

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC CORPORATION,
Petitioner,

v.

UAB RESEARCH FOUNDATION,
Patent Owner.

Case IPR2015-00918
Patent 6,266,563 B1

Before PHILLIP J. KAUFFMAN, BENJAMIN D. M. WOOD, and
JAMES A. WORTH, *Administrative Patent Judges*.

WORTH, *Administrative Patent Judge*.

DECISION
Petitioner's Request for Rehearing
37 C.F.R. § 42.71

I. INTRODUCTION

Petitioner, Boston Scientific Corporation (“Boston Scientific”), filed a Petition (Paper 1, “Pet.”) requesting *inter partes* review of claims 1–20 of U.S. Patent No. 6,266,563 B1 (Ex. 1001, “the ’563 patent”). Patent Owner, UAB Research Foundation (“UAB”), filed a Preliminary Response (Paper 9, “Prelim. Resp.”). On September 24, 2015, we denied institution of an *inter partes* review based on Petitioner’s challenges to claims 1–20 as anticipated by U.S. Patent No. 5,797,967 (Ex. 1008, “KenKnight ’967”). Paper 10 (“Decision”).

On October 20, 2015, Boston Scientific filed Petitioner’s Request for Rehearing Under 37 C.F.R. § 42.71(c) and (d) (Paper 11, “Rehearing Request” or “Request”), asking the Board to reconsider its denial of institution. On November 3, 2015, UAB filed Patent Owner’s Response to Request for Rehearing (Paper 12, “Opposition”).

For the reasons stated below, Petitioner’s Rehearing Request is granted, and we institute an *inter partes* review.

II. STANDARD OF REVIEW

Under 37 C.F.R. § 42.71(c), “[w]hen rehearing a decision on petition, a panel will review the decision for an abuse of discretion.” An abuse of discretion occurs when a “decision was based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment.” *PPG Indus. Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988) (citations omitted). The request must identify, specifically, all matters the party believes the Board misapprehended or overlooked. 37 C.F.R. § 42.71(d).

III. DISCUSSION

A. *Rehearing Request*

In the Decision, we concluded that the '563 patent was entitled to benefit from the filing date of Application No. 08/818,261 (“the '261 Application,” Ex. 1002) (filed Mar. 14, 1997),¹ and therefore that KenKnight '967 is not prior art to the '563 patent. Decision 7–11. In reaching this conclusion, we examined the disclosure of the '261 Application and determined that the implantable cardiac defibrillation device described therein was configured to deliver the type of antitachycardia pacing later claimed in the subject '563 patent, i.e., in claims 1–20 challenged in the Petition. This analysis was based in turn on an analysis of the placement of the electrodes in the '261 Application, the energies of the shocks delivered by the electrodes in the '261 Application, and the statements in the '261 Application that “[t]he present invention may be used to treat all forms of cardiac tachyarrhythmias, including ventricular fibrillation, with defibrillation (including cardioversion) shocks or pulses. The treatment of polymorphic ventricular tachycardia and ventricular fibrillation are particularly preferred.” Decision 6–10; Ex. 1002, 7:4–9. The Decision also observed that the '261 Application described electrode 54 as a “pace/sense” electrode. Decision 10–11.

¹ The '563 patent issued on July 24, 2001, from Application No. 09/391,026 (filed Sept. 7, 1999), which is a continuation-in-part of Application No. 09/039,143, now U.S. Patent No. 5,978,705 (“the '705 patent”), which in turn is a continuation-in-part of Application No. 08/818,261 (filed Mar. 14, 1997) (“the '261 Application,” Ex. 1002), now abandoned. Ex. 1001, at [63].

However, the Rehearing Request points out, and Patent Owner agrees, that the Decision misplaced the decimal point in stating the energy identified by Petitioner's declarant as the energy of a typical pacing pulse. Request 2; Opposition 1.² Petitioner's Declarant submitted that a typical pacing pulse is 25 microjoules. We now correct page 9 of our Decision to state that value as 0.000025 Joules (as opposed to 0.025 Joules). *See* Ex. 1006 (Benditt Decl.) ¶¶ 66–67 (citing Ex. 1011; Ex. 1015). *See also* Part III.C., *infra*.

Patent Owner submits that this difference is immaterial because of the other considerations set forth in the Decision. Opposition 1–6. In view of our correction of the above value, we re-analyze the issues as set forth below. In so doing, we grant the Rehearing Request and institute an *inter partes* review.

B. Claim Construction

Claims are construed to the extent necessary to resolve a controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). In light of the above correction, we address the meaning of two claim terms for purposes of institution: (1) “antitachycardia pacing” in claims 1–20, and (2) “ventricles” as recited by dependent claims 2, 8, and 15, i.e., “primary electrodes are configured for delivering antitachycardia pacing to the ventricles of said heart.”³

² We note that the energies listed for the “auxiliary pulse” are the same for the '261 Application as for the '563 patent, but for purposes of the priority analysis, the discussion is with respect to the written description of the '261 Application.

³ Petitioner also proposed a construction for “control circuit” (Pet. 7), which Patent Owner does not address. We do not find it necessary to construe “control circuit” at this time.

1. Applicable Law

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); see *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs., LLC v. Lee*, 84 U.S.L.W. 3218 (U.S. Jan. 15, 2016) (No. 15-446). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. See *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. See *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

2. “antitachycardia pacing”

The parties set forth similar constructions for “antitachycardia pacing,” but differ in one respect, i.e., the energy in Joules required. Petitioner states that “antitachycardia pacing” means that “pacing pulses in response to tachycardia.” Pet. 7 (citing Ex. 1001, 3:63–4:3, 7:23–30; Ex. 1006 ¶¶ 56–65, 199, 201–203). Patent Owner states that “antitachycardia pacing” is “cardiac pacing with stimuli timed to terminate a tachyarrhythmia.” Prelim. Resp. 4 (citing Ex. 2001). However, Patent Owner continues that “[t]o the extent that Petitioner’s proposed construction, particularly the phrase ‘pacing pulses,’ attempts to limit ATP to the delivery of pulses in a particular range of microjoules in magnitude, it is improper.” Prelim. Resp. 5.

Patent Owner points to the Specification of the '563 patent and the disclosure of the '261 Application, which provide that “[p]articular voltage, current, and energy outputs will depend upon factors such as the condition of the tissue and the particular disorder being treated.” Prelim. Resp. 4–5 (quoting Ex. 1001, 8:52–57; Ex. 1002, 16).

Consistent with the positions of both parties, we construe “antitachycardia pacing” to mean “pulses of electrical energy that stimulate the heart when in a state of tachycardia with the intent to terminate the arrhythmia.” *See* Pet. 7, 10; Prelim. Resp. 4–6; Ex. 2001; Ex. 1006 ¶¶ 24, 26, 39–41. However, on this record, we further credit the testimony of Dr. Benditt at this stage of the proceeding that the typical pacing pulse delivers a level of energy on the order of microjoules, in contrast to cardioversion and defibrillation pulses of higher energy. Ex. 1006 ¶¶ 42, 56–67, 199, 201–203. In contrast, Patent Owner has not proposed a construction with any parameters. Although Patent Owner has not yet had an opportunity to submit new testimonial evidence (*see* 37 C.F.R. § 42.107(c)), Patent Owner has also not pointed to any evidence for the proposition that a person of ordinary skill in the art would understand pacing pulses to be functionally defined without any specific energy values that would distinguish them from cardioversion or defibrillation. On this record, we thus conclude that a pacing pulse delivers a level of energy on the order of microjoules, as stated by Dr. Benditt.

3. “ventricles”

Claim 1 recites, in pertinent part, “a first one of said primary stimulation electrodes configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of said heart . . .

.” Ex. 1001, 21:44–58. Claim 2 depends from claim 1 and further recites “wherein said primary electrodes are configured for delivering antitachycardia pacing to the ventricles of said heart.” *Id.* at 21:59–61. For purposes of this Decision, and on this record, we infer that the antecedent of “said primary electrodes” in claim 2, is the plurality of “primary stimulation electrodes” recited in independent claim 1. *See Energizer Holdings, Inc. v. Int’l Trade Comm’n*, 435 F.3d 1366, 1371 (Fed. Cir. 2006) (“In that regard, we conclude that ‘anode gel’ is by implication the antecedent basis for ‘said zinc anode.’”).

Patent Owner argues, as a matter of claim differentiation, that the term “ventricles” in dependent claims 2, 8, and 15 refers to both the left and the right ventricle because the independent claims already recite delivery of ATP to the left ventricle. *See* Prelim. Resp. 36 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005)). In other words, Patent Owner argues that the implantable system of claims 2, 8, and 15, must be capable of delivering pacing to both ventricles at the same time. *See* Prelim. Resp. 36–37.

The principle of claim differentiation is not an inexorable canon, as the proper interpretation of a claim may depend on other contextual factors. However, the presence of a dependent claim that adds a particular limitation may give rise to a presumption that the limitation in question is not present in the independent claim. *See Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004). Patent Owner’s argument appears to be premised on an interpretation of claim 1, whereby the electrode that is “positioned through the coronary sinus ostium and within a vein on the surface of the left ventricle of said heart,” is configured to deliver pacing

pulses only to the left ventricle. *See* Prelim. Resp. 36–37. However, no such limitation is explicit in the language of claim 1. Indeed, both the preamble and the first clause state that the pacing is delivered to the heart without limiting it to the left ventricle. Claim 1 sets forth the position of the first of the plurality of electrodes, but does not set forth the position of any other electrodes and does not specify whether the recited position (of the first of the plurality of electrodes) will determine where the energy will be delivered. Further, Patent Owner does not address whether the electrode of claim 1 delivers energy to the atria. Patent Owner relies on Figure 1 of the '563 patent, but does not point with any further specificity to the text of the Specification at this stage of the proceeding.

Notwithstanding the claim differentiation argument, we note that Figure 1 of the '563 patent illustrates two electrodes at the same time, where C52 lies near LV34 and B51 lies near RV32. Ex. 1001, Fig. 1; *see also id.* at 6:62–7:2. We further note that the '563 patent describes that the primary electrode placed through the coronary sinus ostium and within a vein on the surface of the left electrode “may be coupled to or yolked [sic] to an *additional* electrode,” an electrode positioned in the right ventricle. Ex. 1001, 6:6–9 (emphasis added). Further, “[a]ntitachycardia pacing may be delivered from the right ventricle and then the left ventricle electrode, or may be delivered from the left ventricle and then the right ventricle electrode.” *Id.* at 6:11–15. In this connection, the Specification of the '563 patent is consistent with the notion that the same implantable device may be configured to deliver pacing to either or both ventricles.

In the anticipation section of the Petition, Petitioner proposes that the broadest reasonable construction of the “ventricles” limitation is “a system

where said electrodes [of claims 1, 7, and 14] are configured for delivering pacing pulses in response to tachycardia to the ventricles of the heart.” Pet. 48. It is not clear from Petitioner’s exposition whether Petitioner agrees with Patent Owner that the same implantable system must be capable of delivering pacing to both ventricles without reconfiguration of leads. Petitioner has not yet had an opportunity to reply to Patent Owner’s proposed construction.

Therefore, we do not construe “ventricles” at this time, awaiting further development of the record during trial. We note that claim constructions and other determinations at this stage of the proceeding are preliminary in nature. We invite the parties to brief this and other issues more fully in the Patent Owner Response and Petitioner Reply.

C. Priority Date of the ’563 Patent

We agree with Petitioner that the auxiliary pulse of the ’261 Application (from .01 or .05 to 1 or 2 Joules) is greater than the value of a typical pacing pulse (0.000025 Joules). *See* Pet. 12; Ex. 1006 ¶¶ 132–133; *compare* Ex. 1002, 12:29–31, *with* Ex. 1006 ¶ 66). We credit Dr. Benditt’s testimony that the smallest disclosed energy for the auxiliary pulse in the ’261 Application is about ten thousand times stronger than a pacing pulse, and a person of ordinary skill in the art would understand that such a pulse does not correspond to a pacing pulse. *Id.* Based on this difference, and based on our claim construction, we conclude that Petitioner has established a reasonable likelihood that the “auxiliary” pulses disclosed in the ’261 Application are not antitachycardia pacing energies, and do not otherwise qualify as antitachycardia pacing.

Patent Owner, nevertheless, asserts that the '261 Application states the intent to treat ventricular tachycardia (*see supra*), i.e., “[t]he present invention may be used to treat all forms of cardiac tachyarrhythmias, including ventricular fibrillation, with defibrillation (including cardioversion) shocks or pulses.” *See* Opposition 3 (quoting Ex. 1002, 7:4–9). However, the intent to treat ventricular tachycardia by itself is not enough because the claims require antitachycardia *pacing* as the treatment for tachycardia. In this regard, Petitioner correctly observes that the disclosure of the '261 Application describes in large part defibrillation in combination with cardioversion shocks, including in the above passage relied on by Patent Owner. In other words, the above passage discloses defibrillation and cardioversion but does not necessarily include pacing.

Patent Owner also points to electrode 54 as a “pace/sense” electrode but the device consists of multiple electrodes and the claims require that at least one of the *pacing* electrodes overlie the left ventricle, i.e., “a plurality of primary stimulation electrodes configured for sensing cardiac [sic] signals and delivering antitachycardia pacing to said heart; a first one of said primary stimulation electrodes configured for positioning through the coronary sinus ostium and within a vein on the surface of the left ventricle of said heart,” as recited by claim 1. Neither the Patent Owner Preliminary Response nor the Decision relied on electrode 54 standing on its own. In the Patent Owner Preliminary Response, Patent Owner relies on electrodes 54, 54' for “delivering antitachycardia pacing” but does not rely on these electrodes for the claimed placement of the electrodes. *Compare* Prelim. Resp. 24 (claim chart), *with* Prelim. Resp. 25 (claim chart).

Patent Owner relies on the '261 Application's recitation of the background art in which two other patents described "pacing or pretreatment pulses" delivered through the same electrodes as defibrillation. *Id.* (citing Ex. 1002, 7). We recognize that Patent Owner has not yet had an opportunity to introduce testimonial evidence as to whether a person of ordinary skill would understand the '261 Application to disclose the use of pacing (in addition to pretreatment pulses) through an electrode with the claimed positioning. At this stage of the proceeding, we determine that Petitioner has shown a reasonable likelihood of prevailing on its assertion that the patentee was not in possession of the claimed configuration of electrodes at the time of the filing of the '261 Application. As such, Petitioner has demonstrated a reasonable likelihood of prevailing on its related assertion that the claims of the '563 patent cannot benefit from the priority from the '261 Application. Thus, Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that KenKnight '967 is prior art to the '563 patent.

D. Anticipation by KenKnight '967

1. Claims 1, 3-7, 9-14, and 16-20

Relying on the Declaration of Dr. Benditt, Petitioner sets forth argument and evidence as to how KenKnight '967 would anticipate each element of claims 1, 3-7, 9-14, and 16-20. Pet. 25-48. Patent Owner does not appear to dispute in its Preliminary Response that KenKnight '967, if prior art, would anticipate claims 1, 3-7, 9-14, and 16-20.

As above, we determine that there is a reasonable likelihood that KenKnight '967 is prior art to the '563 patent. Further, based on our own independent review of KenKnight '967, we determine that Petitioner has

shown a reasonable likelihood of prevailing on its assertion that KenKnight '967 would anticipate claims 1, 3–7, 9–14, and 16–20.⁴

2. *Claims 2, 8, and 15*

Claim 2 depends from claim 1, and further recites “wherein said primary electrodes are configured for delivering antitachycardia pacing to the ventricles of said heart.” Ex. 1001, 21:45–58. Claims 8 and 15 contain similar limitations. Petitioner sets forth argument and evidence as to how KenKnight '967 would anticipate claims 2, 8, and 15. Pet. 48–58.⁵ In particular, Petitioner relies on KenKnight's transverse lead (10) and its associated electrodes 18a and 18b. Pet. 48–49 (citing Ex. 1008, 6:13–17; Ex. 1006 ¶¶ 288–292). Petitioner's Declarant (Dr. Benditt) states that a person of ordinary skill would have understood lead 10 of KenKnight '967 to be configurable for placement in a variety of locations. Ex. 1006 ¶ 195 (discussing Ex. 1008, Fig. 10).

In the Preliminary Response, Patent Owner argues that claims 2, 8, and 15 would not be anticipated by KenKnight '967 based on its proposed claim construction of the “ventricles” limitation, i.e., that the claims require the implantable system to be configured to deliver pacing to both ventricles. Prelim. Resp. 36. Patent Owner observes that KenKnight '967 discloses the

⁴ Nevertheless, we note that KenKnight '967 does not provide energy values for “pacing” other than to state a potential of 1–10V and a current of 10mA +/- 0.1mA. Ex. 1008, 5:44, 10:64–67. For purposes of this Decision, for the same reasons as for the above discussions relating to claim construction and the priority date of the '563 patent, we credit the testimony of Dr. Benditt that “pacing” would have had a standard meaning to a person of ordinary skill in the art, e.g., to mean microjoule energy values. See Ex. 1006 ¶ 66.

⁵ The Rehearing Request does not separately address claims 2, 8, and 15.

delivery of pacing pulses with the disjunctive connector “*or*,” i.e., “pacing pulses . . . administered from a transvenous lead (10) residing in or near the coronary sinus along the postero-basal region of the left ventricle (LV) *or* in the right ventricle (RV) outflow tract.” Prelim. Resp. 37 (citing Ex. 1008, 6:13–17 (emphasis added)).⁶ Patent Owner thus raises an important question as to whether Petitioner has met its burden of showing KenKnight ’967 discloses one implantable system capable of pacing both ventricles rather than two alternative embodiments of the system. *See In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (“Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”).⁷

As above, we have not set forth a claim construction at this time, and we invite the parties to develop the record further on these points. Although we do not make any factual findings at this time, we note that Petitioner’s requirements of proof would be greater under Patent Owner’s proposed construction for the reasons set forth herein. We, nevertheless, determine

⁶ Although the Patent Owner’s Preliminary Response mistakenly groups together claims 2, 8, and 16 for this purpose (*id.*), the Patent Owner’s Opposition correctly list the claims with this requirement as claims 2, 8, and 15.

⁷ We note for completeness of discussion that there are situations in which the context of the reference might lead to a conclusion that the use of “*or*” is not to the exclusion of both. *Linear Tech. Corp. v. Int’l Trade Comm’n*, No. 2007-1572, 2008 WL 4097482 at **6 (Fed. Cir. Aug. 28, 2008) (non-precedential).

that Petitioner has a reasonable likelihood of prevailing on its assertion with respect to claims 2, 8, and 15.

IV. CONCLUSION

We determine that Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 1–20 of the '563 patent are anticipated by KenKnight '967.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that rehearing is granted;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to whether claims 1–20 are anticipated by KenKnight '967;

FURTHER ORDERED that no other grounds are instituted; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

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