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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* ROBERT A. BETZOLD and JAMES W. BUSACKER

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Appeal 2014-002978  
Application 11/538,711<sup>1</sup>  
Technology Center 3700

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Before DEMETRA J. MILLS, RICHARD M. LEBOVITZ, and  
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims directed to an implantable medical device. The Examiner finally rejected the claims under 35 U.S.C. § 112, first and second paragraphs, under 35 U.S.C. § 103(a), and as non-statutory obvious-type double-patenting. We have jurisdiction under 35 U.S.C. § 134. The Examiner's decision is affirmed.

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<sup>1</sup> "The '711 Application."

## STATEMENT OF CASE

This is the second time the claims have been appealed to the Board. In the first Appeal, the rejections of all the appealed claims were affirmed. Board Decision of Aug. 30, 2012. After the Appeal, Appellants requested continued examination under 37 C.F.R. § 114. Claim 1 was amended, and claims 5 and 6 were cancelled. Submission dated Oct. 30, 2012. New claims 25 and 26 were added. Claim 1 shows the amendment (underlining) relative to claim 1 in the first appeal.

1. An implantable medical device, the implantable medical device comprising:
  - a battery to power the implantable medical device; and
  - a replacement indicator timer defining a replacement time period, wherein the replacement time period is the time from the start of the replacement time period to a determined replacement date for the implantable medical device, wherein the determined replacement date is the date at which the implantable medical device should be replaced, wherein the replacement indicator timer is configured such that the replacement indicator timer is activated to start the replacement time period when an operational characteristic of the battery reaches a [selected] non-varying defined value, and further wherein the implantable medical device is configured to make a status indicative of a remaining time of the replacement time period available after the replacement indicator timer has been activated.

The rejections are summarized below.<sup>2</sup>

1. Claims 1–4, 7–18, 21, 22, 25, and 26 stand rejected on the ground of non-statutory obviousness-type double-patenting over claims 1–35 of U.S. Pat. No. 7,123,964. Ans. 8.

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<sup>2</sup> The Examiner included claims 5 and 6 in the statement of several of the rejections, but these claims were cancelled.

2. Claims 1–4, 7–18, 21, 22, 25, and 26 stand rejected under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. Ans. 9.

3. Claim 26 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Ans. 2.

4. Claims 1–4, 7–18, 21, 22, 25, and 26 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Ekwall (U.S. Pat No. 5,193,538, granted Mar. 16, 1993) in view of Gurewitsch (U.S. Pat. No. 6,400,988 B1, granted June 4, 2002). Ans. 9, 12

Appellants did not provide arguments as to why the Examiner erred in rejecting the claims on the ground of non-statutory obviousness-type double-patenting. Consequently, we summarily affirm the rejection.

#### 1. Written description rejection

Claim 1 recites “the replacement indicator timer is configured such that the replacement indicator timer is activated to start the replacement time period when an operational characteristic of the battery reaches a non-varying defined value.” The Examiner rejected the claims as lacking a written description because:

The original specification did not describe a “non-varying” defined value and further described the value as being “varying” by saying “the selected value used to trigger the start of the timer could be dependent upon the rate of power consumption in the device” ([’711 Application,] paragraph 26).

Final Rej. 4.

Paragraph 26 of the ’711 Application, as indicated by the Examiner, describes utilizing a “varying” value as the trigger:

Furthermore, the selected value used to trigger the start of the timer could be dependent upon the rate of power consumption in the device. In this case, the implantable medical device could monitor power consumption and select a value to trigger the start of the timer based on the monitored power consumption.

However, this is not the only disclosure of trigger values in the '711 Application. Paragraph 24 of the '711 Application discloses (emphasis added):

As time progresses, the battery voltage drops slightly. When the battery voltage reaches a defined level V2 (at time T2) the replacement indicator timer starts counting through the replacement time period. The replacement time period ends at time T3, with the battery voltage at V3. Thus, time T3 comprises the determined replacement date for this example, and the time between T2 and T3 comprises the replacement time period.

Paragraph 25 further discloses (emphasis added):

As time progresses, the battery impedance rises slightly. When the battery impedance reaches a defined level I2 (at time T2) the replacement indicator timer starts counting through the replacement time period. The replacement time period ends at time T3, with the battery impedance at I3. Again, time T3 comprises the determined replacement date for this example, and the time between T2 and T3 comprises the replacement time period.

Each of paragraphs 24 and 25 describe a “defined level” of voltage and impedance, respectively, when the timer “is activated to start the replacement time period” as required by claim 1. The disclosed “defined levels[s]” of battery voltage and impedance constitute “operational characteristic[s] of the battery” of a “non-varying defined value[s]” as recited in claim 1 because a “defined” level is an established or fixed value.<sup>3</sup>

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<sup>3</sup> <http://www.dictionary.com/browse/define>

Consequently, we conclude that the disputed limitation is described in the '711 Application. The written description rejection of claims 1–4, 7–18, 21, 22, 25, and 26 is reversed.

2. 112, 2<sup>nd</sup> paragraph rejection

Claim 26 recites: “The implantable medical device of claim 1 wherein the non-varying defined value of the operational characteristic of the battery is selectable by a clinician when the device is implanted.” The Examiner stated that dependent claim 26 is indefinite because it “conflicts” with claim 1. Final Rej. 3. The Examiner stated that, if the recited operational characteristic of the battery is “non-varying,” then “it should not be selectable since that would mean that the value varies based on what is programmed/selected.” *Id.*

We will not sustain this rejection. Claim 26 specifies that the “non-varying defined value” is “selectable by a clinician when the device is implanted.” Once the value is chosen by the clinician, the timer is “configured” to be “activated” when it reaches the non-varying defined value selected by the clinician. Consequently, we see no inconsistency between claims 1 and 26.

3. Obviousness rejection

The Examiner found that Ekwall teaches an implantable medical device with all the claim limitations except “wherein the implantable medical device is configured to make a status indicative of a remaining time of the replacement time period available after the replacement indicator timer has been activated” which the Examiner found is taught by

Gurewitsch. Final Rej. 5–6. The Examiner determined it would have been obvious to one of ordinary skill in the art to have modified Ekwall with Gurewitsch’s teaching to “provide the predictable results of allowing the physician with the suggested time for replacing” the medical device. *Id.* at 5.

Appellants contend that Ekwall does not teach a medical device having a replacement timer in which “the replacement indicator timer is activated to start the replacement time period when an operational characteristic of the battery reaches a non-varying defined value.” Appellants argue that Ekwall describes a threshold value or elective replacement time (“ERT”) value which is varied depending on the stimulating mode and its degree of utilization. Appeal Br. 10. Appellants cite various support in Ekwall for these teachings.

We begin the discussion with Ekwall. Ekwall teaches that pacemakers are programmable “in order to adjust stimulating mode, including other parameters such as output energy, to different physiological needs.” Ekwall, col. 2, ll. 34–38. For this reason, Ekwall explains that, as a result, the energy consumption of the device changes and the time period from the beginning of the battery life to the replacement time such that “an estimate of the EOL [end of battery life] is no longer accurate or valid, so that during the safety time, the function of the device cannot be guaranteed.” *Id.* at col. 2, ll. 39–40. To address this problem, Ekwall teaches:

In accordance with the invention, this object is achieved in that the sensing and evaluating means of the device specified at the beginning are arranged to vary the first threshold value (ERT-value) in dependence on the utilized stimulating mode and in dependence on the degree of utilization of previously selected stimulating modes recorded in and available from the

stimulating mode selector means in such a way that a higher threshold value is selected for stimulating modes with a higher energy consumption and higher degree of utilization and a lower threshold value is selected for stimulating modes with a lower energy consumption and lower degree of utilization.

Ekwall, col. 2, ll. 56–68.

Appellants are correct that Ekwall’s invention is to vary the threshold ERT value in contrast to the claim which activates the timer when a “non-varying defined value” is reached. However, Ekwall explains that a defined ERT-value is determined from an assumed standard stimulating mode, and then adjusted based on the utilization of the pacemaker.

Thus, an adaptation and stabilization of the time duration between the appearing of the ERT-value and the point in time of the EOL-value is achieved according to the utilized stimulating mode, which deviates from an assumed standard stimulating mode. Thus the required safety time is always present.

*Id.* at col. 3, ll. 1–6.

Ekwall further explains that the battery is connected to a sensing and evaluating means “to enable sensing of remaining or instantaneous battery capacity and to establish whether said battery capacity, on a sensing event, is higher or lower than a predetermined first threshold value.” *Id.* at col. 4, ll. 54–59. The “predetermined first threshold value” corresponds to the “non-varying value” of the battery as recited in claim 1. The “predetermined first threshold value” is determined from the “assumed standard stimulating mode.” *See* above passage at col. 3, ll. 1–6.

Ekwall teaches:

This threshold value or ERT-value is adjusted to guarantee, in an assumed standard or normal operation of the pacemaker 2, a continuous normal function of the same up to a point in time,

when the battery capacity exceeds a lower second threshold value or EOL-value, which represents the end of life of the battery.

*Id.* at col. 4, ll. 59–65.

Ekwall explicitly describes adjusting the replacement time threshold (ERT) “to achieve a safety time equally long regardless of whether the selected stimulating mode requires the standard energy consumption or any other higher or lower energy consumption.” *Id.* at col. 5, ll. 38–41. In other words, the battery has a fixed EOL or end-of-life value. The safety period, when the battery reaches the EOL, is adjusted from a “predetermined threshold” ERT value depending on the utilization of the pacemaker.

Ekwall explains (*id.* at col. 6, ll. 45–56) that in one embodiment (shown in Fig. 4 of Ekwall):

The voltage on the line 46 [from a current source or battery] is now compared to a fixed reference voltage on the line 48a corresponding to a predetermined value in the counter 49. This predetermined value may be the ERT-value selected for the operation of the pacemaker 2 in the standard stimulating mode.

*Id.* at col. 6, ll. 57–62.

It is thus clear from reading Ekwall’s disclosure that a “non-varying defined value” of the battery’s operational characteristics is determined – which corresponds to the assumed standard operating mode of the pacemaker – and this value is only adjusted when the energy consumption is either higher or lower than the standard, predetermined value. Ans. 10–11. Appellants are correct that Ekwall’s invention is adjusting the standard, predetermined threshold value based on energy utilization, but this fails to take into account circumstances when the threshold does not requirement

adjustment because the energy utilization is not higher nor lower than the predetermined value.

Accordingly, we conclude that the Examiner did not err in determining that claim 1 is obvious over Ekwall and Gurewitsch.

#### 4. Dependent claims

Appellants contend that the Examiner erred in finding the dependent claims 3, 7, 9–13, 18, and 21 obvious because “zero” additional prior art references were cited to “teach or suggest what the Examiner has expressly asserted ‘modified Ekwall does not specifically disclose.’” Appeal Br. 16. Appellants also criticize the Examiner for taking Official Notice that such elements were known in the art. *Id.* at 17.

In response to these arguments, the Examiner in the Answer cited two additional publications – Gustavsson and Snell – that were discussed in the Examiner’s Answer of Mar. 22, 2011 from first appeal. Ans. 12–13. Appellants point out that neither publication was discussed in the Final Rejection. Reply Br. 9. Appellants also contend that the Examiner has “not provided any articulated reasoning with rational underpinnings describing how the devices of Ekwall or Gurewitsch would be modified with elements of Gustavsson and Snell et al.” *Id.*

We disagree. On pages 6–8 of the Final Rejection, the Examiner provided explicit reasons for finding the dependent claims obvious. Thus, it is not correct that the Examiner failed to provide “any” articulated reasoning with rational underpinning as to why the claims would have been obvious to one of ordinary skill in the art. Appellants did not specifically identify a defect in the Examiner’s reasoning and we find none.

In the Answer, the Examiner noted that, in the first appeal, the rejections of the dependent claims had been affirmed. Ans. 12. The Examiner further quoted from the previous Answer which had identified the teachings in Gustavsson and Snell and how they were pertinent to the claimed subject matter. *Id.* at 13. Appellants were therefore aware of these publications prior to the Final Rejection.

Appellants did not identify an error in the Examiner's fact-based reasoning, but merely argued the reasoning was not provided. This argument has no merit because the Examiner clearly articulated reasons why the claims were obvious (*e.g.*, "Gustavsson (WO 01/34243) cited by the applicant shows claim 13 of determining RRT with battery impedance (*e.g.* abstract) and claims 11 and 12 of changing/varying the replacement time period/counting rate when an operation of the implantable device is modified by the clinician (*e.g.* pages 3, 4, 9).") *Id.*

For the foregoing reasons, we affirm the obviousness rejection of claims 1–18, 21, 22, 25, and 26. Claims not argued separately fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

#### SUMMARY

The non-statutory obviousness type double-patenting rejection of claims 1–4, 7–18, 21, 22, 25, and 26 is affirmed.

The written description rejection of claims 1–4, 7–18, 21, 22, 25, and 26 is reversed.

The indefiniteness rejection of claim 26 is reversed.

The obviousness rejection of claims 1–4, 7–18, 21, 22, 25, and 26 is affirmed.

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**TIME PERIOD**

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**