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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHEAL MORIARTY and BRIAN KELLY

Appeal 2018-000257¹
Application 14/200,944
Technology Center 3700

Before: JENNIFER D. BAHR, JEREMY M. PLENZLER, and
LEE L. STEPINA, *Administrative Patent Judges*.

STEPINA, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant appeals under 35 U.S.C. § 134 from a rejection of claims 1–
15. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ The Applicant is Medtronic Ardian Luxembourg S.a.r.l, which the Appeal Brief indicates is the real party in interest. Appeal Br. 1.

CLAIMED SUBJECT MATTER

The claims are directed to a method of performing cryotherapy with a refrigerant-cooled cryotherapeutic element positioned in a patient's body.

Spec. ¶ 1. Claim 1, reproduced below with emphasis added, is illustrative of the claimed subject matter:

1. A method, comprising:
 - advancing an elongate shaft of a catheter toward a treatment location within a body lumen of a human patient;
 - directing a flow of refrigerant toward a cryotherapeutic element at a distal end portion of the shaft via a supply line extending along at least a portion of a length of the shaft;
 - expanding the directed refrigerant to cause cooling within a balloon of the cryotherapeutic element;
 - exhausting the expanded refrigerant via an exhaust line extending along at least a portion of the length of the shaft;
 - measuring pressure within the cryotherapeutic element and/or within a distal portion of the exhaust line via a monitoring line extending along at least a portion of the length of the shaft;
 - calculating a rate of change of the measured pressure;*
 - processing the rate of change of the measured pressure using a first feedback loop during a first monitoring window of a treatment cycle, the first feedback loop being configured to cause the flow of refrigerant through the supply line to stop if the rate of change of the measured pressure falls outside a range from a first lower threshold to a first upper threshold;*
 - switching from the first monitoring window to a second monitoring window of the treatment cycle; and
 - processing the rate of change of the measured pressure using a second feedback loop during the second monitoring window, the second feedback loop being configured to cause the flow of refrigerant through the supply line to stop if the rate of change of the measured pressure falls outside a range from a second lower threshold to a second upper threshold, wherein (a) the first lower threshold is different than the second lower threshold and/or (b) the first upper threshold is different than the second upper threshold.

Appeal Br. 20–21 (Claims App.).

REFERENCES RELIED ON BY THE EXAMINER

Pang	US 6,477,658 B1	Nov. 5, 2002
Mandel	US 2006/0235374 A1	Oct. 19, 2006
Watson	US 8,187,261 B2	May 29, 2012
Gerber	US 2012/0277823 A1	Nov. 1, 2012

THE REJECTIONS ON APPEAL

(I) Claim 14 is rejected under 35 U.S.C. § 112(a) as failing to comply with the enablement requirement.²

(II) Claims 1–11 are rejected under 35 U.S.C. § 102(a)(1) as anticipated by Watson.

(III) Claim 12 is rejected under 35 U.S.C. § 103 as unpatentable over Watson and Mandel.

(IV) Claims 13 and 14 are rejected under 35 U.S.C. § 103 as unpatentable over Watson and Pang.

(V) Claim 15 is rejected under 35 U.S.C. § 103 as unpatentable over Watson, Pang, and Gerber.

OPINION

Rejection (I)

² The Final Office Action discusses this rejection on pages 2–4 (the Response to Arguments) and formally lists the rejection on page 2 of the Answer.

Dependent claim 13 depends from claim 1 and recites first and second algorithms operating at first and second cycle speeds, respectively. Appeal Br. 24 (Claims App.). Claim 14 depends from claim 13 and recites that the first cycle speed is *at least 10 times* as fast as the second cycle speed. *Id.*

In rejecting claim 14 as not enabled, the Examiner determines (i) “[a] generic recitation of an algorithm is clearly not enabling for all types of algorithms, given the complexities associated with the differing types of algorithms” (Final Act. 3), and (ii) Appellant’s disclosure “does not enable speeds that are, for example, 1000 times that of the second cycle speed or hundreds of thousands of times that of the second cycle speed” (*id.* at 4). In support of part (ii) of the rejection, the Examiner refers to MPEP 2164.06(a) and *MagSil Corp. v. Hitachi Global Storage Technologies, Inc.*, 687 F.3d 1377, 103 USPQ2d 1769 (Fed. Cir. 2012). Final Act. 3.

Appellant contends “the specification provides numerous relevant working embodiments described in conjunction with Figures 2-4 and elsewhere,” and the disclosure need not teach all possible algorithms usable with the claimed method. Appeal Br. 10–11. Appellant also contends that *MagSil* is inapposite because the limitation in claim 14 recites a relationship between two variables that are capable of being specified by a user, whereas, in *MagSil*, the variable was “a lower boundary for a single variable.” *Id.* at 12. Appellant also analogizes the “at least 10 times” limitation in claim 14 to a theoretical claim reciting “a plurality of widgets,” which, in theory, encompasses an infinite number of widgets. *Id.*

In the Answer, the Examiner focuses on the holding in *MagSil* and reiterates that Appellant’s disclosure does not enable a first cycle speed that is hundreds of thousands of times the second cycle speed. *See* Ans. 15.

Appellant has the better position. The facts of *MagSil* are distinguishable inasmuch as the limitation at issue in that case involved a physical property that, according to the record, the inventor had never been able to increase by more than 11.8% and had a theoretical upper limit of a 100% increase. *Magsil*, 687 F.3d at 1381–1382. In contrast, it appears that the *ratio* of the first and second cycle speeds in Appellant’s method is not physically limited, even if, for example, the second cycle speed at an extremely low rate might be impractical. In other words, we agree with Appellant’s argument that, as the first and second cycle speeds are capable of being specified by the user (Appeal Br. 12), the disclosure enables the “at least 10 times” limitation in claim 14. Accordingly, we do not sustain the rejection of claim 14 as failing to comply with the enablement requirement.

Rejection (II)

The Examiner finds that Watson discloses all the elements recited in claim 1, and, in particular, that Watson’s disclosure of a *differential pressure* measurement corresponds to the requirement to calculate a rate of change of a measured pressure. Final Act. 7–8 (citing Watson, 7:38–57, 11:15–28, Figs. 1A–2A, 3A–4).

Appellant contends that the Examiner erred on this point because “[d]ifferential pressure, as disclosed in Watson, is merely pressure relative to an ambient pressure at a given time[, and, i]n contrast, *rate of change* in pressure, as recited in claim 1, is change in pressure divided by time.” Appeal Br. 14.

In response, the Examiner refers to a definition of the word “differential” that uses the word “derivative.” Ans. 16 (citing www.thefreedictionary.com). The Examiner then refers to a definition of

the word “derivative” indicating that it means an instantaneous rate of change and the slope of a tangent line to the graph of a function. *Id.* (citing www.thefreedictionary.com). The Examiner concludes, “[b]ased on these definitions, it is seen that a differential pressure measurement necessarily constitutes a measurement of the rate of change of pressure.” *Id.* at 17.

In reply, Appellant contends the Examiner errs in referring to mathematical definitions of the words “differential” and “derivative” because Watson uses the term “differential” with the word “pressure” merely to refer to a pressure difference, not to refer to an instantaneous rate of change in pressure. *See Reply Br.* 2–3.

Appellant’s argument is persuasive. The Examiner refers to column 7, lines 38–57 of Watson as supporting the finding that Watson discloses calculating a rate of change of measured pressure in a cryotherapeutic element. Final Act. 8. Watson describes its pressure measurement process as follows:

Individual pressure sensors can measure pressure in different ways. In some implementations, each sensor measures absolute pressure, for example, in pounds per square inch absolute (PSIA). In such implementations, two pressure sensors may typically be used to obtain a differential measurement that inherently eliminates any effect of local atmospheric pressure (e.g., ambient pressure). For example, if P1 and P2 are absolute pressure sensors in the catheter 100, the controller 228 can employ both P1 and P2 to differentially determine a pressure in the supply lumen 212.

Watson 7:37–47 (emphasis omitted).³ Thus, we agree with Appellant’s assertion that the cited portion of Watson uses the term “differential” merely

³ Lines 48–57 of column 7 of Watson describe measuring pressure relative to atmospheric pressure rather than measuring absolute pressure. This

to describe a difference between measurements taken by two different pressure sensors in the system, not to describe a mathematical derivative (slope). In other words, Watson describes finding a difference in pressures at two different locations, i.e., a pressure *differential*. This, by itself, is not the same as calculating a rate of change of pressure. Accordingly, the Examiner's finding that Watson discloses calculating a rate of change of a measured pressure within a cryotherapeutic element as recited in independent claim 1 is not supported by a preponderance of the evidence, and we do not sustain the rejection of claim 1, and claims 2–11 depending therefrom, as anticipated by Watson.

Rejections (III)–(V)

The Examiner does not rely on any of Mandel, Pang, or Gerber in any manner that would remedy the deficiency discussed above regarding Rejection (II). *See* Final Act. 13–17. Accordingly, we do not sustain Rejections (III)–(V).

DECISION

The Examiner's decision to reject claims 1–15 is reversed

REVERSED

difference does not support the Examiner's finding that Watson discloses a mathematical derivative any more than does Watson's disclosure regarding the use of absolute pressure. The Examiner also refers to column 11, lines 15–28 (Final Act. 8), but this portion of Watson uses the term “differential” in a manner consistent with its use in the cited portion of column 7.