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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MANFRED FRANKE, BRYAN ALLEN CLARK,
AIDEN FLANAGAN, JUAN GABRIEL HINCAPIE ORDONEZ,
and DAVID J. TERNES

Appeal 2018-008945¹
Application 14/597,131²
Technology Center 3700

Before HUBERT C. LORIN, NINA L. MEDLOCK, and
MATTHEW S. MEYERS, *Administrative Patent Judges*.

MEDLOCK, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ Our decision references Appellants' Appeal Brief ("App. Br.," filed March 16, 2018) and Reply Brief ("Reply Br.," filed September 17, 2018), and the Examiner's Answer ("Ans.," mailed July 17, 2018) and Final Office Action ("Final Act.," mailed August 23, 2017).

² Appellants identify Cardiac Pacemakers, Inc. as the real party in interest. App. Br. 2.

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134(a) from the Examiner’s final rejection of claims 1–4, 8, 10–13, 16, 17, and 19–21.³ We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

CLAIMED INVENTION

Appellants’ claimed invention “relates generally to medical devices, and more particularly, to systems, devices and methods for delivering pulmonary therapies using a synaptic junction block” (Spec. ¶ 3).

Claims 1, 16, and 20 are the independent claims on appeal. Claim 1, reproduced below with bracketed notations and indentation added, is illustrative of the claimed subject matter:

1. A system for delivering depletion block stimulation to a neural target that innervates airways using an implantable electrode near the neural target where the depletion block stimulation at a measurable activation threshold (AT) begins to increase nerve activity with increasing current amplitude and the depletion block stimulation at a measurable saturation threshold is where all or nearly all nerve fibers propagate action potentials such that nerve activity does not significantly increase in response to further increases in current amplitude, the system comprising:

[(1)] the electrode which is configured to be implanted near the neural target that innervates airways; and

[(2)] a pulse generation system configured to be operably connected to the electrode and programmed to deliver through the electrode

³ Claims 5–7, 9, and 18 are withdrawn. Final Act. 1. Claims 14 and 15 are canceled. App. Br. 28 (Claims Appendix).

[(2.f)] a full depletion block stimulation where a current amplitude is at or above the saturation threshold followed by

[(2.p)] a partial depletion block where a stimulation intensity is reduced to a level below the saturation threshold and above the activation threshold to alleviate symptoms of pulmonary disease,

[(3)] the programmed pulse generation system and the electrode configured to cooperate to

[(3.p)] capture only some of the axons in the neural target when the partial depletion block is delivered to cause those captured axons to propagate action potentials and to

[(3.f)] capture all or almost all of the axons in the neural target when the full depletion block stimulation is delivered to cause those captured axons to propagate action potentials

[(4)] wherein both the full depletion block stimulation and the partial depletion block stimulation include a series of pulses within a depletion frequency range between about 100 Hz to about 1 kHz such that the series of pulses generate action potentials in the captured axons but block communication across synaptic clefts.

REJECTIONS

Claims 1–4, 8, 10–13, 16, 17, and 19–21 are rejected under 35 U.S.C. § 112(a) as failing to comply with the written description requirement.

Claims 1, 16, 20, and 21 are rejected under 35 U.S.C. § 103(a) as unpatentable over Boveja et al. (US 2005/0216070 A1, pub. Sept. 29, 2005) (“Boveja”) and Kilgore et al. (US 2004/0127953 A1, pub. July 1, 2004) (“Kilgore”).

Claims 2–4, 8, 17, and 19 are rejected under 35 U.S.C. § 103(a) as unpatentable over Boveja, Kilgore, and Rezai (US 2009/0155336 A1, pub. June 18, 2009).

Claims 10 and 11 are rejected under 35 U.S.C. § 103(a) as unpatentable over Boveja, Kilgore, and Shuros (US 2010/0228310 A1, pub. Sept. 9, 2010).

Claims 10 and 12 are rejected under 35 U.S.C. § 103(a) as unpatentable over Boveja, Kilgore, and Swoyer et al. (US 2010/0217347 A1, pub. Aug. 26, 2010).

Claim 13 is rejected under 35 U.S.C. § 103(a) as unpatentable over Boveja, Kilgore, and Parnis et al. (US 2007/0027496 A1, pub. Feb. 1, 2007).

Claims 1, 16, and 20 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as unpatentable over Hlavka et al. (US 8,483,831 B1, iss. July 9, 2013) (“Hlavka”) and claims 1 and 15 of co-pending application Serial No. 14/597,145.⁴

Claims 1, 16, and 20 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as unpatentable over Hlavka and claims 1, 9, and 13 of co-pending application Serial No. 14/597,137.⁵

ANALYSIS

Written Description

Whether a Specification complies with the written description requirement of 35 U.S.C. § 112, first paragraph (now 35 U.S.C. § 112(a)), is

⁴ Application Serial No. 14/597,145 has issued as U.S. Patent No. 10,413,731.

⁵ Application Serial No. 14/597,137 has issued as U.S. Patent No. 10,201,709.

a question of fact and is assessed on a case-by-case basis. *See, e.g., Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (citing *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991)). The disclosure, as originally filed, need not literally describe the claimed subject matter (i.e., using the same terms or *in haec verba*) in order to satisfy the written description requirement. But the Specification must convey with reasonable clarity to those skilled in the art that, as of the filing date, Appellants were in possession of the claimed invention. *See id.*

Independent Claims 1, 16, and 20 and Dependent claims 2–4, 8, 10–13, 17, and 19

The Examiner maintains here that the Specification lacks written description support for “a full depletion block . . . followed by a partial depletion block,” as recited in independent claim 1, and similarly recited in independent claims 16 and 20 (Final Act. 7–8; *see also* Ans. 3–8).^{6,7} We, however, agree with Appellants that the Specification provides the requisite written description support such that a person skilled in the art would understand that Appellants were in possession of the claimed invention, including the requirement that a full depletion block stimulation be followed by a partial depletion block, at the time the application was filed (*see* App. Br. 14–16 (discussing paragraph 73 of the Specification)).

⁶ Each of claims 16 and 20 recites “delivering a partial depletion block stimulation *after* delivering the full depletion block.” App. Br. 28, 29 (emphasis added).

⁷ The question of whether changing the word “matters” to “parameters” in paragraph 73 constitutes new matter (Ans. 4–5; Reply Br. 3) is not before us on appeal.

Paragraph 73 describes that “a full or partial depletion block of a nerve [is provided] . . . by finding a saturation threshold (ST) of nerves driving muscle using force and/or EMG, and [that] the nerves may be depolarized using about a 200 Hz frequency or higher frequency at 100% to 200% of the ST.” Paragraph 73 discloses that “[f]or a full block, the depletion signal may be kept at 100% to 200% of the ST and at 200 Hz” and that “[f]or a partial block, the depletion signal may *continue* to be delivered at 200 Hz but the intensity of the stimulation may be *reduced* to 10 to 90% of ST” (emphasis added). A person of ordinary skill in the art would understand that the words “continue” and “reduced” refer back to the previously-mentioned signal by which “the nerves may be depolarized using about a 200 Hz frequency or higher frequency at 100% to 200% of the ST,” i.e., a full block. In other words, a person of ordinary skill in the art would understand from paragraph 73 that the process of providing a partial block begins by providing a full block, i.e., that “a full depletion block . . . [is] followed by a partial depletion block,” as called for in independent claims 1, 16, and 20.

Therefore, we do not sustain the Examiner’s rejection of claims 1–4, 8, 10–13, 16, 17, 19, and 20 under 35 U.S.C. § 112(a), as failing to comply with the written description requirement.

Dependent Claim 21

The Examiner further maintains that the Specification lacks adequate written description support for “wherein the full depletion block is delivered for less than one second before delivering the partial depletion block,” as recited in claim 21 (Final Act. 8; *see also* Ans. 8).

Appellants assert that the Specification provides the requisite written description support in paragraphs 50–56, 61, 73, and Table 2 (App. Br. 17–18; Reply Br. 11). We, however, agree with the Examiner that although the Specification discloses that a 90% depletion block may be obtained in less than one second (e.g., a mean time of 0.53 seconds for a 200 Hz signal, as shown in Table 2), there is nothing in the cited portions of the Specification, including the highlighted portion of paragraph 61 to which Appellants refer (*see* App. Br. 17), that describes switching from a full depletion block to a partial depletion block within any particular timeframe, such as immediately after the mean time to a 90% block has elapsed. Rather than disclosing switching to a partial block within a one-second timeframe, paragraph 61 merely discloses that a 90% depletion may be achieved in less than one second; there is no discussion of switching to a partial block. And, although we agree with Appellants that paragraph 73 broadly describes that a partial block may occur at some time after a full block, we see no disclosure in paragraph 73 of any particular timeframe for switching from a full block to a partial block.

We are not persuaded for the reasons set forth above that the Examiner erred in rejecting claim 21 under 35 U.S.C. § 112(a). Therefore, we sustain the Examiner’s rejection.

Obviousness

Although the parties address independent claims 1, 16, and 20 together, we reach different conclusions as to the system and method claims.

Independent Claim 1 and Dependent Claims 2–4, 8, and 10–13

Claim 1 is directed to a system for delivering depletion block stimulation to a neural target, and recites that the system comprises, *inter*

alia, “a pulse generation system configured to be operably connected to the electrode and programmed to deliver through the electrode a full depletion block stimulation where a current amplitude is at or above the saturation threshold followed by a partial depletion block.”

In rejecting claim 1 under 35 U.S.C. § 103(a), the Examiner found that Boveja discloses substantially all of the limitations of claim 1 except the Examiner acknowledged that Boveja does not explicitly disclose “configuring current amplitude for full or partial block” (Final Act. 10). The Examiner cited Kilgore to cure the deficiency of Boveja (*id.* (finding that Kilgore teaches nerve blocking “wherein full or partial block can be selectively achieved by modifying stimulus amplitude” at paragraphs 32–39)). And the Examiner concluded that it would have been obvious to a person of ordinary skill in the art at the time of Appellants’ invention to “modify Boveja as taught by Kilgore to include configuring for full or partial block as recited, in order to selectively block the neural target” (*id.*).

The Examiner conceded that Boveja and Kilgore “do not explicitly disclose a pulse generation system programmed to specifically deliver a combination of full depletion block followed by partial depletion block” (*id.*). The Examiner, nonetheless, found that “the modified system of Boveja and Kilgore is capable of being programmed to deliver full and/or partial depletion block therapies as needed” (*id.*). Citing *In re Burhans*, 154 F.2d 690 (CCPA 1946), the Examiner, thus, reasoned that “[s]election of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results” (*id.*).

The law is well settled that where, as here, a claim recites that an element is “configured to” perform a particular function, the specific

element in the prior art, on which the Examiner relies, to disclose the claimed element, must be not only capable of performing the claimed function but must also be designed specifically to accomplish the function claimed. *See Aspex Eyewear, Inc. v. Marchan Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012) (The court indicated that claim language “configured to” is construed more narrowly than “capable of,” and held that where claim language is construed consistent with “configured to,” the claim language requires that the structure must be “designed or configured to accomplish the specified objective, not simply that [it] can be made to serve that purpose.”).

The Examiner determined here, as described above, that the modified system of Boveja and Kilgore is capable of being programmed to deliver full and/or partial depletion block therapies as needed. However, as Appellants observe, and we agree, “‘capable of being programmed’ does not indicate that a system is in fact programmed” (App. Br. 20), i.e. designed or configured, to deliver full and partial depletion block therapies sequentially, as claimed. The Examiner has not adequately established on the present record that the combination of Boveja and Kilgore discloses a pulse generating system that is designed to specifically deliver a full depletion block followed by a partial depletion block, as opposed to a system that is merely capable of being programmed to perform the required function.

Therefore, we do not sustain the Examiner’s rejection of claim 1 under 35 U.S.C. § 103(a). For the same reasons, we also do not sustain the Examiner’s rejection of claims 2–4, 8, and 10–13, each of which ultimately depends from claim 1. *Cf. In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir.

1992) (“dependent claims are nonobvious if the independent claims from which they depend are nonobvious”).

Independent Claims 16 and 20 and Dependent Claims 17 and 19

In rejecting the independent claims under 35 U.S.C. § 103(a), the Examiner additionally observed that full and partial depletion block therapies were known in the prior art, and the Examiner took the further position that “one of ordinary skill in the art could have combined the therapies sequentially as claimed with no change in their respective functions, and the combination would have yielded nothing more than the predictable results of [a] full block followed by [a] partial block” (Final Act. 10). Therefore, according to the Examiner, it would have been obvious at the time of Appellants’ invention “to modify Boveja and Kilgore to include a combination of [a] full depletion block followed by [a] partial depletion block as recited, in order to deliver full and/or partial block[s] as needed” (*id.* at 11).

Paragraph 33 of Kilgore discloses:

Larger nerve fibers have a lower threshold for membrane depolarization, and are therefore blocked at low stimulus amplitudes. As a result, it is possible to block only the largest nerve fibers in a whole nerve, while allowing conduction in the smaller fibers. At higher stimulus amplitudes, all sizes of fibers can be blocked completely.

Kilgore further discloses that it is possible to achieve a full block by “gradually [increasing] the stimulus amplitude over time with each successive pulse, until even the smallest nerve fibers are blocked” (Kilgore ¶ 39; *see also id.* (“The amplitude can be progressively increased until all nerve fibers are blocked. This progressive increase can occur rather quickly, probably within a few hundred milliseconds.”)). In other words, Kilgore

discloses that a full block is achieved by starting with a partial block and increasing the amplitude.

We agree with the Examiner that *Burhans* is applicable to Appellants' method claims, and that the selection of any particular sequence of performing process steps is prima facie obvious in the absence of new or unexpected results. Appellants have the burden to establish unexpected results. *See In re Geisler*, 116 F.3d 1465 1469–70 (Fed. Cir. 1997). In doing so, Appellants must establish “(1) that there actually is a difference between the results obtained through the claimed invention and those of the prior art, . . . and (2) that the difference actually obtained would not have been expected by one skilled in the art at the time of invention.” *In re Freeman*, 474 F.2d 1318, 1324 (CCPA 1973) (citation omitted). *See also In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984) (“It is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements in the specification does not suffice.”); *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991) (“[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art.”).

As discussed above, Kilgore discloses providing a partial block before increasing amplitude to deliver a full block. On this record, we are not persuaded that reversing the order disclosed in Kilgore, i.e., “delivering a partial depletion block stimulation after delivering the full depletion block stimulation” as set forth in claims 16 and 20, results in a patentable distinction.

Citing paragraphs 56 and 73 of the Specification, Appellants assert that “[t]he blocking effect may be quickly implemented by implementing a

high frequency depletion block before transitioning into a lower energy (e.g., lower frequency) depletion block” (App. Br. 20). We have reviewed the cited portions of the Specification and we find no discussion of any unexpected result or benefit of performing a full block followed by a partial block. We agree with the Examiner (Ans. 3) that the discussion of changing the frequency of stimulation cited by Appellants is not germane to switching from a full block to a partial block. As the Specification makes clear, the controlling characteristic of the signal for determining whether a full block or partial block is achieved is amplitude or pulse width, not frequency. *See, e.g.*, Spec. ¶ 58 (“The current amplitude and pulse width may be controlled to select only larger fibers for the depletion block. For example, the current amplitude and pulse width may be controlled to deplete the A fibers and not the smaller fibers, or may be controlled with higher amplitudes and/or wider pulse widths to deplete both A and B fibers.”); *id.* ¶ 59 (“the amplitude of the depletion stimulation signal may be approximately 125% of the saturation threshold of the fibers that are intended to be blocked.”).

Appellants further argue:

benefits may also include that, after quickly instituting the depletion block as a full block, the depletion block can accurately transition into a partial block using the intensity of the signal at the saturated threshold as a benchmark. As evidenced on page 152 of Manfred Franke’s thesis entitled “Translating Electric KHFAC and DC Nerve Block from Research to Application,” this may increase selectivity of the stimulation.

*Id.*⁸

⁸ A thesis entitled “Translating Electric KHFAC and DC Nerve Block from Research to Application” by Manfred Franke (hereinafter “Franke thesis”) was entered into the record on March 28, 2016.

Responding to Appellants' argument in the Answer, the Examiner reproduces pages 152 and 24 of the Franke Thesis (Ans. 12–13). According to the Examiner, the pertinent portion of page 152 “is not even about depletion block” but rather “concerns Charge-Balanced DC block (CBDC) and Kilohertz-Frequency Alternating Current block (KHF AC), which the author recognizes as different from depletion block on Page 24 of the same thesis” (*id.* at 12).

Page 152 of the Franke Thesis provides a bullet-point list of “[p]otential applications for electric nerve block include in the future” including, as reproduced below and on page 17 of the Reply Brief:

Increase of stimulation selectivity (e.g. fiber size) and specificity (e.g. target location). Partial CBDC and KHFAC nerve block; see [51] – starting KHFAC above block threshold, then lowering it to e.g. 70% block, later increase without onset.

We do not see, and Appellants do not explain, how the above disclosure is germane to “delivering a partial depletion block stimulation after delivering the full depletion block,” as recited in independent claims 16 and 20. In particular, we see no discussion of any “transition into a partial block,” as argued. Appellants assert that “[t]his provides evidence that selectivity is a reason why one would start with a full block and then progress to the partial block” (Reply Br. 17). But, the cited portion of the Franke Thesis does not state that starting with a full block and then progressing to a partial block improves selectivity or specificity. Nor does the cited portion indicate any unexpected result or benefit of “delivering a partial depletion block stimulation after delivering the full depletion block.” At best, it indicates that lowering the stimulation from some unspecified block level to “e.g., 70% block” can be used with “later increase without onset.” It is unclear

how this relates to the claimed subject matter. Accordingly, we find that Appellants have not persuasively shown how the claimed order of steps produces results that are unexpected compared with the closest prior art.

In view of the foregoing, we sustain the Examiner's rejection of claims 16 and 20 under 35 U.S.C. § 103(a). We also sustain the Examiner's rejection of dependent claims 17 and 19, which are not argued separately.

Dependent Claim 21

In rejecting dependent claim 21, the Examiner determined that "it would have been obvious to one with ordinary skill in the art before the effective filing date of the claimed invention to modify Boveja and Kilgore to include a full depletion stimulation duration of less than one second, in order to optimize the desired amount of therapy delivered to the patient" (Final Act. 11 (citing *In re Aller*, 220 F.2d 454, 456 (CCPA 1955))).

Appellants argue, and we agree, that "the assertion that 'less than one second' is only discovering an optimum or workable range by routine experiment is improper as the rejection does not provide the required basis for that conclusion" (App. Br. 22). We find no disclosure or suggestion in Boveja or Kilgore that the claimed duration of delivering a full depletion block before switching to delivering a partial depletion block is a result-effective variable. *Cf. In re Antonie*, 559 F.2d 618, 620 (CCPA 1977) (One exception to "the rule that the discovery of an optimum value of a variable in a known process is normally obvious" applies where "the parameter optimized was not recognized to be a result-effective variable.").

Accordingly, we do not sustain the Examiner's rejection of claim 21 under 35 U.S.C. § 103(a).

Double Patenting

Double patenting is a matter of what is claimed. *General Foods Corp. v. Studiengesellschaft Kohle*, 972 F.2d 1272, 1277 (Fed. Cir. 1992). At the time the Final Office Action was mailed, application Serial Nos 14/597,137 and 14/597,145 were both still pending before the USPTO. The claims in these applications have subsequently been amended, and the applications have issued as patents.

We do not have before us any discussion regarding the merits of the Examiner's provisional double-patenting rejections with regard to the issued claims of application Serial Nos 14/597,137 and 14/597,145. As such, the Examiner's provisional double-patenting rejections are not ripe for decision by the Board. Therefore, we do not reach the double patenting rejections of claims 1, 16, and 20. *Cf. Ex parte Moncla*, 95 USPQ2d 1884 (BPAI 2010) (precedential) (Panels have the flexibility to reach or not reach provisional obviousness-type double patenting rejections).

DECISION

The Examiner's rejection of claims 1–4, 8, 10–13, 16, 17, 19, and 20 under 35 U.S.C. § 112(a) as failing to comply with the written description requirement is reversed.

The Examiner's rejection of claim 21 under 35 U.S.C. § 112(a) as failing to comply with the written description requirement is affirmed.

The Examiner's rejections of claims 1–4, 8, 10–13, and 21 under 35 U.S.C. § 103(a) are reversed.

The Examiner's rejections of claims 16, 17, 19, and 20 under 35 U.S.C. § 103(a) are affirmed.

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We do not reach the Examiner's provisional rejections of claims 1, 16, and 20 on the ground of non-statutory obviousness-type double patenting.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART