NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

BOSTON SCIENTIFIC NEUROMODULATION CORPORATION,
Appellant

v.

NEVRO CORP.,
Cross-Appellant

ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2019-1582, 2019-1635

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2017-01812, IPR2017-01920.

Decided: May 29, 2020

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Before LOURIE, MOORE, and O'MALLEY, *Circuit Judges.*

O'MALLEY, *Circuit Judge.*

This is an appeal from a consolidated inter partes review proceeding requested by Nevro Corp. ("Nevro"). The U.S. Patent Trial and Appeal Board (the "Board") concluded that certain claims of U.S. Patent No. 6,895,280 ("the '280 patent"), claims 8, 18, 22–24, and 27, are unpatentable as obvious. J.A. 39–66, 73–97,103–151. The Board concluded that claims 26 and 28–30 are not unpatentable as obvious. Patent Owner Boston Scientific Neuromodulation Corp. ("Boston Scientific") appeals the Board's invalidity findings. Nevro cross-appeals the Board's conclusion that claims 26 and 28–30 are not unpatentable as obvious. Because we agree with the Board's claim constructions and conclude that substantial evidence supports the Board's underlying factual findings, we *affirm* the Board's conclusions as to all challenged claims.

I. BACKGROUND

Resolution of this appeal does not require a detailed recitation of the various prior art references and grounds of unpatentability addressed in the Board's decisions. Accordingly, only the facts relevant to this appeal are discussed below.

A. The '280 Patent

The '280 patent, entitled, "Rechargeable Spinal Cord Stimulator System," relates to the use of a spinal cord stimulation ("SCS") system to reduce a patient's chronic pain. '280 patent, col. 1 ll. 13–17. The '280 patent states that prior art SCS systems struggled with a host of problems, such as internal power storage and memory issues, large physical size, and the need to utilize unwieldy surgical techniques and tools. *Id.*, col. 2 ll. 10–24. The inventors of the '280 patent developed a SCS system with "(1) a recharging system, (2) a system for mapping current fields, (3) optional pulse ramping control, and (4) electrode impedance measurements." *Id.*, col. 1 ll. 19–22. The disclosed system also "offers a simple connection scheme for detachably connecting a lead system thereto." *Id.*, col. 2 ll. 62–64. Although "the lead system [(comprising lead extension 120 and electrode array 110)] is intended to be permanent, the IPG may be replaced should its power source fail, or for other reasons." *Id.*, col. 27 ll. 26–38.

As relevant to this appeal, claims 8, 22, 26, and 27 recite an SCS system and method for implanting an SCS system with the above-recited features. Independent claim 8 recites:

> 8. A spinal cord stimulation system comprising:
>
> a multi-channel implantable pulse generator (IPG) having a replenishable power source, the IPG having a housing which contains IPG processing circuitry;
>
> an implantable electrode array detachably connected to the IPG, the electrode array having a multiplicity of n electrodes (En) thereon;
>
> a multiplicity of m stimulation channels provided by the IPG, wherein each stimulation channel is independently programmable with different stimulation parameters,

> wherein m is equal to or less than n, and m is 2 or greater;
>
> an external trial stimulator (ETS); and
>
> a percutaneous extension which temporarily couples the ETS with the implantable electrode array.

'280 patent, col. 53 ll. 3–18. Independent claim 22 recites:

> 22. A spinal cord stimulation system comprising:
>
> an implantable, multi-channel implantable pulse generator (IPG) having a replenishable power source;
>
> an implantable electrode array detachably connected to the IPG, the electrode array having a multiplicity of n electrodes (En) thereon;
>
> a secondary, implanted coil coupled electrically to the replenishable power source;
>
> an external battery charger including:
>
> > a primary coil;
> >
> > a rechargeable battery contained in the charger, electrically coupled to the primary coil; and
> >
> > a power amplifier for applying alternating current derived from the rechargeable battery in the charger to the primary coil,
>
> whereby the alternating current in the primary coil is transcutaneously transferred to the secondary implanted coil to the replenishable power source contained in the IPG; and
>
> alignment circuitry for detecting alignment between the primary and secondary coils, the alignment circuitry including a back telemetry receiver

> for monitoring the magnitude of the ac voltage at the primary coil as applied by the power amplifier,
>
> wherein reflected impedance associated with energy magnetically coupled through the primary coil is monitored.

'280 patent, col. 55 l. 62–col. 56 l. 21. Independent claim 26 recites:

> 26. A method for implanting a spinal cord stimulator system into a patient for stimulation therapy, the method comprising:
>
> (a) implanting a nerve stimulation lead with a distally located, multi-electrode array placed near target tissue, said lead having a lead connector on the proximal end;
>
> (b) connecting the lead connector to a percutaneous extension;
>
> (c) externalizing the percutaneous extension through the skin;
>
> (d) connecting an external trial stimulator (ETS) to the externalized lead extension;
>
> (e) programming the stimulation parameters at first optimal values;
>
> (f) waiting a specified period of time and reprogramming the stimulation parameters to second optimal values;
>
> (g) disconnecting the percutaneous extension from the lead connector;
>
> (h) connecting a multi-channel, implantable pulse generator to the lead connector;
>
> (i) implanting the implantable pulse generator, while programmed to the second, optimal stimulation parameters.

'280 patent, col. 57 ll. 13–36. Independent claim 27 recites:

> 27. A method of charging a rechargeable battery contained within an implantable pulse generator (IPG), which IPG is connected to an implanted, secondary coil antenna, the method employing an external battery charger, which charger contains a rechargeable battery electrically connected to an external, primary antenna coil, the method comprising:
>
> (a) charging the rechargeable battery in the eternal battery charger using an external power source;
>
> (b) aligning the primary antenna coil with the implanted secondary coil;
>
> (c) broadcasting electromagnetic energy through the primary antenna coil;
>
> (d) receiving the broadcast electromagnetic energy through the secondary antenna coil, whereby an alternating current is produced in the secondary coil;
>
> (e) rectifying the induced, alternating current received by the secondary coil;
>
> (f) charging the rechargeable battery carried within the IPG, while monitoring the charging current or voltage across the battery as the battery is being charged to prevent overcharging; and
>
> (g) stopping the charging at the battery charger when the current or voltage at the battery in the IPG reaches a prescribed level.

'280 patent, col. 57 l. 37–col. 58 l. 20.

B. Asserted Prior Art References

i. Holsheimer

Holsheimer is a U.S. patent entitled, "Multichannel Apparatus for Epidural Spinal Cord Stimulation," and discloses a pulse generator that drives a plurality of electrodes implanted near a patient's spinal cord. J.A. 2136–37. The implanted apparatus uses a "multi-channel neurological pulse generator which provides independently controlled voltage or current pulses." J.A. 2156, col. 2 ll. 21–26; J.A. 2157, col. 3 ll. 56–59. The pulse generator is connected to a lead with electrodes at the distal end, corresponding to the number of channels. J.A. 2156, col. 2 ll. 26–29.

ii. Schulman

Schulman is a U.S. patent entitled, "Battery-Powered Patient Implantable Device," and discloses a device that may be implanted under the skin of a patient for nerve or muscle stimulation. J.A. 2293. An embodiment of the invention includes a charging circuit that is capable of producing a "charging current in response to an externally produced AC magnetic field." J.A. 2307, col. 2 ll. 1–3.

iii. Loeb

Loeb is a U.S. patent entitled, "Implantable Multichannel Stimulator." Loeb discloses an implantable multichannel stimulator that includes a microstimulator array and an electrode array "sealed or molded in a body compatible material" to form an "integral implantable multichannel stimulator unit." J.A. 2621; J.A. 2636–37, col. 8 l. 66–col. 9 l. 3. The microstimulator array 45 is powered through inductive coupling with an external power source. J.A. 2637, col. 9 ll. 33–58. Loeb discloses that the stimulator 50 includes "alignment means, such as a magnet or marker 48, that helps align the implanted microstimulator array 45, and more particularly the coils 30 . . . of the implanted microstimulator arrays, with an external coil . . . connected

to an external source that generates the modulated power signal." *Id.*, col. 9 ll. 20–27.

iv. Alo

Alo is an article entitled, "Computer Assisted and Patient Interactive Programming of Dual Octrode Spinal Cord stimulation in the Treatment of Chronic Pain." J.A. 2221. Also discloses a study comparing two types of multi-electrode stimulation systems with continuous stimulation ("C-stim"): "patient controlled SCS" ("PC-stim") and "multi-stim SCS" ("M-stim"). J.A. 2223. The study involved patients with low-back pain, wherein electrodes were placed at the T9 and T10 intervertebral disc spaces. J.A. 2224. Patients tried different C-stim programs over a five- to seven-day trial period. J.A. 2224–25.

C. The Board Proceedings

After Boston Scientific sued Nevro for patent infringement in the District of Delaware, Nevro filed two separate petitions, requesting inter partes review of claims 8, 18, 22–24, and 26–30 of the '280 patent. J.A. 2. On February 5, 2018, the Board instituted review on the grounds challenging claim 27 in both petitions and consolidated the two proceedings. *Id.* The Board, however, denied institution on the grounds challenging claims 8, 18, 22–24, 26, and 28–30. J.A. 2–3. After the Supreme Court issued its decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018), the Board modified its institution decisions to review all challenged claims, on all grounds presented in the petitions. J.A. 3.

On February 1, 2019, the Board issued its Final Written Decision in the consolidated action. J.A. 1. The Board concluded that Nevro had established, by a preponderance of evidence, that challenged claims 8, 18, 22–24, and 27 of the '280 patent are unpatentable as obvious. J.A. 39–66, 73–97, 103–151. The Board did not find claims 26 and 28–30 unpatentable, however. J.A. 66–72, 97–103.

Boston Scientific timely appeals the Board's final written decision, challenging its obviousness determinations on claims 8, 18, 22–24, and 27 of the '280 patent. Nevro cross appeals, challenging its non-obviousness determinations on claims 26 and 28–30. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

II. DISCUSSION

Boston Scientific appeals: (1) the Board's findings that the prior art discloses "detachable leads"; (2) the Board's claim construction of "aligning" and "alignment"; (3) the Board's claim construction of "back telemetry receiver"; (4) the Board's finding that a person of ordinary skill in the art ("POSA") would have been motivated to combine the Schulman and Loeb references; and (5) the Board's refusal to consider Exhibit C of Dr. Lipson's declaration. Appellant Br. 29–32. Nevro cross-appeals the Board's construction of "waiting" and its factual findings with respect to the Alo reference. Appellee Br. 87. We address each issue in turn.

A. Substantial Evidence Supports the Board's Factual Findings Regarding "Detachable Leads"

We review the Board's legal determination of obviousness de novo, and its underlying factual findings for substantial evidence. *PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 747, 751 (Fed. Cir. 2016). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000).

In holding that claims 8, 18, and 22–24 would have been obvious over a combination of Holsheimer, Schulman, and Loeb, prior art U.S. patents, the Board concluded that both Holsheimer and the combination of Schulman and Loeb disclose "detachable leads." Boston Scientific argues that the Board's factual findings are erroneous because

they are unsupported by substantial evidence. We disagree.

The Board reasoned that Holsheimer discloses "detachable leads" based on its findings that: (1) Holsheimer discloses an SCS system; and (2) "all known SCS systems at the time of the '280 patent used detachable leads." J.A. 79–80. Substantial evidence supports both findings. The claimed invention in Holsheimer "provides a number of superimposed current generated electrical fields for epidural spinal cord stimulation." J.A. 2156 at col. 2 ll. 21–23; J.A. 2157 at col. 3 ll. 54–55 ("a neurological stimulation system employing the present invention to stimulate spinal cord 12 of the patient"). Four inventors of the '280 patent testified, moreover, that prior to the critical date, "all SCS systems known to them employed detachable leads." J.A. 80; J.A. 3127; J.A. 3318; J.A. 3679–3680; J.A. 3899. And Boston Scientific's expert, Dr. Lipson, testified that he is not aware of any SCS systems that do *not* utilize detachable leads, and that he had never implanted an SCS lead while it was attached to an implantable pulse generator ("IPG"). J.A. 81; J.A. 6506.

The Board further explained why, at the time of the invention, all SCS systems required detachable leads. Relying on Dr. Lipson's testimony, the Board explained that, during the SCS system implantation process for percutaneous leads, "the lead is not attached to the IPG and, in fact, could not be so attached, because the lead's distal end must remain free so that the needle can be removed by sliding it back and over the free distal end of the lead." J.A. 82 (citing J.A. 2960–61). Dr. Lipson also testified that even implantation of SCS systems with paddle electrodes—like those described in Holsheimer—required the use of detachable leads. J.A. 82–83 (citing 2961–62 at col. 30 ll. 2–7, col. 30 l. 24–col. 31 l. 10, col. 32 l. 3–col. 33 l. 9). The Board properly relied on this substantial evidence to conclude

that Holsheimer's SCS system discloses "detachable leads."[1]

Similarly, substantial evidence supports the Board's finding that a POSA "would have found it obvious" to combine Schulman and Loeb into an SCS system that uses detachable leads. In determining that a POSA would have been motivated to combine the disclosures of both patents, the Board relied on evidence that it had discussed in its findings regarding Holsheimer. J.A. 113 ("Much of the evidence considered in Section V.C.3.iii., above, is relevant here."). For example, the Board cited to the testimony from four inventors of the '280 patent that, prior to the critical date, "*all* SCS systems known to them employed detachable leads." J.A. 113 (emphasis included). The Board explained that this evidence "documents the knowledge a POSITA would bring to bear in evaluating the appropriate lead arrangement for an SCS system, e.g., that rendered obvious by Schulman." *Id.* The Board again considered the testimony of Boston Scientific's expert, Dr. Lipson, who testified that he was not aware of any SCS systems that do

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[1] Appellant argues that the Board's finding is "legally erroneous" because it "rests on a conclusion that Holsheimer *inherently* discloses detachable leads." Appellant Br. 37. But the Board made no such finding. The Board concluded that a POSA, at the time of the invention, would have concluded that Holsheimer's SCS system discloses "detachable leads"—its conclusion did not rely on our inherency precedent. J.A. 79–83. In any event, even if the Board concluded that Holsheimer discloses detachable leads inherently (as opposed to expressly), for the reasons stated above, we conclude that substantial evidence supports such a finding. *See Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1362 (Fed. Cir. 1999) ("Whether a claim limitation is inherent in a prior art reference for purposes of anticipation is . . . a question of fact.").

not utilize detachable leads, and that "the process by which an SCS system is implanted requires a detachable connection to the IPG." *Id.* (citing J.A. 6506). And, the Board considered the testimony of Nevro's expert, Dr. Kroll, who also testified that a POSA would have found it obvious to use detachable leads. J.A. 114–115 ("We also do not agree with Patent Owner's argument that Dr. Kroll's analysis involves hindsight reasoning . . . record evidence also demonstrates that, in an SCS system, detachability is required and expected by those skilled in the art.").

Accordingly, we conclude that the Board's findings with respect to the prior art's disclosures of "detachable leads" are supported by substantial evidence.

B. The Board's Construction of "Aligning" and "Alignment" is Not Erroneous

This court reviews the Board's ultimate construction of a claim de novo, with subsidiary factual findings involving extrinsic evidence reviewed for substantial evidence. *Knowles Elecs. LLC v. Cirrus Logic, Inc.*, 883 F.3d 1358, 1361–62 (Fed. Cir. 2018). The broadest reasonable interpretation standard applies in this IPR proceeding. *Personalized Media Commc'ns., LLC v. Apple, Inc.*, 952 F.3d 1336, 1340 (Fed. Cir. 2020). *See also Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (codified at 37 C.F.R. § 42.100(b)). Thus, the Board's interpretation must be reasonable in light of the specification, prosecution history, and the understanding of one skilled in the art. *See Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015), *overruled on other grounds by Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (en banc).

Claims 22 and 27 recite an "alignment circuitry for detecting alignment between the primary and secondary coils" and "aligning the primary antenna coil with the implanted secondary coil." J.A. 12–13. In the underlying

proceedings, Boston Scientific proposed construing these "alignment" and "aligning" limitations as: "achieving a spatial arrangement of the primary and secondary coils such that charging efficiency is optimized based on measurement of an electrical parameter." J.A. 12. The Board rejected this construction and instead construed the terms to mean "achieving a relative position between the primary and secondary coils to permit energy transfer." J.A. 12–13. We find no error in the Board's construction.

Intrinsic evidence supports the Board's construction. The plain language of the claims does not require positioning that achieves optimal charging efficiency. '280 patent, col. 55 l. 62–col. 56 l. 21; col. 57 l. 37–col. 58 l. 20. Rather, the claim language simply identifies that the primary and secondary coils must be aligned. *Id.*[2] The '280 patent specification, moreover, uses the phrase "in terms of a relative position between two elements, for example between electrodes or between inductive coils." J.A. 14 (citing '280 patent, col. 1 ll. 51–55, col. 10 ll. 58–61, col. 41 ll. 12–17). And although the specification addresses "efficient" charging or "maximum power transfer," it discusses this optimized charging efficiency in the context of *proper* alignment, as opposed to alignment generally. *See* J.A. 14–15 (citing '280 patent, col. 5 ll. 6–9, col. 41, ll. 14–17, col. 44 ll. 27–28). Thus, the '280 patent supports the Board's determination that "alignment" only requires a relative position between the two coils to allow some energy transfer.

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[2] We do not agree, however, that the Board's construction of "alignment" and "aligning" is broad enough to include "misalign[ment]." *See* J.A. 14. After all, misalignment suggests that the coils have not achieved a "relative position . . . to permit energy transfer." J.A. 12. That being said, we agree with the Board that the proper construction of the limitation covers concepts that fall short of "perfect" or "optimized" alignment.

Beyond the intrinsic evidence, the Board also cited to dictionary definitions that are consistent with its construction of the "alignment" and "aligning" limitations. J.A. 16. Thus, extrinsic evidence further supports the Board's construction that "align" requires coil placement in "relative position" to permit energy transfer. J.A. 16 (citing J.A. 4572).

Accordingly, we agree with the Board that the broadest reasonable interpretation of the "alignment" and "aligning" limitations is "achieving a relative position between the primary and secondary coils to permit energy transfer."

C. The Board's Construction of "Back Telemetry Receiver" is Not Erroneous

Claim 22 recites "alignment circuitry" that includes a "back telemetry receiver for monitoring the magnitude of the ac voltage" and "reflected impedance." '280 patent, col. 56 ll. 15–21. In its Final Written Decision, the Board did not explicitly construe the "back telemetry receiver" limitation, but it rejected Boston Scientific's argument that the receiver "must, at a minimum, receive transmitted data or information." J.A. 17, 20–21. The Board's determination that a "back telemetry receiver" need not receive transmitted data or information—only that it must monitor voltage or impedance, or transmitting power—is not erroneous.

First, the claim language supports the Board's construction. Claim 22 recites that a "back telemetry receiver" is part of the "alignment circuitry," and its role is "monitoring the magnitude of the ac voltage at the primary coils as applied by the power amplifier." '280 patent, col. 56 ll. 14–18. Therefore, "claim 22 already specifies what the 'back telemetry receiver' is and what it *does*—it is circuitry that monitors voltage and impedance." J.A. 18 (emphasis included). We agree with the Board that the claim does not require the "back telemetry receiver" to additionally "receive transmitted data or information." J.A. 18 ("[E]ven if we agree that 'back telemetry receiver . . . must, at a

minimum, receive transmitted data or information,' we disagree in light of Patent Owner's argument that monitoring voltage or impedance, or transmitting power, is not 'receiv[ing] transmitted data or information.'").

Second, the '280 patent specification supports the Board's construction. Like the claim language, the specification states that the "back telemetry receiver" "monitor[s] the magnitude of the ac power . . . thereby monitoring reflected impedance." '280 patent, col. 4 l. 64–col. 5 l.1, col. 42 ll. 36–43. Boston Scientific cites to portions of the '280 patent that allegedly compel a different conclusion. Appellant Br. 51, 53–54. But these portions describe the back telemetry *transmitter*, not the back telemetry *receiver*. For example, the specification explains that the back telemetry transmitter 690 transmits information regarding changes in rectification, while the back telemetry *receiver* 692 monitors voltage and reflected impedance. '280 patent, col. 42 ll. 33–43. None of these passages suggest that the "back telemetry receiver" must receive transmitted data or information, other than monitoring voltage or impedance, or transmitting power.

Accordingly, we agree with the Board that the broadest reasonable interpretation of "back telemetry receiver" does not require that the element "receive transmitted data or information," other than monitoring voltage or impedance, or transmitting power.

D. Substantial Evidence Supports the Board's Factual Findings that a POSA Would Have Been Motivated to Combine Schulman and Loeb

In its obviousness determination for claims 8, 18, 22–24, and 27, the Board found that a POSA would have been motivated to combine Schulman and Loeb to create an SCS system. J.A. 108–09. Substantial evidence supports the Board's factual findings.

The Board first relied on Schulman's teachings that its tissue stimulation system may be used for stimulating nerves and neural pathways to relieve pain. J.A. 107 (citing J.A. 2293 (Abstract). It then credited Dr. Kroll's unrebutted testimony that SCS systems fall into the category of systems described in Schulman, and that "it would have been obvious to a POSA that Schulman's system could be used for SCS." J.A. 107 (citing 2450 ¶ 22, J.A. 2476 ¶ 73).

The Board concluded that a POSA would have been motivated to combine the teachings of Schulman and Loeb based on the disclosures in those references, and Dr. Kroll's testimony. J.A. 108–110. Schulman and Loeb are both directed to tissue stimulation systems, J.A. 109 (citing J.A. 2293 (Abstract), J.A. 2636), and Schulman expressly incorporates Loeb, describing it as a known "[i]mplantable device for tissue stimulation." J.A. 110 (citing J.A. 2307, col. 1, ll. 15–19.). And while Loeb discloses an "exemplary" cochlear electrode array, the reference clarifies that this is "one of many possible types of implantable electrode arrays that may be used with the invention." J.A. 2636, col. 8 ll. 1–6. Dr. Kroll, moreover, testified that a POSA would have found it obvious to arrange Schulman's microstimulators in Loeb's array configuration because: "(1) the array is less likely to migrate from its implantation site, which provides better control in stimulating a targeted area, and (2) the array allows for better alignment of the charging coils of the implanted and external components of the system, thus allowing more efficient charging of the rechargeable power sources." J.A. 109 (citing J.A. 2472–73). We conclude that substantial evidence supports the Board's factual findings regarding a POSA's motivation to combine.

E. The Board Did Not Abuse its Discretion When it Excluded Exhibit C of Dr. Lipson's Declaration

37 C.F.R. § 42.6(a)(3) provides that "[a]rguments must not be incorporated by reference from one document into

another document." The Board's determination that a party improperly incorporated arguments by reference from another document in violation of 37 C.F.R. § 42.6(a)(3) is reviewed for an abuse of discretion. *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016).

Boston Scientific argues that the Board's decision to exclude Exhibit C of Dr. Lipson's declaration was an abuse of discretion because the excluded document was allegedly "*evidence* not argument." Appellant Br. 63. Boston Scientific alleges that the Board "faulted Boston Scientific for not putting more words in its brief (which is not evidence) rather than simply citing to testimony from an expert directly *showing* why its argument is correct." *Id.* We disagree with Boston Scientific's characterization of the Board's determination.

In the "Objective Indicia of Non-Obviousness" section of its Patent Owner Response, Boston Scientific alleged that certain products practice claim 27 of the '280 patent. J.A. 601–604. In support of these assertions, Boston Scientific cited to Dr. Lipson's declaration. *Id.* As the Board noted, however, the Patent Owner Response failed to address "certain elements of claims 8, 18, and 22–24 that are not present in exemplary claim 27." J.A. 56. For example:

> [W]ith respect to claim 8, the Response does not address "a multi-channel implantable pulse generator having a replenishable power source, the IPG having a housing which contains IPG processing circuitry," "wherein m is equal to or less than n, and m is 2 or greater," or "a percutaneous extension." With respect to claim 18, the Response does not address the "soft ramping circuit" limitation. And with respect to claim 22–24, the Response does not address the "alignment circuitry" limitation.

J.A. 56 (citations omitted). These missing elements are only addressed in Exhibit C of the Lipson Declaration. *See* J.A. 7062–91.

Boston Scientific's reliance on Exhibit C for its objective indicia arguments for claims 8, 18, and 22–24 is clearly an attempt to incorporate arguments by reference. Thus, we conclude that the Board did not abuse its discretion in excluding Exhibit C of Dr. Lipson's declaration.

F. The Board's Construction of "Waiting" is Not Erroneous and Substantial Evidence Supports the Board's Factual Findings Regarding Alo

Having considered the issues Boston Scientific raises on appeal, we now turn to Nevro's cross-appeal.

Independent claim 26 recites, *inter alia*, "(e) programming the stimulation parameters at first optimal values; (f) waiting a specified period of time and re-programming the stimulation parameters to second optimal values." '280 patent, col. 57 ll. 25–29. In concluding that claim 26 is not obvious over the combined teachings of Holsheimer and Alo, the Board concluded that claim 26 requires sequential steps of "programming," then "waiting," and then "re-programming," and that Alo does not disclose these limitations. We conclude that the Board's construction of the "waiting" limitation is not erroneous, and that substantial evidence supports its factual finding regarding the Alo reference.

The broadest reasonable interpretation of claim 26 supports a construction wherein the steps of "programming," "waiting," and "re-programming" must be completed in that specific order. Claim 26 recites sequential steps of programming the stimulation parameters, waiting a specified period of time, and re-programming the parameters to "second optimal values." '280 patent, col. 57 ll. 25–29. And as the Board noted, the prefix "re-," in step (f) of

the claim suggests that the recited "re-programming" is a "new, second occurrence of programming that occurs *after* the first 'programming' occurrence, recited in step (e)." J.A. 101. Therefore the "waiting" limitation must occur after the first "programming" step (e) and before the second "re-programming" step (f). J.A. 100–101. To hold otherwise would render the "waiting" element superfluous and effectively obviate the need to "re-program" the stimulation parameters.

Substantial evidence also supports the Board's conclusion that Alo does not disclose the "waiting" limitation, much less for a "specified period of time." Alo discloses a study in which two electrodes were placed in the epidural spaces of eighty patients. J.A. 2224. The electrode leads were connected to a trial stimulator, which was programmed with various options, to be tested over a five to seven-day trial period. J.A. 2224–25. In particular,

> [t]he patient was sent home for the first 24 hours of the trial with a simple C-stim program. This allowed the patient to become familiar with the basic controls of amplitude and the sensation of paresthesia. The next day the patient was given up to 24 programs to choose from (PC-stim) . . . . These 24 programs could be activated individually by the patient at home using the transmitter. The patient was instructed to try each program one at a time and to rate each of the programs . . . .
>
> Programs that did not provide effective paresthesias were deleted. Treatment evolved via this direct interactive approach to a set of optimal programs that were stored in the transmitter.

J.A. 2225. The reference explains that, even on the first day of the trial period, while in "C-stim" mode, the patient may immediately re-program stimulation parameters, e.g., amplitude and frequency, to second optimal values, without waiting for any period of time. J.A. 2225, 2227

("Patient control is limited to turning the single program on or off and control of amplitude and frequency"). In the "PC-stim" mode, moreover, the patient may immediately re-program stimulation parameters, e.g., amplitude and frequency, to second optimal values, without waiting for any period of time. J.A. 2227.

Accordingly, we conclude that the Board's construction of the "waiting" limitation in claim 26, and its factual finding that Alo does not disclose the "waiting" limitation, are not erroneous.

III. CONCLUSION

For the foregoing reasons, the Board's conclusions that (1) claims 8, 18, 22–24, and 27 are unpatentable as obvious; and (2) claims 26 and 28–30 are not unpatentable as obvious are *affirmed*.

AFFIRMED

COSTS

No costs.