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Medtronic Vascular - APV Division
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EXAMINER

WOZNICKI, JACQUELINE

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* YOSI TUVAL, ILIA HARITON,  
IGOR KOVALSKY, and ELI BEN-HAMOU

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Appeal 2018-001155  
Application 12/914,611  
Technology Center 3700

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Before DANIEL S. SONG, WILLIAM A. CAPP, and  
JEFFREY A. STEPHENS, *Administrative Patent Judges*.

CAPP, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants seek our review under 35 U.S.C. § 134(a) of the final rejection of claims 1, 8–13, 15–19, and 41–48 under 35 U.S.C. § 112, first paragraph, as failing to satisfy the written description requirement. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

## THE INVENTION

Appellants' invention relates to prosthetic heart valves. Spec. ¶ 1.  
Claim 1, reproduced below, is illustrative of the subject matter on appeal.

1. Apparatus comprising a mitral valve prosthesis for implantation at a native mitral valve complex of a subject, the prosthesis comprising:

an inner support structure having a downstream section and an upstream section, the upstream section having a cross-sectional area greater than the downstream section, the inner support structure being configured to be positioned at least partially on an atrial side of the native valve complex, and to prevent the prosthesis from being dislodged into a left ventricle by applying an axial force directed toward the left ventricle;

a prosthetic valve having prosthetic valve leaflets coupled to the inner support structure; and

an outer support structure coupled to the inner support structure, the outer support structure having more than two arms, wherein the more than two arms of the outer support structure extend in an upstream direction, are disposed radially outside of the inner support structure, and at least partially overlap the inner support structure, wherein a first arm of the more than two arms is longer than a second arm of the more than two arms, and wherein at least the first arm is configured to clamp portions of leaflets of the native valve between the inner support structure and the first arm.

## OPINION

### *35 U.S.C. § 112, First Paragraph, The Written Description Requirement*

The specification of a patent as filed must “contain a written description of the invention.” 35 U.S.C. § 112. A specification has an adequate written description when it “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date” of the patent. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598

F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). “[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art . . . [to] show that the inventor actually invented the invention claimed.” *Id.* The written description requirement is met when the disclosure “allow[s] one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002).

*Claims 1, 8–13, and 15–19*

The Examiner determines that there is no support in the written description, as originally filed, for a mitral valve prosthesis with “more than two arms” as claimed in claim 1. Final Action 4. Claims 8–13 and 15–19 are rejected as being dependent, directly or indirectly, from claim 1. *Id.*

Appellants argue, among other things, that support for “more than two arms” appears on page 19 of the Specification, which recites:

For some applications, mitral valve prosthesis 100 includes *three engagement arms 106*, three leaflets, and/ or three commissure posts 108, or a different number of the aforementioned components.

Spec. 19, ll. 16–19 (emphasis added). In response, the Examiner concedes that there is support for “more than two arms.” Ans. 11. However, the Examiner then takes the position that there is no support in the Specification for a first arm being longer than a second arm as recited in claim 1. *Id.*

However, in their Appeal Brief, Appellants argued that anterior engagement arm 106A is longer than the posterior engagement arm 106P, a position that the Examiner failed to specifically address in the Answer. Appeal Br. 8. In their Reply Brief, Appellants reiterated that they pointed

out in their Appeal Brief where the Specification discloses that one engagement arm may be longer than another. Reply Br. 3.

In the Specification, Appellants disclose various ratios of differential length between the anterior and posterior engagement arms. *See* Spec. 9, ll. 18–30. This is sufficient to support Appellants’ position that one engagement arm is longer than another.

In view of Appellants’ explicit disclosure of three engagement arms (Spec. 19) and explicit disclosure that the anterior and posterior arms may have different lengths (Spec. 9), the Examiner’s position on lack of written description support for these limitations is not supported by the record before us. Accordingly, we do not sustain the Section 112, first paragraph, rejection of claims 1, 8–13, and 15–19.

#### *Claims 41–48*

The Examiner determines that there is no support in the Specification for the limitation in claim 41 that the outer support structure includes four arms. Final Action 5. Appellants argue that the embodiment of Figure 11A includes four arms. Appeal Br. 11. Appellants’ position is based on the underlying premise that each of two connecting frame 121 elements in Figure 11A constitutes an “arm.” *Id.* at 11–12. In response, the Examiner takes the position that Figures 11A–D show only two arms (engagement arms 106), each of which is connected to a connecting frame 121. Ans. 5. According to the Examiner, connecting frame elements 121 do not constitute “arms.” *Id.* In reply, Appellants reiterate that connecting frame elements 121 should be considered “arms” for purposes of claim 41. Reply Br. 3–4.

The Examiner has stated the better position. Engagement arms 106 and connecting frame 121 are described as separate structures in the

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Specification and called out as separately numbered elements in the drawings. The term “arm” is not operationally defined in the Specification. *See generally* Spec. Appellants do not direct our attention to any language in the Specification by which a person of ordinary skill in the art would understand that connecting frame 121 is an “arm” or vice versa.

We sustain the Examiner’s Section 112, first paragraph, rejection of claim 41 and of claims 42–48 that depend therefrom.

#### DECISION

The decision of the Examiner to reject claims 1, 8–13, and 15–19 is REVERSED.

The decision of the Examiner to reject claims 41–48 is AFFIRMED.

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-IN-PART