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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/064,801	10/28/2013	Scott R. Stanslaski	C00003291.USU1	1022

87562 7590 10/02/2020
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EXAMINER	
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ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
10/02/2020	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SCOTT R. STANSLASKI, PENG CONG, WESLEY A. SANTA, and TIMOTHY J. DENISON

Appeal 2019-006832[1]
Application 14/064,801
Technology Center 3700

Before PHILLIP J. KAUFFMAN, TARA L. HUTCHINGS, and ALYSSA A. FINAMORE, *Administrative Patent Judges*.

FINAMORE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[2] appeals from the Examiner's decision to reject claims 11, 12, and 15–20. We have jurisdiction under § 6(b). We REVERSE.

[1] The citations herein refer to the Specification filed October 28, 2013 ("Spec."), Final Office Action mailed August 2, 2018 ("Final Act."), Appeal Brief filed January 22, 2019 ("Appeal Br."), Examiner's Answer mailed July 22, 2019 ("Ans."), and Reply Brief filed September 19, 2019 ("Reply Br.").

[2] "Appellant" refers to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Medtronic, Inc., a subsidiary of Medtronic plc, as the real party in interest. Appeal Br. 4.

SUBJECT MATTER ON APPEAL

The invention relates to "devices and methods for sensing physiological signals while stimulation therapy is being conducted in proximity to the location where the physiological signals are being sensed." Spec. ¶ 1. Claims 11 and 18 are independent. Independent claim 11 is illustrative of the subject matter on appeal, and reproduced below with italics to emphasize the limitation at issue.

> 11. A device for sensing a physiological signal while stimulation therapy is being provided, comprising:
>
> a sensing electrode;
>
> a blanking switch;
>
> a first electrically conductive pathway connected between the sensing electrode and the blanking switch;
>
> a sensing amplifier;
>
> a second electrically conductive pathway connected between the sensing amplifier and the blanking switch; and
>
> a controller that *maintains the blanking switch in a non-conducting state during at least a portion of the recharge phase and a next stimulation phase of a stimulation signal that follows the recharge phase and that maintains the blanking switch in a conducting state for a period of time after the next stimulation phase that follows the recharge phase and prior to a next recharge phase that follows the next stimulation phase*, the next recharge phase occurring prior to any stimulation phase that occurs after the next stimulation phase, the period of time that the controller maintains the blanking switch in the conducting state being longer than an amount of time between an end of the recharge phase and a beginning of the next stimulation phase that follows the recharge phase.

Appeal Br., Claims App. (emphasis added).

REJECTIONS[3]

Claim(s) Rejected	35 U.S.C. §	References/Basis
11, 15–18	103	Zhu,[4] Bardy[5]
12	103	Zhu, Bardy, Hemming[6]
19, 20	103	Zhu, Bardy, Wanasek[7]

ANALYSIS

Independent claim 11 recites, in pertinent part, a controller that

> maintains the blanking switch in a non-conducting state during at least a portion of the recharge phase and a next stimulation phase of a stimulation signal that follows the recharge phase and that maintains the blanking switch in a conducting state for a period of time after the next stimulation phase that follows the recharge phase and prior to a next recharge phase that follows the next stimulation phase.

Appeal Br., Claims App. Independent claim 11 thus requires a controller for providing a blanking scheme that blanks, i.e., maintains the blanking switch in a non-conducting state, during a recharge phase and a subsequent stimulation phase, and does not blank, i.e., maintains the blanking switch in a conducting state, during the time period after the subsequent stimulation phase and before a subsequent recharge phase.

In regard to the recited blanking scheme, the Examiner finds Zhu's controller 32 enables blanking during a pace pulse, i.e., stimulation, and a

[3] The Examiner has withdrawn rejections of claims 11 and 15–18 under 35 U.S.C. § 103 over Zhu and Stancer, claim 12 under 35 U.S.C. § 103 over Zhu, Stancer, and Hemming, and claims 19 and 20 under 35 U.S.C. § 103 over Zhu, Stancer, and Wanasek. Ans. 3.
[4] Zhu et al., US 6,044,296, issued Mar. 28, 2000.
[5] Bardy et al., US 2002/0049476 A1, published Apr. 25, 2002.
[6] Hemming et al., US 5,871,512, issued Feb. 16, 1999.
[7] Wanasek, US 2010/0324618 A1, published Dec. 23, 2010.

recharge phase, as shown in Figure 5, reproduced below. Final Act. 13–14 (citing Zhu 8:62–67, 9:1–23, Fig. 5); Zhu 7:30–37.

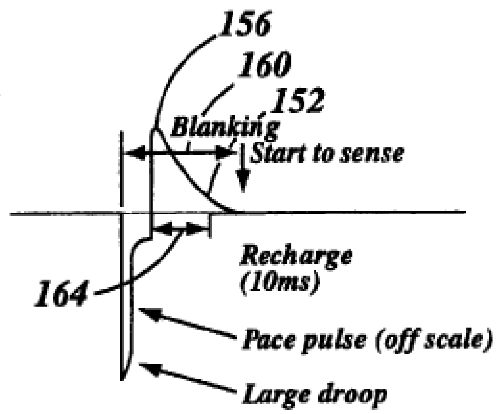

Fig.5

Figure 5 shows resulting pacing waveform 152 comprising a pace pulse and recharge time 164 that occur during blanking period 160. Zhu 6:13–16, 8:62–9:19.

The Examiner acknowledges Zhu does not disclose the recited blanking scheme that blanks during a recharge phase and a subsequent stimulation phase following the recharge phase. Final Act. 14. The Examiner further finds Bardy teaches biphasic pacing waveform 1902 having positive portion 1904, i.e., recharge phase, followed by negative portion 1906, i.e, stimulation phase, as shown in Figure 19, reproduced below. *Id.* at 15 (citing Bardy ¶¶ 34–35, 68–71, Fig. 19).

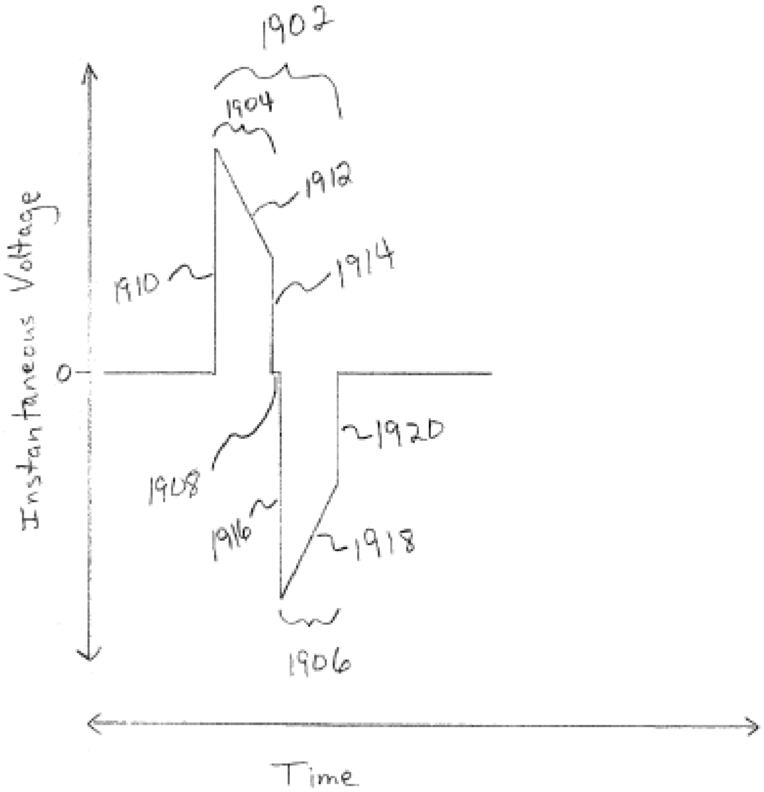

Fig. 19

Figure 19 shows biphasic pacing waveform 1902 for anti-bradycardia pacing plotted as a function of time versus instantaneous voltage. Bardy ¶¶ 33, 68.

The Examiner determines it would have been obvious to modify Zhu's controller by substituting Zhu's waveform having a stimulation phase proceeded by a recharge phase with Bardy's waveform comprising a recharge phase followed by a stimulation phase to result in a controller providing the recited blanking scheme that blanks during a recharge phase and a subsequent stimulation phase and does not blank during the time period after the subsequent stimulation phase and before a subsequent recharge phase. Final Act. 15; Ans. 10–11. According to the Examiner, the proposed modification would have been a simple substitution of one waveform for another to yield the predictable result of adequate pacing of the heart because Bardy teaches the polarities of the pacing waveform can be reversed so that positive can precede the negative and vice versa. Final Act. 15 (citing Bardy ¶¶ 67, 69); Ans. 10–11 (citing same).

Appellant argues it is not reasonable to combine the teachings of Zhu and Bardy as the Examiner proposes because the proposed combination would have rendered Zhu ineffective for its intended purpose of sensing the heart's response to the stimulation pulse, i.e., capture verification. Appeal Br. 11; Reply Br. 2–4. According to Appellant, a person of ordinary skill in the art would not have modified Zhu's controller to include Bardy's waveform having a recharge phase followed by a stimulation phase because "[t]he whole point of Zhu is to adequately remove the afterpotentials via the accelerated passive recharge before the evoked response occurs at the 20ms mark after the stimulation pulse." Reply Br. 2. For the reasons that follow, Appellant's argument is persuasive.

The Examiner acknowledges that the goal of Zhu's pacing system is to facilitate capture verification by quickly attenuating polarization voltages or "afterpotentials" that mask the evoked response of the heart (Ans. 11–12 (citing Zhu 8:9–18)), but disagrees that replacing Zhu's waveform with Bardy's biphasic waveform would thwart Zhu's capture verification (*id.* at 13). According to the Examiner, Zhu discloses a blanking period of 12 milliseconds, which encompasses a stimulation phase of 2 milliseconds and a recharge phase of 10 milliseconds, and Bardy teaches a biphasic waveform having a pulse width from approximately 2 milliseconds to

40 milliseconds. *Id.* (citing Zhu 9:51–56, 10:46–67, 11:1–6, Figs. 5, 7; Bardy ¶ 71). The Examiner determines:

> [A] skilled artisan would know that incorporating the teachings of Bardy into Zhu would entail substituting the waveform of Zhu with the biphasic waveform shown at fig. 19 of Bardy having a reversed polarity from the waveform of Zhu and a pulse width consistent with that required by Zhu, such as 12 milliseconds, for example, such that the evoked response is easily distinguishable with a stimulus waveform having a blanking period of 12 milliseconds to achieve capture verification as explained in Zhu. In other words, a skilled artisan would know to shape the biphasic waveform to achieve a desired active recharge, i.e. by providing a biphasic waveform having a *pulse width that achieves capture verification*.

Id. at 13–14 (emphasis added).

Even if the Examiner's proposed combination of Zhu and Bardy would result in waveform having a pulse width that enables recharging and stimulation to occur before the evoked response, Zhu does not associate the ability to sense capture with the pulse width of the waveform. Rather, as Appellant argues, Zhu discloses that the attenuation of afterpotentials, and thus the facilitation of capture verification, is tied to the recharge cycle. Reply Br. 2–3 (citing Zhu 10:29–67). According to Zhu, during the recharge cycle, first coupling capacitor 94 and second coupling capacitor 96 are connected in series, which causes the overall capacitance to approximate a lower capacitance, resulting in a quicker attenuation of afterpotentials resulting from a stimulation pulse. Zhu 10:29–66, Fig. 3.

Modifying Zhu's controller to substitute Zhu's waveform with that of Bardy, as the Examiner proposes, would result in a blanking period that encompasses a recharge phase a subsequent stimulation phase, and thus encompasses the attenuation that occurs during the recharge phase and before the subsequent stimulation phase. The proposed modification would also result in sensing capture after the stimulation phase of the blanking period and before the subsequent recharge phase of the next blanking period such that sensing capture would occur without the afterpotential attenuation associated with the recharge phase. Regardless of the pulse width, the Examiner's proposed combination of Zhu and Bardy would result in a controller that blanks during attenuation of the afterpotentials where sensing would be enhanced, and senses without attenuating the afterpotentials, thus yielding a controller that is completely contrary to Zhu's aim of facilitating capture verification by attenuating afterpotentials.

In view of the foregoing, the Examiner has not demonstrated sufficiently that a person of ordinary skill in the art would have combined the teachings of Zhu and Bardy to result in a controller enabling the blanking scheme recited in independent claim 11. We, therefore, do not sustain the rejection of independent claim 11 and claims 15–17 depending therefrom.

Independent claim 18 recites a controller for providing a blanking scheme similar to that of independent claim 11. Appeal Br., Claims App. The Examiner's rejection of independent claim 18 is similar to the rejection of independent claim 11. *Compare* Final Act. 18–20, *with id.* at 12–16. We do not sustain the rejection of independent claim 18 for the same reasons as independent claim 11.

Claim 12 depends from independent claim 11, and claims 19 and 20 depend from independent claim 18. Appeal Br., Claims App. The Examiner does not rely on Hemming or Wanasek in any manner that would remedy the deficiency in the combination of Zhu and Bardy with respect to the independent claims. Final Act. 20–23. For the same reasons as the independent claims, we do not sustain the rejections of claims 12, 19, and 20.

CONCLUSION

We do not sustain the rejections of claims 11, 12, and 15–20. We, therefore, reverse the Examiner's decision to reject claims 11, 12, and 15–20.

DECISION SUMMARY

Claim(s) Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
11, 15–18	103	Zhu, Bardy		11, 15–18
12	103	Zhu, Bardy, Hemming		12
19, 20	103	Zhu, Bardy, Wanasek		19, 20
Overall Outcome				11, 12, 15–20

REVERSED