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Row 1: 15/707,131, 09/18/2017, Niall Duffy, P0035321.USV1, 8560
Row 2: 28390, 7590, 09/16/2020, MEDTRONIC VASCULAR, INC., IP LEGAL DEPARTMENT, 3576 UNOCAL PLACE, SANTA ROSA, CA 95403
Row 3: EXAMINER, PREBILIC, PAUL B
Row 4: ART UNIT, PAPER NUMBER, 3774
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte NIALL DUFFY,
YUEQIANG XUE, and LUKE HUGHES

Appeal 2020-001186
Application 15/707,131
Technology Center 3700

Before CHARLES N. GREENHUT, MICHAEL L. HOELTER, and
ANNETTE R. REIMERS, *Administrative Patent Judges*.

HOELTER, *Administrative Patent Judge*.

DECISION ON APPEAL
STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner’s decision to reject claims 8, 10, and 22–29. Final Act. 1 (Office Action Summary). Claims 11 and 21 are objected to as being dependent upon a rejected base claim but indicated as containing allowable subject matter. Final Act. 1, 4.² We have jurisdiction under 35 U.S.C. § 6(b). We

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as “Medtronic, Inc.” Appeal Br. 2.

² We note that claims 11 and 21 are not included in Appellant’s Claims Appendix. Appeal Br. 12 (Claims App.).

REVERSE and enter a NEW GROUND OF REJECTION under 35 U.S.C. § 41.50(b).

CLAIMED SUBJECT MATTER

The claimed subject matter “relates generally to devices and methods for repair of heart valves, and more particularly to devices and methods for use in repair of the mitral valve.” Spec. ¶ 1. Apparatus claims 8 and 28 are independent.

Claim 8 is illustrative of the claims on appeal and is reproduced below.

8. A chordae support device for repairing the native chordae of a heart valve, the device comprising:
 - an elongated member having first and second ends;
 - a first anchor extending from the first end of the elongated member, the first anchor comprising a delivery configuration and a deployed configuration, wherein the first anchor comprises a coiled wire segment, wherein the delivery configuration is a straightened configuration of the coiled wire segment and the deployed configuration is a coiled configuration of the coiled wire segment; and
 - a second anchor spaced from the first anchor and slideably moveable along the elongated member relative to the first anchor,wherein the first anchor is configured to engage a leaflet of the heart valve, wherein the second anchor is configured to engage a papillary muscle or a wall of a heart, and wherein a length of the elongated member between the first anchor and the second anchor following tissue engagement is adjustable.

EVIDENCE

Name	Reference	Date
St. Goar et al. (“St. Goar”)	US 6,629,534 B1	Oct. 7, 2003
Spence et al. (“Spence”)	US 2004/0088047 A1	May 6, 2004
Buckman et al. (“Buckman”)	US 2007/0255315 A1	Nov. 1, 2007
Ketai et al. (“Ketai”)	US 2011/0060407 A1	Mar. 10, 2011

THE REJECTIONS ON APPEAL

Claims 8, 10, 22–24, 26, and 28 are rejected under 35 U.S.C. § 103(a) as unpatentable over Spence and St. Goar. Final Act. 2.

Claims 25, 27, and 29 are rejected under 35 U.S.C. § 103(a) as unpatentable over Spence, St. Goar, and Buckman or Ketai. Final Act. 3.

ANALYSIS

NEW GROUNDS OF REJECTION³

Pursuant to our authority under 37 C.F.R. § 41.50(b), we reject claims 8, 10, 11, and 21–29⁴ under 35 U.S.C. § 112, second paragraph, as indefinite.

³ Because Appellant’s application claims priority to an application that was filed before September 16, 2012, the effective date of the amendments to 35 U.S.C. § 112 enacted by the Leahy-Smith America Invents Act (AIA), the AIA version of the statute does not apply. *See* AIA, Pub. L. No. 112–29, § 4(e), 125 Stat. 284, 297 (2011).

⁴ Although claims 11 and 21 are indicated as containing allowable subject matter, because they are dependent on either claim 8 or claim 28, which are

Independent claims 8 and 28 recite “wherein the first anchor *is configured to* engage a leaflet of the heart valve” and “wherein the second anchor *is configured to* engage a papillary muscle or a wall of a heart.” Appeal Br. 12, 14 (Claims App.; emphasis added).

In the Final Office Action, and with respect to this “configured to” language, the Examiner states that “[i]f the prior art device is fully capable of performing the function or intended use as claimed, then the claimed feature is considered fully met.” Final Act. 2. In the Answer, the Examiner asserts that the prior art anchors of Spence and St. Goar “are fully capable of engaging the leaflets of a native heart valve because all are designed to engage soft tissue of the human heart.” Ans. 4.

Appellant contends that the Examiner’s “use of a ‘capable of’ standard is improper.” Appeal Br. 7. Citing to *In re Giannelli*,⁵ Appellant argues that

it was reaffirmed that claim terms such as “adapted to”, “made to”, and “**configured to**” mean that the device “is designed or constructed to be used” in a specific manner and therefore must be accorded significant weight. In *Giannelli*, the Federal Circuit confirmed that the mere “capability” of an apparatus is not the proper inquiry. *Id.* at 1380. Therefore, a device in a reference cited by the Office must also be designed and constructed to be used in the same **specific** manner. In the present situation, the Office is asserting that replacing the **bottom anchor** of Spence with a coiled anchor somehow results in a device with a coiled **top anchor** configured to engage leaflets of a native heart valve. The Office has not satisfied the burden of showing that the **top anchor** of Spence is a coiled anchor designed and constructed to

being rejected as indefinite, we include claims 11 and 21 in the new ground of rejection as well.

⁵ 739 F.3d 1375, 1379 (Fed. Cir. 2014).

engage a leaflet of a heart valve, as claimed. To the contrary, as noted above, the *top anchor* (312, 314 and 302) of Spence is not a coiled anchor as claimed and is configured to engage the annulus, not a leaflet of a heart valve.

Appeal Br. 7; *see also* Reply Br. 5–6.

In the Office Action, the Examiner proposes modifying an anchor of Spence to be in the form of a coil, much like the coiled wire segment as claimed by Appellant. *See* Final Act. 2–3. Appellant indicates that the modified (i.e., coiled) anchor of Spence is not “designed and constructed to be used” to engage a leaflet of the heart valve, yet the form of Spence’s modified anchor and that of Appellant’s are the same—a coil. Appellant’s Specification discloses that “[t]he anchoring mechanism 240 *is configured to* be a ‘stapler’ type of device that is made of a material having [a] shape memory characteristic.” Spec. ¶ 49 (emphasis added). Appellant’s Specification, however, does not address how a first anchor “*is configured to* engage a leaflet of the heart valve” or how a second anchor “*is configured to* engage a papillary muscle or a wall of a heart.” Spec., *passim*. There is nothing wrong with the use of “configured to” language to define the claimed subject matter *per se*. However, the Specification must make clear to the reader what structure is necessary for some claim element to be regarded as “configured to” perform the acts associated with that phrase. Here, Appellant’s Specification does not adequately inform us of such information. Accordingly, it is unclear how or what aspect of Appellant’s “first anchor” makes that anchor “designed and constructed to be used” to engage a leaflet of the heart valve, rather than other tissues, such as a papillary muscle or a wall of a heart. Likewise, it is unclear how or what aspect of Appellant’s “second” anchor makes that anchor “designed and

constructed to be used” to engage a papillary muscle or a wall of a heart, rather than other tissues, such as a leaflet of the heart valve.

Thus, the claims should be clarified to indicate how the “first anchor” is designed and constructed to be used to engage a leaflet of the heart valve and how the “second anchor” is designed and constructed to be used to engage a papillary muscle or a wall of a heart. In their current form, the claims do not provide sufficient certainty for the potential infringer to evaluate the possibilities of being held liable for direct and/or contributory infringement. “[T]he claims must make it clear what subject matter they encompass.” *In re Hammack*, 427 F.2d 1378, 1382 (CCPA 1970).

For these reasons, we enter a new ground of rejection of claims 8, 10, 11, and 21–29 under 35 U.S.C. § 112, second paragraph, in order for this ambiguity to be definitively resolved, one way or another, during prosecution. *See Ex parte Miyazaki*, 89 USPQ2d 1207, 1211 (BPAI 2008) (precedential); *accord In re Packard*, 751 F.3d 1307, 1324 (Fed. Cir. 2014) (Plager, J., concurring); *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989).

OBVIOUSNESS REJECTIONS

We do not reach the merits of the prior art rejections of claims 8, 10, and 22–29 because we are unable to review them without having to make speculative assumptions about the meaning of the language of the rejected claims, as discussed above for the rejection under 35 U.S.C. § 112, second paragraph. Consequently, we are constrained to reverse the prior art rejections (*see* Final Act. 2–4). *See In re Steele*, 305 F.2d 859, 862 (CCPA 1962) (A prior art rejection cannot be sustained if the hypothetical person of

ordinary skill in the art would have to make speculative assumptions concerning the meaning of claim language.).

DECISION

For the above reasons, we REVERSE the decision of the Examiner to reject claims 8, 10, and 22–29.

We enter a NEW GROUND OF REJECTION of claims 8, 10, 11, and 21–29 under 35 U.S.C. § 112, second paragraph, as indefinite.

DECISION SUMMARY

Claims Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed	New Ground
8, 10, 22–24, 26, 28	103(a)	Spence, St. Goar		8, 10, 22–24, 26, 28	
25, 27, 29	103(a)	Spence, St. Goar, Buckman		25, 27, 29	
25, 27, 29	103(a)	Spence, St. Goar, Ketai		25, 27, 29	
8, 10, 11, 21–29	112, second paragraph	Indefiniteness			8, 10, 11, 21–29
Overall Outcome				8, 10, 22–29	8, 10, 11, 21–29

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). Section 41.50(b) provides “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.” Section 41.50(b) also provides:

When the Board enters such a non-final decision, [Appellant], within two months from the date of the decision, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the prosecution will be remanded to the Examiner. The new ground of rejection is binding upon the Examiner unless an amendment or new Evidence not previously of Record is made which, in the opinion of the Examiner, overcomes the new ground of rejection designated in the decision. Should the Examiner reject the claims, Appellant may again appeal to the Board pursuant to this subpart.

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same Record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

Further guidance on responding to a new ground of rejection can be found in the Manual of Patent Examining Procedure § 1214.01.

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).

REVERSED; 37 C.F.R. § 41.50(b)