battery." Ex. 1006, 1:41-46. Battery information thus allows the user and clinician to monitor a battery's condition and, if necessary, recharge or replace it. Ex. 1003, ¶71.

- 3. <u>Claim 1</u>
 - i. *Preamble*

Claim 1 recites "[*a*]*n implantable medical device system having a replenishable power source*." To the extent the preamble is limiting, <u>Barreras</u> discloses this limitation. Ex. 1003, ¶72-75. For example, <u>Barreras</u> discloses an "an implantable medical device including a rechargeable back-up power source" Ex. 1005, 1:7-8. Figure 1 of <u>Barreras</u> shows an "implantable, rechargeable tissue stimulator system" ("*implantable medical device system*") that "includes a receiver 14 ... being surgically implanted beneath a patient's skin 16," shown in the red box below:



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Ex. 1005, Fig. 1 (annotated), 7:33-37; Ex. 1003, ¶73.

<u>Barreras</u>' receiver 14 has a rechargeable power source 44 (shown in the tan box above) that provides operating power for receiver 14. Ex. 1005, 8:33-35. In particular, <u>Barreras</u> explains that the rechargeable power source 44 is a "rechargeable battery contained within the implanted receiver." *Id.*, 5:3-8. The '690 patent likewise describes that a rechargeable battery is a "*replenishable power source*." Ex. 1001, 1:66-2:2, 50:4-5 (claim 2); Ex. 1003, ¶74.

ii. An implantable medical device, the device having a housing which contains processing circuitry

<u>Barreras</u> discloses this feature of claim 1. Ex. 1003, ¶¶76-78. <u>Barreras</u> discloses a receiver 14 ("*implantable medical device*") that is "surgically implanted beneath a patient's skin." Ex. 1005, 7:33-37. Receiver 14 has a micro-controller 46 (the receiver's "*processing circuitry*"), (*id.*, 8:43-49), and non-volatile memory 27, (*id.*, 7:26-33). Ex. 1003, ¶77. <u>Barreras</u>' receiver 14, including its microcontroller 46 and non-volatile memory 27 (shown in tan boxes below), is enclosed in a "hermetic titanium encasement 150" ("*a housing*"), shown in Figure 1 below:



Ex. 1005, Fig. 1 (annotated), 6:54-59, 11:1-5; Ex. 1003, ¶77.

iii. An external programmer that may be placed in telecommunicative contact with the implantable medical device

<u>Barreras</u> discloses this feature of claim 1. Ex. 1003, ¶¶79-81. Barreras discloses, for example, a transmitter 12 ("*external programmer*") that communicates—*i.e.*, sending and receiving values or commands—with the implanted receiver 14 via communication link 61. Ex. 1005, 7:44-48, 8:33-39. The transmitter sends "therapy parameter values" and "start"/"stop" commands to receiver 14 over communication link 61. *Id.*, 7:44-47, 7:54-55, 7:60-67. Conversely, the receiver sends "recharge" commands to transmitter 12 using the same communication link 61 whenever the receiver's battery 44 reaches a depleted level. *Id.*, 8:33-39. Accordingly, both <u>Barreras</u>' transmitter 12 ("*external programmer*") and receiver 14 ("*implantable medical device*") telecommunicate by sending messages over communication link 61, shown below:



Id., Fig. 1 (annotated); Ex. 1003, ¶80.

Both transmitter 12 and receiver 14 use RF signals to telecommunicate and must be "*placed*" near each other to do so. Ex. 1005, 7:44-48, 8:33-39. <u>Barreras</u>" transmitter 12 and receiver 14 must be near each other to use communication link 61. Ex. 1003, ¶81; *see also* Ex. 1005, 5:67-6:3 ("If 'RF power' is selected, the implanted receiver will only operate when the transmitter unit is proximate to the

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implanted receiver"). Hence, both <u>Barreras</u>' transmitter and receiver must be placed in proximity to each other ("*placed in telecommunicative contact*") to use communications link 61. Ex. 1003, ¶81.

iv. A means for recording battery charging information, which may be recalled later

Claim 1 recites "a *means for recording battery charging information, which may be recalled later.*" As explained above, *see* §V.A above, the structure disclosed in the '690 patent that corresponds to the claimed "*means*" for performing the recited function of "*recording battery charging information*" is a computer memory.

As explained below, <u>Barreras</u> discloses a "*means for recording*" information, "*which may be recalled later*," but does not expressly disclose that such information may be battery charging information. <u>Kaib</u>, however, discloses a battery monitoring technique that "*records battery charging information*" that is recalled later. It would have been obvious to incorporate <u>Kaib</u>'s battery monitoring technique in <u>Barreras</u>' receiver, as further explained below. Ex. 1003, ¶84.

a. <u>Barreras</u> discloses a "*means for recording*" information, "*which may be recalled later*"

<u>Barreras</u> discloses EEPROM 27 ("*means for recording*"), which is a nonvolatile computer memory, that is connected to a micro-controller 46, shown in

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Figure 1 below:



Ex. 1005, Fig. 1 (annotated), 7:44-47; Ex. 1003, ¶85.

Non-volatile memory 27 ("*means for recording*") stores stimulation values, therapy values, and critical data. Ex. 1005, 5:21-28 ("According to still another aspect of the present invention, there is provided a method for recording into a non-volatile memory contained within the implanted receiver the stimulation values and other critical data"); *see also id.*, 7:44-47, 7:56-59. In addition, receiver 14 also stores patient diagnostic data in non-volatile memory 27 and sends that data to the transmitter 12 when the transmitter 12 requests it. *Id.*, 12:25-36. Receiver 14 thus stores information in non-volatile memory 27 until it is requested

("*which may be recalled later*") by the transmitter 12. Ex. 1003, ¶86; Ex. 1005, 12:25-36; *see also id.*, 6:37-43 ("According to still another aspect of the present invention, there is provided an implantable monitor and diagnostic system ... used to collect vital physical data from the patient which can be interrogated by a receiver external to the patient.")

Accordingly, <u>Barreras</u> discloses a "*means for recording*" information "*which may be recalled later.*" <u>Barreras</u> does not, however, explicitly disclose recording "*battery charging information*" on non-volatile memory 27. It would have been obvious, however, to record "*battery charging information*" on <u>Barreras</u>' nonvolatile memory 27 in view of <u>Kaib</u>, which discloses "*recording battery charging information*" in computer memory "*which may be recalled later.*" Ex. 1003, ¶87.

> b. <u>Kaib</u> discloses "*recording battery charging information*" for later recall

<u>Kaib</u> discloses a system for monitoring the status of a rechargeable battery in a portable medical device. As shown in Figure 1 below, <u>Kaib</u>'s monitordefibrillator 12 uses a processor and corresponding data storage 22 to monitor the status of a rechargeable battery 18. Ex. 1006, Fig. 1, 4:1-8, 7:46-49.



Ex. 1006, Fig. 1 (annotated), 1:5-12; Ex. 1003, ¶88.

<u>Kaib</u>'s system monitors various examples of "*battery charging information*" for the monitor-defibrillator's rechargeable battery and uses this information to determine the rechargeable battery's health status and remaining lifespan. Ex. 1003, ¶89. For example, <u>Kaib</u>'s system monitors and stores "useful energy remaining [in] the battery" (Ex. 1006, 4:11-13), the number of charging cycles performed (*id.*, 9:44-48), the start and completion times of battery operations (*id.*, 16:47-53), and the length of charge/discharge cycles (*id.*, 16:47-53). <u>Kaib</u> discloses that battery information, such as a low battery power condition and

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number of charging cycles, is recorded in the non-volatile memory of the data storage/processor 22. *Id.*, 4:18-21, 9:44-48. A patient's base station 30 later recalls battery information, *e.g.*, the number of charging cycles performed ("*which may be recalled later*") via interface 26. *Id.*, 6:48-63. Further, Kaib's base station logs the battery maintenance information into a maintenance log, and the maintenance log is stored in the data storage module. *Id.*, 16:47-54.

Each of <u>Kaib</u>'s battery information type is an example of "*battery charging information*." Ex. 1003, ¶90. The '690 patent identifies the following as examples of "battery charging information": (1) level of charge, (2) number of charge times, (3) duration of charge, (4) time of charge, (5) rate of charge, and (6) countdown. Ex. 1006, 50:51-54. Kaib discloses each type, as explained below.

Level of Charge – <u>Kaib</u> discloses monitoring and storing the "useful energy remaining [in a] battery." Ex. 1006, 4:11-21, 16:47-54. The "useful energy remaining [in a] battery" represents a battery's charge level. Ex. 1003, ¶91. As the '690 patent confirms, a battery's charge level is "*battery charging information*." Ex. 1001, 4:13-21 ("charge level" of a battery), 23:22-28 (storing periodic measurements of battery voltage and reporting those measurements to an HHP), 35:26-31 ("battery status icon 248 for indicating the level of battery charge"), 50:52-53 (a battery's "level of charge" is an example of battery information).
Number of Charge Times – <u>Kaib</u> discloses monitoring and storing the number of charging cycles that a battery has undergone. Ex. 1006, 9:44-48; Ex. 1003, ¶92. As the '690 patent confirms, the number of charging cycles that a battery has undergone is "*battery charging information*." Ex. 1001, 35:55-61 ("the number of times the battery has been recharged"), 50:51-52 ("the number of charge times").

Duration of Charge – <u>Kaib</u> discloses monitoring and storing the "length of charge... cycles." Ex. 1006, 16:46-53; Ex. 1003, ¶93. <u>Kaib</u> explains that a "charging cycle" is when the battery is being recharged: "[d]uring the rapid charge cycle the charger interface module 34 supplies charging current at the one hour charge rate of the battery pack 18." Ex. 1006, 11:66-12:1. <u>Kaib</u>'s reference to a "length" of a "charge cycle" represents how long it took the battery to recharge. Ex. 1003, ¶93. As the '690 patent confirms this "duration of the last charge" is "*battery charging information*." Ex. 1001, 35:55-61; *see also id.*, 3:29-35 ("duration of the last recharge"), 4:13-24 ("the duration of the recharging in the last recharge").

Time of Charge – <u>Kaib</u>'s system discloses logging the start and completion times of battery operations, such as when the battery is charged. Ex. 1006, 7:4-7, 16:47-53. As the '690 patent confirms, such charge time information is "*battery charging information*." Ex. 1003, ¶94; Ex. 1001, 50:16 ("time of charge") 50:52 (same), 50:66 (same); *see also id.*, 3:29-35 (explaining "time of charge" is "the time when the last charge occurred").

Rate of charge – As explained above, Kaib discloses monitoring the length of battery charge cycles and the battery's capacity level. Ex. 1006, 4:11-13, 16:46-53; Ex. 1003, ¶95. This information is also "battery charging information," as confirmed by the '690 patent. For example, the '690 patent identifies "rate of charge" as an example of "battery charging information." Ex. 1001, 50:53-54. A POSA would have understood "rate of charge" in the context of the '690 patent to mean the rate at which a battery charges. Ex. 1003, ¶95. Kaib's discloses, at a minimum, render obvious a rate of charge because it could be easily derived by dividing Kaib's battery capacity level by the duration of the last recharge cycle, both of which Kaib expressly monitors and stores. Ex. 1003, ¶95; Ex. 1006, 16:46-53 (length of charge cycle and duration of charge). A POSA would have further been motivated and found it obvious to store the derived rate of charge in the IPG's memory because it would indicate that a battery is malfunctioning or there are other circuitry problems. Ex. 1003, ¶96.

Countdown – <u>Kaib</u> discloses monitoring and storing "available device operating time (prior to recharging the battery)," which represents the remaining time a battery can operate before needing to be recharged. Ex. 1006, 4:10-14, 5:36-49; Ex. 1003, ¶97. The '690 patent confirms that such information is "*battery* *charging information.*" Ex. 1001, 50:51 ("countdown"); *see also id.*, 35:6-10 (explaining "*countdown*" as a "battery recharge countdown number 246 [that] shows the estimated time left before the battery of the IPG needs to be recharged."). Accordingly, <u>Kaib</u>'s available operating time is a "*countdown*." Ex. 1003, ¶97.

c. It would have been obvious to use <u>Kaib</u>'s battery monitoring technique in <u>Barreras</u>' receiver

<u>Barreras</u> and <u>Kaib</u> are analogous art to the '690 patent because each is in the field of medical device systems that have rechargeable batteries. Ex. 1001, 1:10-15; Ex. 1005, 1:7-11; Ex. 1006, 1:8-12; Ex. 1003, ¶98. Moreover, <u>Barreras</u> and <u>Kaib</u> are analogous art for being reasonably pertinent to problems addressed by the inventors of the '690 patent. <u>Kaib</u>, for example, is reasonably pertinent to a problem mentioned in the '690 patent: namely, monitoring how long the battery is expected to last before replacement is needed and providing battery status information to the patient. Ex. 1001, 35:15-18; Ex. 1006, 9:38-50. Similarly, <u>Barreras</u> is reasonably pertinent to the '690 patent's identified goal of ensuring patients are alerted when their implanted medical device needs to be recharged. Ex. 1001, 2:42-46; Ex. 1005, 6:22-24. Accordingly, <u>Barreras</u> and <u>Kaib</u> are both analogous art to the '690 patent. Ex. 1003, ¶98.

It would have been obvious to a POSA to modify Barreras using <u>Kaib</u>'s battery monitoring technique by monitoring and storing battery charging

information in Barreras receiver's memory and micro-controller for later use. Ex. 1003, ¶99. That person would have recognized the benefit of such an implementation, such as the ability to later retrieve and display battery charging information in a "specific message" on Barreras' transmitter display. Ex. 1005, 4:55-61 ("The receiver includes [] mechanism[s] for alerting the patient when the back-up power source is nearing depletion and needs to be recharged ... includ[ing] ... 3) a specific message shown in the transmitter's display combined with a specific audible tone generated by the transmitter."). The prevailing industry trend was to design all battery-powered devices, including medical devices, to monitor, store, and send battery information. See §IV.A. Kaib describes the monitoring, storing, and sending of the same types of battery information found in the smart battery specifications shown above. See §IV.A. As Mr. Pless explained, and as explained below, a POSA would have been motivated to use Kaib's battery monitoring technique in Barreras' system for several reasons as of the '690 patent's priority date. Ex. 1003, ¶99.

First, <u>Kaib</u>'s system monitors battery information that can be used to monitor a battery's future health to indicate when it needs to be replaced. For example, <u>Kaib</u> discloses that the number of charging cycles is used to determine whether to "notif[y] the patient when replacement of the battery 18 is required." Ex. 1006, 9:39-41. As explained by Mr. Pless, a POSA would have recognized that this battery information would be important and applicable to Barreras for the same reasons. Ex. 1003, ¶100.

Next, and as Mr. Pless explained, a POSA would have recognized that monitoring battery information as described by <u>Kaib</u> would be especially critical for an implanted battery, like that in <u>Barreras</u>. Ex. 1003, ¶101. Such a person would have understood that a patient could be severely injured if an implanted battery malfunctions or is not replaced when needed. *Id*. Moreover, knowing whether an implanted battery was failing to hold a charge or needed to be replaced is important to ensuring that the patient receives uninterrupted therapy (*e.g.*, stimulation) and to identifying when an implanted battery needs replacing. *Id*. Even this alone would have motivated a POSA to have <u>Barreras</u>' system monitor and store battery information as described by <u>Kaib</u>. *Id*.

Third, both <u>Kaib</u> and <u>Barreras</u> provide express reasons to modify <u>Barreras</u>' system to implement <u>Kaib</u>'s battery monitoring technique. Ex. 1003, ¶102-103. <u>Kaib</u> provides an express motivation that medical devices need to "inform[] the patient, as precisely as possible, of the status of that patient's device, and particularly the status of the device battery." Ex. 1006, 1:41-46. Indeed, the battery specifications confirm that this rationale was important to all users of various battery-powered devices, including medical devices. Ex. 1009, 2-3 ("In most systems today, the user never knows how much charge is left in the battery.... The Smart Battery provides the user with accurate state of charge information along with an accurate prediction of the remaining operating time."); Ex. 1011, 5 (using the smart battery specification in a medical device); Ex. 1003, ¶102. Accordingly, a POSA would have been motivated to combine Barreras and Kaib for the rationale provided by Kaib.

Moreover, <u>Barreras</u> provides another express reason to monitor recharge cycles by describing problems that occur over a battery's service life (*e.g.*, electrolyte loss and generating harmful gases). Ex. 1005, 5:43-50. As explained by Mr. Pless, a POSA would have recognized that these problems result from a battery being recharged multiple times over a prolonged period. Ex. 1003, ¶103. A POSA would have recognized that, by monitoring the number of recharge cycles, therapy interruptions can be avoided by replacing the battery when needed. *Id*.

In addition, it would have been obvious use <u>Kaib</u>'s well-known technique in <u>Barreras</u>' system to achieve the same benefit achieved by other devices using the same technique at that time, *i.e.*, to inform a user of helpful battery information. As explained above, *see* §IV.A, the SBS specifications confirm that <u>Kaib</u>'s technique of storing and using battery information was well-known and used in various battery-powered devices, including medical devices, to advantageously provide the user with accurate state of charge information and prediction of the

remaining operating time for power management. Ex. 1009, 1, 3; see also Ex. 1006, 1:41-46 ("inform[] the patient, as precisely as possible, of the status of that patient's device, and particularly the status of the device battery."). Indeed, industry leaders wrote specifications addressing how to use the same battery information to improve battery-powered devices over three years before the '690 patent was filed. See §IV.A; Ex. 1009, 3, 9, 13, 16, 20. As Mr. Pless explained, a POSA would have found it obvious to use the same technique described in Kaib in the system of Barreras to improve it in the same way—that is, inform the user of helpful information. Ex. 1003, ¶104-106. Moreover, and explained by Mr. Pless, storing and sending battery information was well within the level of a POSA at the time of the '690 Patent. Ex. 1003, ¶105; Ex. 1020 1:77-67 (showing a battery communicating battery information as early as 1980); Ex. 1021, 3:40-64 (storing and sending battery information as early as 1995). Accordingly, it would have been obvious use Kaib's well-known battery monitoring technique in Barreras' system of to improve that system for the same reasons that Kaib and other industry leaders implemented that technique in other battery-powered devices, *e.g.*, inform a user of a battery's status, such as the remaining time that the battery can power the device. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007) ("For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in

the same way, using the technique is obvious unless its actual application is beyond his or her skill.")

Finally, and as Mr. Pless explained, a POSA would have also been motivated to track battery information to determine whether the implant was potentially defective thereby allowing correction of any latent defects, such as having a defective battery. Ex. 1003, ¶107. Using this battery information, a POSA would have recognized that a manufacturer would be able to correct any latent defects, such as receiving multiple defective batteries from one supplier. *Id.* Such a POSA would have recognized that there may be a problem with a set of batteries if they need replacement after a low number of recharge cycles. *Id.* Mr. Pless explained that a POSA would have recognized that analyzing these potential problems would provide valuable insight to improving batteries for future implanted devices by fixing any latent defects. *Id.*

v. Wherein the external programmer includes a status indicator for indicating the status of the replenishable power source within the implantable medical device

<u>Barreras</u> discloses this feature of claim 1. For example, <u>Barreras</u>' system has alarms that are triggered based on the status of rechargeable power source 44 ("*the replenishable power source*") in the receiver 14 ("*the implantable medical device*"). Microcontroller 46 triggers these alarms (a "*status indicator for indicating the status of the replenishable power source*") to alert a user when the charge in the rechargeable power source 44 falls below a threshold. Ex. 1005, 4:55-61 ("The receiver includes [] mechanism[s] for alerting the patient when the back-up power source is nearing depletion and needs to be recharged"); *see also id.*, 9:63-67. These alarms indicate that the rechargeable power source 44 needs to be recharged ("*status of the replenishable power source*"). *Id.*; Ex. 1003, ¶110.

One of <u>Barreras</u>' alarms alerts the patient using "a specific message shown on the transmitter's display combined with a specific audible tone generated by the transmitter." Ex. 1005, 4:55-61 ("The receiver includes [] mechanism[s] for alerting the patient when the back-up power source is nearing depletion and needs to be recharged ... includ[ing] ... 3) a specific message shown in the transmitter's display combined with a specific audible tone generated by the transmitter."). Accordingly, this alarm or specific message ("*status indicator*") uses the transmitter's ("*external programmer*") display to alert the patient that the rechargeable power source in the receiver 14 needs to be recharged ("*indicating the status of the replenishable power source within the implantable medical device*"). Ex. 1003, ¶111.

4. <u>Claim 2</u>

Claim 2 recites "wherein the replenishable power source is a rechargeable battery." <u>Barreras</u> discloses that its rechargeable power source 44 may be a

"rechargeable battery contained within the implanted receiver." Ex. 1005, 5:3-8; Ex. 1003, ¶113.

5. <u>Claim 3</u>

Claim 3 recites "wherein the status indicator provides an indication of battery status, including the level of battery charge."

Barreras discloses that receiver 14 sends a "recharge" command to transmitter 12 when the charge in the rechargeable power source 44 falls below a threshold. Ex. 1005, 8:35-39; see also id., 4:55-61 ("The receiver includes [] mechanism[s] for alerting the patient when the back-up power source is nearing depletion and needs to be recharged"), 9:63-67. Once the "recharge" command is received by the transmitter, <u>Barreras</u>' alarm ("status indicator") alerts the patient using "a specific message shown on the transmitter's display combined with a specific audible tone generated by the transmitter." Id., 4:55-61 ("The receiver includes [] mechanism[s] for alerting the patient when the back-up power source is nearing depletion and needs to be recharged ... includ[ing] ... 3) a specific message shown in the transmitter's display combined with a specific audible tone generated by the transmitter."). This alarm shows that Barreras' power source has a charge level lower than a predetermined threshold thereby indicating the "level of *battery charge.*" Ex. 1003, ¶115.

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To the extent that Patent Owner argues that the teachings of <u>Barreras</u> alone do not render this limitation obvious, the combination of <u>Barreras</u> and <u>Kaib</u> also renders this limitation obvious based on <u>Kaib</u>'s battery monitoring technique.

Like <u>Barreras</u>, <u>Kaib</u> also discloses that "[e]nergy usage of the monitordefibrillator 12 is monitored in real time to determine the useful energy remaining of the battery per charge." Ex. 1006, 4:10-13. The "useful energy remaining of a battery charge 18" is consistent with the '690 patent's description of "*level of battery charge*" as explained above. *See* §VI.A.3.iv.b. The "useful energy remaining of the battery" represents the remaining charge level of a battery (*e.g.*, percentage of battery charge level). Ex. 1003, ¶117. This information is displayed to the patient upon request "at any time," and "indicates the operating time remaining for the battery 18." Ex. 1006, 4:13-17.

As shown above, *see* §VI.A.3.iv.c, it would have been obvious to modify <u>Barreras</u> to include <u>Kaib</u>'s battery monitoring technique such that <u>Barreras</u> would monitor and store battery information, such as the battery charge level disclosed by <u>Kaib</u>, in <u>Barreras</u> non-volatile memory 27 so that it can be provided to the user when requested. Accordingly, and as combined above, <u>Barreras'</u> non-volatile memory 27 would store the "useful energy remaining of the battery" (*"level of battery charge"*) and provide that information to a user upon request (*"the status* *indicator provides an indication of battery status, including the level of battery charge*"). Ex. 1003, ¶118.

6. <u>Claim 5</u>

Claim 5 recites "wherein the means for recording charging information is a memory storage contained within the implantable device, which can record battery status data, including time of charge, duration of charge, rate of charge, and level of charge, and which battery status data can be recalled from the memory storage by the external programmer using RF communication."

<u>Barreras</u>' non-volatile memory 27 is contained within an implantable device, shown below:



Ex. 1005, Fig. 1 (annotated), 7:44-47; Ex. 1003, ¶121.

As shown above, *see* §VI.A.3.iv, it would have been obvious to modify <u>Barreras</u> to include <u>Kaib</u>'s battery monitoring technique that would monitor and store battery charging information in Barreras' non-volatile memory 27. Ex. 1003, ¶122. <u>Kaib</u>'s disclosures of battery charging information similarly disclose *"battery status data." Id.*

<u>Kaib</u> discloses a medical device system that monitors a battery's status using various information about the battery. For example, <u>Kaib</u>'s battery monitoring technique stores battery information to monitor the condition of a device's battery.

Ex. 1006, 1:55-58. As shown above, *see* §VI.A.3.iv.b, <u>Kaib</u> discloses the following "*battery status data*": (1) logging the start and completion times of battery operations (each being a "*time of charge*"), (2) monitoring and storing the length of charge cycles ("*duration of charge*"), (3) monitoring and storing the length of charge cycles along with the battery's capacity level ("*rate of charge*"), and (4) monitoring and storing the "useful energy remaining in a battery" ("*level of charge*"). Ex. 1003, ¶123.

As combined, a POSA would have been motivated to use in <u>Barreras</u>' system the above battery status data, as disclosed by <u>Kaib</u>, to monitor detailed information regarding the status of rechargeable power source 44 in Barreras. *See* §VI.A.3.iv.c. As shown above, <u>Barreras</u> non-volatile memory 27 stores values and critical data that can be recalled later when requested. *See* §VI.A.3.iv.a. Barreras' non-volatile memory 27, as modified, would have stored such battery status data until it is requested by transmitter 12 ("*which battery status data can be recalled from the memory storage by the external programmer using RF communication*"). Ex. 1003, ¶124; *see also* §VI.A.3.iv.c.

7. <u>Claim 8</u>

Claim 8 recites "wherein the status indicator is selected from the group consisting of an audible signal emanating from the external programmer and a visual signal on the external programmer."

Barreras discloses an audible alarm and visual alarm located on the transmitter ("external programmer"). For example, Barreras describes "a specific message shown on the transmitter's display" ("a visual signal on the external programmer") that can be "combined with a specific audible tone generated by the transmitter" ("an audible signal emanating from the external programmer"). Ex. 1005, 4:55-61 ("The receiver includes [] mechanism[s] for alerting the patient when the back-up power source is nearing depletion and needs to be recharged ... include[ing] ... 3) a specific message shown in the transmitter's display combined with a specific audible tone generated by the transmitter."). Barreras thus discloses two ways that the transmitter alerts a patient: (1) a visual alarm shown on a display, and (2) an audible alarm emanating from a speaker. Ex. 1003, ¶126; see also Ex. 1005, 4:55-61, Fig. 1 (transmitter display 32 and a speaker appears on left side of micro controller 26). Both alarms (each being a "status indicator") alert the patient that the back-up power source needs to be recharged. See Ex. 1005, Fig. 1 (showing transmitter display 32 and speaker); Ex. 1003, ¶126.

8. <u>Claim 9</u>

Claim 9 recites a "*means for non-invasively recharging the replenishable power source through the skin.*" As shown above, *see* §V.B, the corresponding structure in the '690 patent for performing the recited function: an external power source 277, power amplifier 275, an external coil 279, and an implanted coil 680 placed both inside and outside the patient. *See* Ex. 1001, Fig. 9. Ex. 1003, ¶128.

<u>Barreras</u> discloses a battery and two coils—one located inside the implanted IPG and the other located outside the patient in the transmitter. Although <u>Barreras</u> does not expressly disclose a power amplifier, <u>Barreras</u> discloses that battery power is converted from DC-to-AC before being transmitted over coil 64. This is the same conversion performed by the power amplifier in the '690 patent. Ex. 1003, ¶129. To the extent Patent Owner argues <u>Barreras</u> does not expressly disclose a power amplifier, a power amplifier would be inherent to <u>Barreras</u>' transmitter or, at a minimum, would have been obvious to include a power amplifier in Barreras' transmitter.

i. <u>Barreras</u> discloses a power source and two coils

Barreras discloses a method for "non-invasively recharging the power source within a receiver" by using an "inductive RF power link between the external transmitter (recharging unit) and the implanted receiver (unit being recharged)." Ex. 1005, 5:34-41, 6:28-31. Barreras further discloses that transmitter 12, after receiving a "recharge" command, will generate high energy RF waves via battery 62 ("a power source" for the "*means for non-invasively recharging*...") that is sent output inductor 64, shown in Figure 1 below:



Ex. 1005, Fig. 1 (annotated), 8:35-43, Ex. 1003, ¶130.

As depicted in annotated Figure 1 above, inductors 64 and 60 are both coils. Ex. 1003, ¶131. <u>Barreras</u>' second inductor 60 receives high energy RF waves and converts them to into a current level in order to recharge the rechargeable battery source 44. Ex. 1005, 8:56-58. Microcontroller 46 regulates the current level and sends feedback to the transmitter 12 to alter the high energy RF waves if needed. *Id.*, 8:43-53; Ex. 1003, ¶131. Accordingly, <u>Barreras</u> discloses recharging the implanted battery by sending RF energy through a patient's skin using inductors 64 and 60 and battery 62 (two coils of the "*means for non-invasively recharging* ... "); Ex. 1003, ¶131.

<u>Barreras</u> thus discloses this limitation by having the transmitter's battery 62 send RF power using two coils 64 and 60, which satisfies the corresponding structures for a "*means for non-invasively recharging the replenishable power source through the skin.*" Ex. 1003, ¶130-132.

ii. <u>Barreras</u> discloses a power amplifier or alternatively renders it obvious

As Mr. Pless explained, power received by <u>Barreras</u>' battery 41 is converted from direct current (DC) to alternating current (AC) before transmitting over coil 64. Ex. 1003, ¶133; *see* Ex. 1005, 8:39-43 ("This will cause the transmitter 12 to generate, via the battery 62, the DC/DC converter 28 and [the] output inductor 64, high energy RF waves which are coupled into the inductor 60 contained within the receiver 14."), 4:64-67 ("This RF coupled power, which is alternating current or AC in nature, is rectified, filtered and converted into a high DC voltage within the receiver."). Accordingly, this conversion must be performed by a DC-to-AC converter, or an equivalent component, found in <u>Barreras</u>' transmitter 12. According to the '690 patent, the purpose of its power amplifier is to perform the same DC-to-AC conversion as <u>Barreras</u>' DC-to-AC converter. Ex. 1001, 41:53-61 ("A power amplifier ... essentially comprises DC-to-AC conversion circuitry that

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converts dc power from the battery 277 to an ac signal that may be inductively coupled through a coil"), Ex. 1003, ¶133.

As Mr. Pless explained, a POSA would have read <u>Barreras</u>' disclosure about the DC-to-DC converter to be actually a DC-to-AC converter because it outputs an alternating current. Ex. 1003, ¶134; Ex. 1005, 4:64-67 ("This RF coupled power, which is alternating current or AC in nature, is rectified, filtered and converted into a high DC voltage within the receiver."). To the extent that one argues that <u>Barreras</u> does not disclose a DC-to-AC converter, it would be inherent in <u>Barreras</u> transmitter because coil 64 transmits AC power that originates from DC power from battery 41. Ex. 1003, ¶134.

Alternatively, it would have been obvious to include a power amplifier in <u>Barreras</u>' transmitter. As the '690 patent admits, power amplifiers were known in the art. Ex. 1001, 41:56-61; Ex. 1007, Fig. 2, 78, 10:38-51 (showing power amplifiers were used to recharge an implanted device's power source almost a decade before the '690 patent was filed). Using a power amplifier in <u>Barreras</u>' transmitter would have been obvious because it would merely include a known element (*i.e.*, power amplifier) to perform the same function (*i.e.*, converting power from a battery to send over coil 64) and yielding no more than one would expect from an arrangement. *KSR Intl Co.*, 550 U.S. at 417 (stating "when a patent simply arranges old elements with each performing the same function it had been

known to perform and yields no more than one would expect from such an arrangement, the combination is obvious") (internal quotes omitted); Ex. 1003, ¶135.

9. <u>Claim 10</u>

Claim 10 recites "wherein the means for non-invasively recharging the replenishable power source is transcutaneous, RF power transmissions using a primary, implanted coil connected to the IPG and a secondary, external coil connected to an external recharger, wherein the primary and secondary coils are placed over each other to effect RF power transmission."

As shown above, *see* §VI.A.8, <u>Barreras</u> discloses recharging the implanted battery ("*replenishable power source*") by sending RF energy through a patient's skin ("*transcutaneous*, *RF power transmissions*") using inductor 60 ("*a primary*, *implanted coil connected to the IPG*") and inductor 64 ("*a secondary, external coil*") connected to a battery and power amplifier ("*external recharger*"). *See* §VI.A.8; Ex. 1003, ¶137.

Effective RF power transmission requires placing charging inductors 60 and 62 near each other. Ex. 1005,, 8:53-55 ("A close proximity requires much less RF energy to recharge the rechargeable power source 44 than a longer distance would, in the same time."); *see also id.*, 5:67-6:3 ("If 'RF power' is selected, the implanted receiver will only operate when the transmitter unit is proximate to the

planted receiver."); Ex. 1003, ¶138. Hence, both the transmitter and receiver must be placed in close proximity to each another ("*placed over each other to effect RF power transmission*") for RF power transmission. Ex. 1003, ¶138.

- 10. <u>Claim 32</u>
 - i. *Preamble*

Claim 32 recites "[*a*] *method for detecting and indicating the status of a rechargeable battery contained within an implanted medical device, the device having a memory storage for storing battery status data.*" To the extent the preamble is limiting, the combination of <u>Barreras</u> and <u>Kaib</u> renders this limitation obvious.

As shown above, *see* §§VI.A.3.i and VI.A.3.iv, <u>Barreras</u> discloses an implanted receiver 14 (*"implantable medical device"*) containing a rechargeable power source 44 (*"rechargeable battery"*) and non-volatile memory 27 (*"memory storage"*), shown in Figure 1 below:



Ex. 1005, Fig. 1 (annotated), 7:33-37; Ex. 1003, ¶141.

<u>Barreras</u> further discloses that receiver 14 has a "mechanism for alerting the patient when the back-up power source is nearing depletion and needs to be recharged." Ex. 1005, 4:55-57. Receiver 14 detects when the charge in the rechargeable power source 44 falls below a predetermined level ("*detecting ... the status of a rechargeable battery*"). *Id.*, 9:63-67; Ex. 1003, ¶142. Once detected, receiver 14 notifies the patient using one or more of several alarms indicating that the rechargeable power source needs to be recharged ("*indicating the status of a rechargeable battery*"). Ex. 1005, 9:63-67, 4:55-61; Ex. 1003, ¶142. These alarms

may be located in the receiver 14 (*e.g.*, alarms 96 and 98) and/or in the transmitter 12. Ex. 1005, 4:55-61; Ex. 1003, \P 142.

Though <u>Barreras</u> discloses a non-volatile memory 27 ("*a memory storage*"), <u>Barreras</u> does not explicitly disclose that its memory is "*for storing battery status data.*" <u>Kaib</u>, however, discloses "*a memory storage for storing battery status data.*" For example, <u>Kaib</u> discloses a system for monitoring rechargeable batteries for a portable medical device, shown in Figure 1 below:



Ex. 1006, Fig. 1 (annotated), 1:5-12; Ex. 1003, ¶143.

53 Petition for *Inter Partes* Review Kaib's monitor-defibrillator 12 uses a processor and corresponding data storage 22 ("*a memory storage*") to monitor the status of a rechargeable battery 18. Ex. 1006, Fig. 1. 4:1-8; Ex. 1003, ¶144. The number of charging cycles performed (one type of "*battery status data*") on battery 18 is monitored and recorded in data storage 22. Ex. 1006, 9:44-48; Ex. 1003, ¶144. Patient base station 30 downloads the number of charging cycles performed along with other information via interface 26. Ex. 1006, 6:48-63. The number of charging cycles helps "notif[y] the patient when replacement of the battery 18 is required." Ex. 1006, 9:39-41. In addition, <u>Kaib</u> discloses that battery information, such as a low battery condition (another type of "*battery status data*"), is recorded in the nonvolatile memory of the data storage/processor 22. Ex. 1006, 4:18-21; Ex. 1003, ¶144.

As shown above, *see* §VI.A.3.iv, <u>Barreras</u> and <u>Kaib</u> are analogous art to the 690 Patent. Likewise, and as shown above in §VI.A.3.iv, a POSA would have been motivated to incorporate <u>Kaib</u>'s battery monitoring technique that records battery information ("*battery status data*"), such as low power condition and the number of recharge cycles, in the <u>Barreras</u> receiver's non-volatile memory 27 to be recalled later. Moreover, and as explained by Mr. Pless, a POSA would have been motivated to have <u>Barreras</u>' receiver store a low power condition, as described by <u>Kaib</u>, in order to determine how often a patient lets a battery become depleted

before recharging. Ex. 1003, ¶145. Such a person would have recognized that a battery lasts longer when the battery charge is frequently allowed to fall to a low level before recharging. Ex. 1003, ¶145.

ii. *Implanting the Medical Device*

<u>Barreras</u> discloses this limitation by showing that receiver 14 is "surgically implanted within the patient." Ex. 1005, 4:18-19; 7:36-38 ("The system 10 includes a transmitter 12 and a receiver 14, the latter being surgically implanted beneath a patient's skin"). In addition, Figure 1 shows that the receiver 14 resides beneath a patient's skin 16. *Id.*, Fig. 1, 7:36-38; Ex. 1003, ¶147. Accordingly, Barreras discloses implanting receiver 14 ("*the medical device*").

iii. Interrogating the medical device with [an] external hand held programmer to upload battery status data stored in memory storage

As explained above, *see* §VI.A.3.iii, <u>Barreras</u> discloses a transmitter that communicates therapy values with the implanted device. Barreras further explains that the transmitter is "portable," "worn externally by the patient," and powered by a battery. Ex. 1005, Abstract, 14:22-24. Accordingly, Barrera's transmitter 12 is an "*external hand-held programmer*." Ex. 1003, ¶148.

<u>Kaib</u>'s battery monitoring technique has external devices that request battery status information for numerous uses. A patient may request ("*interrogat[e]*") a battery check on the monitor-defibrillator 12 using a patient display 24 that displays to the user (1) the remaining useful energy in a battery, and (2) the remaining operating time. Ex. 1006, 4:8-16. The patient makes this request by pressing a button on display 24. *Id.*, 4:15-16, 4:21-22. The results are shown on the patient display 24 when requested from <u>Kaib</u>'s monitor-defibrillator 12. *Id.* Similarly, patient base station 30 retrieves (*"interrogating"*) and uses battery information (*e.g.*, the number of charging cycles) stored in the monitor-defibrillator 22 (*"medical device"*) to decide whether a battery needs to be replaced. *Id.*, 9:38-51. Accordingly, <u>Kaib</u> discloses that external devices interrogate a medical device for battery information when that information is needed. Ex. 1003, ¶149.

<u>Barreras</u>, as combined with <u>Kaib</u>, discloses a system where <u>Barreras</u>' transmitter 12 (an "*external hand-held programmer*") requests battery information, as described by Kaib, when needed. As combined, <u>Barreras</u>' transmitter would, for example, request a remaining battery voltage and time when instructed by the patient. Ex. 1003, ¶150. The remaining battery voltage would also be sent from the receiver 14 when the battery reaches a predetermined level indicating that it needs to be recharged. Ex. 1003, ¶150. As another example, <u>Barreras</u>' transmitter 12 would likewise request the number of charging cycles when needing to determine whether the battery needs to be replaced. Ex. 1003, ¶150. Until then, the non-volatile memory 27 in receiver 14 will store the battery information ("*stored in memory storage*"). *Id*. Accordingly, the combination of <u>Barreras</u> and <u>Kaib</u> discloses storing battery status information in non-volatile memory 27 until it is requested (*"interrogating*") from the transmitter 12 (*"external hand held programmer"*). Ex. 1003, ¶151. Once requested, receiver 14 would transmit the requested battery status information to the transmitter 12 (*"upload battery status data"*), which will be shown on the transmitter's display 32. *See* Ex. 1005, 4:58-61 ("The mechanism can include ... 3) a specific message shown in the transmitter's display combined with a specific audible tone generated by the transmitter."); Ex. 1003, ¶151.

A POSA would have been motivated and found it obvious to include <u>Kaib</u>'s teachings in implementing <u>Barreras</u>' system for the same reasons as explained above. *See* §§VI.A.3.iv, VI.A.6; Ex. 1003, ¶152.

iv. Indicating the battery status with a status indicator is vibration emanating from the HHP

<u>Barreras</u> discloses "*indicating the battery status with a status indicator*" located on the external programmer for the same reasons as explained above. *See* §VI.A.3.v. For example, <u>Barreras</u> discloses that the transmitter 12 has an alarm that notifies the patient through a message shown on the transmitter display 32 ("*a status indicator*"). *See* Ex. 1005, 4:55-61; Ex. 1003, ¶153.

<u>Barreras</u> does not expressly disclose where that "*status indicator is vibration emanating from the HHP*." A POSA would have recognized, however, that modifying <u>Barreras</u>' transmitter to include a vibrating alarm would have been obvious for several reasons. Ex. 1003, ¶¶154-156.

First, a POSA would have been motivated to provide an additional alarm (*i.e.*, vibrating alarm) in <u>Barreras</u>' transmitter for alarm redundancy. Ex. 1003, ¶155. As explained above, §IV.A.2, the use of a vibrating alarm in a medical device was a well-known at the time. And as explained by Mr. Pless, a POSA would have been motivated to include a vibrating alarm on <u>Barreras</u>' transmitter to alert patients who may be hearing impaired or have other impairments that inhibit the efficacy of alarms 96 and 98. Ex. 1003, ¶155. Notably, <u>Barreras</u> recognized a need for multiple alarms and a vibrating alarm is a useful way to alert a patient. Ex. 1005, 4:56-61. As Mr. Pless further explained, another alarm would be useful as a back stop in the event that the other alarms happened to fail. Ex. 1003, ¶155.

Second, and as explained by Mr. Pless, including a status indicator on the external programmer would have been a simple arrangement of old elements (*i.e.*, vibrating alarm) with each performing the same function it had been known to perform (*i.e.*, notifying a user) and yield no more than one would expect from such an arrangement. Ex. 1003, ¶156.

11. <u>Claim 33</u>

i. *Preamble*

Claim 33 recites "[*a*] *method for detecting and indicating the status of a rechargeable battery contained within an implanted medical device, the device having a memory storage for storing battery status data.*" To the extent the preamble is limiting, the combination of <u>Barreras</u> and <u>Kaib</u> renders this limitation obvious for the same reasons as explained above. *See* §VI.A.10.i; Ex. 1003, ¶157.

ii. *Implanting the Medical Device*

Barreras discloses this feature of claim 33 for the same reasons as explained above. *See* §VI.A.10.ii; Ex. 1003, ¶158.

iii. Interrogating the medical device with an external programmer to upload battery status data stored in memory storage, wherein the battery status data includes the last time the battery was charged, duration of the last charge, and number of times charging has been performed

The combination of <u>Barreras</u> and <u>Kaib</u> renders this feature of claim 33 obvious for the same reasons as explained above. *See* §§ VI.A.10.iii. As shown above, *see* §VI.A.3.iv.b, <u>Kaib</u> discloses the following "*battery status data*": (1) logging the completion times of battery operations ("*the last time the battery was charged*"), (2) monitoring and storing the length of charge cycles ("*duration of the last charge*"), (3) monitoring and storing the number of charging cycles that a battery has undergone ("*number of times charging has been performed*"). As

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further explained above, a POSA would have been motivated to use in <u>Barreras</u>' system the above battery status data, as disclosed by <u>Kaib</u>, to monitor detailed information regarding the status of rechargeable power source 44 in Barreras. *See* §VI.A.3.iv.c. Ex. 1003, ¶159.

iv. Indicating the battery status with a status indicator included on the external programmer

<u>Barreras</u> discloses this feature of claim 33 for the same reasons as explained above. *See* §VI.A.3.v. In particular, <u>Barreras</u> discloses that the transmitter 12 has an alarm that notifies the patient through a message shown on the transmitter display 32 ("*a status indicator*"). *See* Ex. 1005, 4:55-61; Ex. 1003, ¶160.

12. <u>Claim 34</u>

Claim 34 recites "*wherein the status indicator is a visual sign from a display*." As shown above, the combination of <u>Barreras</u> and <u>Kaib</u> discloses this claim element for the same reasons as explained above. *See* §VI.A.3.v. For example, <u>Barreras</u> discloses that the transmitter 12 has an alarm that notifies the patient through a message shown on the transmitter display 32 ("*a status indicator*"). *See* Ex. 1005, 4:55-61. A message shown through <u>Barreras</u>' transmitter display is a "*visual sign from a display*." Ex. 1003, ¶161; *see also* Ex. 1005, 4:55-61.

- 13. <u>Claim 37</u>
 - i. *Preamble*

Claim 37 recites "A method for detecting and indicating the status of a rechargeable battery contained within an implanted medical device, the device having a memory storage for storing battery status data." To the extent the preamble is limiting, the combination of <u>Barreras</u> and <u>Kaib</u> renders this claim element obvious for the same reasons as explained above. *See* §VI.A.11.i; Ex. 1003, ¶162.

ii. Implanting the Medical Device

The combination of <u>Barreras</u> and <u>Kaib</u> renders this feature of claim 37 obvious for the same reasons as explained above. *See* §VI.A.11.ii; Ex. 1003, ¶163.

> iii. Interrogating the medical device with an external programmer to upload battery status data stored in memory storage

The combination of <u>Barreras</u> and <u>Kaib</u> renders this feature of claim 37 obvious for the same reasons as explained above. *See* §VI.A.11.iii; Ex. 1003, ¶164.

iv. Indicating the battery status with a status indicator included on the external programmer

The combination of <u>Barreras</u> and <u>Kaib</u> renders this feature of claim 37 obvious for the same reasons as explained above. *See* §VI.A.3.v. For example, <u>Barreras</u> discloses that the transmitter 12 has an alarm that notifies the patient

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through a message shown on the transmitter display 32 ("*a status indicator*"). *See* Ex. 1005, 4:55-61; Ex. 1003, ¶165.

v. Indicating the battery status with a second status indicator included in the implantable medical device

The combination of <u>Barreras</u> and <u>Kaib</u> renders this feature of claim 37 obvious for the same reasons as explained above. *See* §VI.A.3.v. Barreras, for instance, has a receiver with a vibrating alarm 98 or audible alarm 96 (each being a "*second status indicator*") that is different from the alarm (a first "*status indicator*") using on the transmitter's display 32. *See* Ex. 1005, Fig. 1, 4:55-61, 9:63-67; Ex. 1003, ¶166.

14. <u>Claim 38</u>

Claim 38 recites "[*t*]*he method of claim 37, wherein the second status indicator is an audible sound emanating from the medical device.*"

As shown above, *see* §VI.A.3.v, <u>Barreras</u> discloses an audible alarm 96 ("*wherein the second status indicator is an audible sound emanating from the medical device*") located in the implanted receiver 14 that alerts a patient when power source 44 needs to be recharged. *See* Ex. 1005, Fig. 1, 4:55-61, 9:63-67. An audible alarm makes an audible sound. Ex. 1003, ¶167.

B. Claim 23 is rendered obvious over <u>Barreras</u> (Ex. 1005) alone

- 1. <u>Claim 23</u>
 - i. *Preamble*

Claim 23 recites "An implantable medical device system having a

replenishable power source." To the extent the preamble is limiting, Barreras

discloses this claim element for the same reasons as explained above. See §

VI.A.3.i; Ex. 1003, ¶168.

ii. An implantable medical device, the device having a housing which contains processing circuitry

Barreras discloses this feature of claim 23 for the same reasons as explained

above. See §VI.A.3.ii; Ex. 1003, ¶169.

iii. An external programmer that may be placed in telecommunicative contact with the implantable medical device

Barreras discloses this feature of claim 23 for the same reasons as explained

above. See §VI.A.3.iii; Ex. 1003, ¶170.

iv. Wherein the external programmer includes a status indicator for indicating the status of the replenishable power source with the implantable medical device

Barreras discloses this feature of claim 23 for the same reasons as explained

above. See §VI.A.3.v; Ex. 1003, ¶171.

v. Wherein the external programmer is a portable, hand held programmer (HHP)

Barreras discloses this feature of claim 23 for the same reasons as explained above. *See* §VI.A.10.iii; Ex. 1003, ¶172; *see also* Ex. 1005, Abstract, 14:22-24.

vi. Wherein the status indicator is a vibration of the HHP <u>Barreras</u> renders this feature of claim 23 obvious for the same reasons as explained above. *See* §VI.A.10.iv; Ex. 1003, ¶173.

C. Claims 9-10 are Obvious Over <u>Barreras</u> (Ex. 1005) in View of <u>Kaib</u> (Ex. 1006), and in Further in View of <u>Schulman</u> (Ex. 1022)

To the extent that one argues that the combination of <u>Barreras</u> and <u>Kaib</u> does not explicitly disclose "*an external recharger*," it would have been obvious over the combination of <u>Barreras</u> and <u>Kaib</u> in further view of U.S. Patent No. 6,185,452 to <u>Schulman</u>.

1. <u>Schulman (Ex. 1022)</u>

US. Patent No. 6,185,452 to Schulman et al. ("<u>Schulman</u>") was filed on February 25, 1998 and is, therefore, prior art to the '690 patent under 35 U.S.C. § 102(e). <u>Schulman</u> discloses an implanted device that communicates with two devices: an external charger 118 and a clinician programmer 172. Ex. 1022, 5:57-60, 6:30-39. In addition, <u>Schulman</u>'s external charger 118 recharges an implanted device's battery via two coils. *Id.*, Fig. 2; 4:27-32; Ex. 1003, ¶176.

2. <u>Claims 9 and 10</u>

Claim 9 recites a "means for non-invasively recharging the replenishable power source through the skin." Claim 10, which depends on claim 9, recites "wherein the means for non-invasively recharging the replenishable power source is transcutaneous, RF power transmissions using a primary, implanted coil connected to the IPG and a secondary, external coil connected to an external recharger, wherein the primary and secondary coils are placed over each other to effect RF power transmission."

To the extent that Patent Owner argues that <u>Barreras</u> does not disclose an "*external recharger*" or that the "*means for non-invasively recharging*…" requires an external recharger as a separate device from <u>Barreras</u>' transmitter, it would have been obvious to use <u>Schulman</u>'s external charger to recharge the <u>Barreras</u>' power source 44 in addition to Barreras' transmitter.

<u>Schulman</u> discloses an implanted micro-stimulator that communicates with an external charger 118 and a clinician programmer 172, shown below:



Ex. 1022, Fig. 3A, 5:57-60 ("In an exemplary charging mode,... each device 100 can individually communicate with charger 118 so that charge 118 can determine when all of the implanted devices 100 have been fully charged"); *see also id.*,
6:30-39 (explaining that the clinician's programmer 172 communicates with implanted devices 100); Ex. 1003, ¶178.

<u>Schulman</u> further discloses an implanted device 100 receives power from the external charger 118 using an internal coil 116. Ex. 1022, Fig. 2; 4:27-32. Specifically, <u>Schulman</u> discloses that "coil 116 receives power in the form of an alternating magnetic field generated from an external power source 118...and responsively supplies an AC current" used to charge the implanted device's
battery. *Id.*, 4:27-32; *see also id.*, 4:40-48. A POSA would have understood that the received power is generated from a DC-to-AC converter (e.g., a power amplifier) found in <u>Schulman</u>'s external charger. Ex. 1003, ¶179; *see* Ex. 1022, 3:40-45. Once the battery is sufficiently charged, the implanted device 100 sends battery status information to show it no longer needs charging. Ex. 1022, 4:51-56; Ex. 1003, ¶179. Like <u>Barreras, Schulman</u>'s system recharges an implanted device's battery using two coils: one on the implanted device and another connected to external charger ("*an external coil connected to an external recharger*"). Ex. 1003, ¶179.

As explained above, <u>Barreras</u> and <u>Kaib</u> are analogous art with the '690 patent. Similarly, <u>Schulman</u> is analogous art with the '690 patent because each is in the field of medical device systems that have rechargeable batteries. Ex. 1001, 1:10-15; Ex. 1022, 1:8-14 ("The present invention relates to...such [implanted] devices incorporating a battery for powering electronic circuitry for various purposes including tissue...stimulation...."); Ex. 1003, ¶180. Moreover, <u>Schulman</u> is reasonably pertinent to the '690 patent's identified goal of ensuring patients are alerted when their implanted medical device needs to be recharged. Ex. 1001, 2:42-46; Ex. 1022, 7:48-51 ("When this low voltage condition is detected, a preferred device periodically emits a corresponding status signal...to request that the battery be recharged."); Ex. 1003, ¶180. It would be obvious to incorporate <u>Schulman</u>'s external charger in the combination of <u>Barreras</u> and <u>Kaib</u> for two reasons. First, it would be an arrangement of old elements (*i.e.*, <u>Schulman</u>'s external charger) that performs the same function it has been known to perform (*i.e.*, recharging an implanted device's battery) and yields no more than one would expect from such an arrangement. Ex. 1003, ¶181. Second, and as Mr. Pless explained, a POSA would have been motivated to make this combination in order to have multiple devices (*i.e.*, <u>Barreras'</u> transmitter and <u>Schulman</u>'s external charger) that can recharge the implanted device's battery in case one device fails or is lost. Ex. 1003, ¶182.

D. Claim 4 Is Obvious Over <u>Barreras</u> (Ex. 1005) in View of <u>Kaib</u> (Ex. 1006), and in Further View of <u>Munshi</u> (Ex. 1007)

1. <u>Munshi (Ex. 1007)</u>

U.S. Patent No. 5,411,537 (Ex. 1007) issued on May 2, 1995 and is, therefore, prior art to the '690 patent under 35 U.S.C. § 102(b). <u>Munshi</u> discloses an implanted cardioverter-defibrillator with a rechargeable battery. Ex. 1007, Abstract. <u>Munshi</u> further discloses that one type of rechargeable battery that powers implanted devices is a lithium-ion battery. *Id.*, 7:54-55; *see also id.*, 7:4-8:32; Ex. 1003, ¶185.

2. <u>Claim 4</u>

Claim 4 depends on claim 2 and recites "*wherein the rechargeable battery is a lithium-ion battery*." As shown above, the combination of <u>Barreras</u> and <u>Kaib</u>

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renders claims 1-2 obvious. See §§VI.A.3, VI.A.4. Although Barreras' receiver 14 has a "rechargeable power source," the combination of Barreras and Kaib, does not expressly disclose "wherein the rechargeable battery is a lithium-ion battery." As Mr. Pless explained, a POSA would have recognized that there were limited number of rechargeable batteries at the time of filing the '690 patent. Ex. 1003, ¶187; see also Ex. 1007, 3:16-25, 3:34-37, 7:10-55. Such a person would have recognized that a lithium-ion battery was one of those options as explained by Munshi. Ex. 1007, 7:49-55, Ex. 1003, ¶187. Accordingly, a POSA would have found it obvious to use a lithium-ion battery as the rechargeable power source in Barreras' receiver. KSR Int'l Co., 550 U.S. at 421 ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103."); Ex. 1003, ¶187. Alternatively, the combination of Barreras and Kaib, in further view of Munshi renders this limitation obvious.

<u>Munshi</u> discloses an implantable medical device, "such as a cardiac pacemaker or a cardioverter-defibrillator," that has a rechargeable lithium power source. Ex. 1007, 1:7-17. <u>Munshi</u> further discloses that there are multiple types of lithium batteries used in implanted medical devices, (*id.*, 7:10-55), including a "*lithium-ion battery*" (*id.*, 7:54-55). Ex. 1003, ¶189.

As shown above, see §VI.A.3.iv, Barreras and Kaib are analogous art to the '690 patent because each is in the field of medical device systems that have rechargeable batteries. Ex. 1001, 1:10-15 ("The present invention relates to powered, implantable medical device systems having a replenishable power source, such as a rechargeable battery"); Ex. 1003, ¶190. Likewise, Munshi is analogous art to the '690 patent by being in the same field of endeavor because Munshi discloses a medical device system with a rechargeable battery. Ex. 1007, 1:1-17 ("Our invention is directed towards a rechargeable battery-powered biomedical device such as a cardiac pacemaker or a cardioverter-defibrillator, incorporating a rechargeable lithium power source"); Ex. 1003, ¶190. As well, Munshi is analogous art to the '690 patent for being reasonably pertinent to a problem faced by the inventors of the '690 patent: increasing the number of times a rechargeable battery can be recharged before it needs to be replaced. Ex. 1001. 2:38-41 ("A disadvantage, however, of an implantable system having a replenishable power source ... is that the user must recharge the battery regularly as it becomes depleted of change."); Ex. 1007, 7:67-8:3 ("Another advantage is that unlike conventional lithium cells, these cells deliver a considerably higher number of cycles without much capacity degradation. The number of cycles for a

conventional lithium battery is only 200 cycles, whereas that for a lithium ion cell is as high as 1200 cycles."); Ex. 1003, ¶190.

As Mr. Pless explained, a POSA would have been motivated to incorporate Munshi's lithium-ion battery in the combined system of Barreras and Kaib for the express reasons provided in by both Munshi and Barreras. Ex. 1003, ¶191. That person would be motivated to use a lithium-ion battery because, as Munshi discloses, it "offer[s] chemical stability, improved cycle life, and added safety compared to [other] lithium metal cells." Ex. 1007, 7:56-58; Ex. 1003, ¶191. Munshi also discloses that lithium-ion batteries "enhance the safety of the rechargeable battery" and "deliver a considerably higher number of cycles without much capacity degradation." Ex. 1007, 7:63-8:1. Mr. Pless explained that these statements show a lithium ion battery can be recharged more times and last longer than a conventional, rechargeable battery. Ex. 1003, ¶191. As Mr. Pless further explained, these statements would have motivated a POSA to use a lithium-ion battery, as taught by Munshi, in the combined system of Barreras and Kaib. Id. These advantages would meet a system's need as described by Barreras: by increasing the life span of a power source thereby "reduc[ing] further surgical trauma to the patient and financial cost to the medical provider." Ex. 1005, 1:28-29; Ex. 1003, ¶191.

Moreover, replacing Barreras' rechargeable battery with Munshi's lithium ion battery would have been obvious as it is a simple substitution of known elements with each performing the same function as they are known to perform and the substitution yields no unexpected results. KSR Int'l Co., 550 U.S. at 417 (stating "when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious") (internal quotes omitted); Ex. 1003, ¶192. Mr. Pless explained that a POSA would have also recognized that this substitution would yield no unexpected results (*i.e.*, the device would simply be powered by a different battery type). Ex. 1003, ¶192. Thus, a POSA would have recognized that using a lithium-ion rechargeable battery, as disclosed in Munshi, in Barreras' rechargeable system would be a simple substitution of known elements that perform their same function and yields no unexpected results. Id.

- E. Claims 6-7 and 35-36 Are Obvious Over <u>Barreras</u> (Ex. 1005) in View of <u>Kaib</u> (Ex. 1006), and in Further View of <u>Bowman</u> (Ex. 1008)
 - 1. <u>Bowman (Ex. 1008)</u>

U.S. Patent No. 5,764,034 to <u>Bowman</u> et al. (Ex. 1008) ("Bowman") issued in June 1998 and is, therefore, prior art to the '690 patent under 35 U.S.C. § 102(b). Like <u>Barreras</u> and <u>Kaib</u>, <u>Bowman</u> is directed to a rechargeable medical device system. <u>Bowman</u> discloses a battery monitoring program used in a medical infusion pump. Ex. 1008, 2:12-19. Further, like <u>Kaib</u>, <u>Bowman</u>'s medical device program tells a user the remaining time before the battery needs to be recharged and other battery information, such as "battery charge level" and "total time on battery." *Id.*, Figs. 8b, 10b, 6:19-22, 9:4-15. Before a user accesses the program, however, the user must enter a password ensuring access to only proper hospital personnel. *Id.*, 8:40-45, 9:4-15; Ex. 1003, ¶195.

2. <u>Claims 6 and 35</u>

Claims 6 and 35 recite "*wherein the battery charging information can only be recalled by a clinician program in the handheld device*." Claims 6 and 35 depend on claims 1 and 33, respectively. And claims 1 and 33 are both shown to be obvious over <u>Barreras</u> and <u>Kaib</u> above. *See* §§VI.A.3, VI.A.10.

As explained above, *see* §§VI.A.3.iv and VI.A.11.i, the combination of <u>Barreras</u> and <u>Kaib</u> renders obvious storing battery information in the implanted device's memory until that information is requested by and transmitted to an external transmitter. Ex. 1003, ¶197. Although neither <u>Barreras</u> nor <u>Kaib</u> expressly disclose that "*battery information can only be recalled by a clinician program*," it would have been obvious in view of <u>Bowman</u>.

Bowman discloses a monitoring system and program for a rechargeable battery used in an infusion pump. Ex. 1008, 2:12-16, 6:20-23. Hospital personnel

must enter a password to interact with the program for operating the infusion pump. *Id.*, 8:40-45, 9:4-15. <u>Bowman</u>'s program allows access to hospital personnel, like clinicians, thereby making it a "*clinician program*." *Id.*, 8:40-45, 9:4-15; Ex. 1003, ¶¶198-199. Such a person would have understood that this password protection ensures that no unauthorized personal tamper with the infusion pump's program. Ex. 1003, ¶199. Once granted permission, an authorized user is allowed to access the "*clinician program*" for operating the infusion pump, as well as access "*battery information*." Ex. 1008, 9:7-15, Fig. 10a; Ex. 1003, ¶199.

Like <u>Barreras</u> and <u>Kaib</u>, <u>Bowman</u> is analogous art to the '690 patent because each is in the field of medical device systems that have rechargeable batteries. Ex. 1001, 1:10-15; Ex. 1005, 1:7-11; Ex. 1006, 1:8-12; Ex. 1008, 1:4-5, 2:12-14; Ex. 1003, ¶200. Moreover, <u>Bowman</u> is analogous art for being reasonably pertinent to problems addressed by the inventors of the '690 patent, *i.e.*, ensuring users are alerted when their medical device needs to be recharged. Ex. 1001, 2:42-46; Ex. 1008, 8:8-14; Ex. 1003, ¶200.

As Mr. Pless explained, a POSA would have been motivated to use a clinician program, like the one in <u>Bowman</u>, to access battery information in the combined system of <u>Barreras</u> and <u>Kaib</u> for several reasons. Ex. 1003, ¶201. For one, <u>Bowman</u> provides an express reason to do so: "[i]t would be further

advantageous to provide a battery monitor capable of such cost-effective, sensitive battery monitoring in environments similar to battery monitoring in medical infusion pumps." Ex. 1008, 2:5-9; Ex. 1003, ¶201. Because <u>Bowman</u>'s clinician program is password-protected, <u>Bowman</u> discloses another reason that would motivate a POSA, *i.e.*, "ensur[ing] that only proper hospital personnel access the configuration/service routine." Ex. 1008, 8:44-45; Ex. 1003, ¶201.

As Mr. Pless explained, a POSA would have been motivated to include a program, like <u>Bowman</u>'s clinician program, because utilizing software allows further improvement to the system (*e.g.*, by adding capabilities, *etc.*) via software updates. *See* Ex. 1008, Fig. 9A (software versions); Ex. 1003, ¶202. For example, <u>Bowman</u>'s program lists the current operating software version on the entry screen. Ex. 1008, 8:49-50. A POSA would have recognized that tracking a software version on a clinician program, as in <u>Bowman</u>, would allow for the tracking of software updates that improve the system. Ex. 1003, ¶202. Furthermore, such a person would have recognized that <u>Bowman</u>'s clinician program technique could be used to improve the devices in the combined system of <u>Barreras</u> and <u>Kaib</u> in the same way as <u>Bowman</u>, and such a change would not be beyond the skill of an ordinary artisan. *Id*.

3. <u>Claims 7 and 36</u>

Claims 7 and 36 depend from claims 6 and 35, respectively. Both claims 7 and 36 further require "wherein the clinician program in the programmer is enabled through a password or key code system that permits access to the clinician program."

The combination of <u>Barreras</u>, <u>Kaib</u>, and <u>Bowman</u> renders obvious this limitation. For example, and as explained in §VI.E.2 above, the combined system would have used a clinician program that requires a password entry, like <u>Bowman</u>'s program. Ex. 1008, 9:4-9, 8:40-44; Ex. 1003, ¶204. "The password ensures that only proper hospital personnel access the configuration/service routine." Ex. 1008, 8:44-45.

F. No Secondary Considerations Exist

Nevro is unaware of and Patent Owner has not asserted that any secondary indicia of non-obviousness exist having a nexus to any invention of the '690 patent. Nevro reserves its right to respond to any subsequent assertion of secondary indicia of non-obviousness advanced by Patent Owner.

VII. CONCLUSION

For the foregoing reasons, the challenged claims are unpatentable.

Dated: July 10, 2019

Respectfully Submitted,

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EXHIBIT LIST

No.	Exhibit Description
1001	U.S. Patent No. 7,177,690
1002	File History of U.S. Patent No. 7,177,690
1003	Declaration of Ben Pless
1004	Curriculum Vitae of Ben Pless
1005	U.S. Patent No. 5,733,313 to Barreras Sr.
1006	U.S. Patent No. 5,929,601 to Kaib et al.
1007	U.S. Patent No. 5,411,537 to Munshi et al.
1008	U.S. Patent No. 5,764,034 to Bowman et al.
1009	Smart Battery Data Specification, Revision 1.0, dated February 15, 1995
1010	Executed Summons, BSX v. Nevro
1011	Smart Battery Charger Specification, Revision 1.0, dated June 27, 1996
1012	Looking for some smart battery spec, EE Times, (November 20, 1995)
1013	The Smart Battery System Benefits
1014	Wayback Machine – SBS-Forum.org website, Specifications (dated Jan. 30, 1998)
1015	Wayback Machine – SBS-Forum.org website, homepage (dated Jan. 30, 1998)
1016	U.S. Patent No. 5,646,912 to Cousin
1017	Wayback Machine – SBS-Forum.org website, Smart Battery Data Specification ("sbdata10") (dated June. 26, 1998)
1018	Wayback Machine – SBS-Forum.org website, Smart Battery System Benefits ("benefits.pdf") (dated June. 26, 1998)
1019	Wayback Machine – SBS-Forum.org website, Smart Battery Charger Specification ("sbc100.pdf") (dated June. 26, 1998)
1020	U.S. Patent No. 4,231,027 to Mann et al.
1021	U.S. Patent No. 5,391,193 to Thompson
1022	U.S. Patent No. 6,185,452 to Schulman et al.

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitations of 37 C.F.R. § 42.24, because it contains 13,993 words (as determined by the Microsoft Word word-processing system used to prepare the brief), excluding the parts of the brief exempted by 37 C.F.R. § 42.24.

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 10th day of July,

2019, I caused to be served a true and correct copy of the foregoing and any

accompanying exhibits by Federal Express on the following counsel:

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