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rs.vasciplegal@medtronic.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL GLOSS, TIMOTHY GROEN,
CAROLYN MAJKRZAK, MATTHEW RUST, TIMOTHY RYAN, and
MATTHEW WESTON

Appeal 2018-007598¹
Application 15/162,909
Technology Center 3700

Before DANIEL S. SONG, RICHARD H. MARSCHALL, and
ALYSSA A. FINAMORE, *Administrative Patent Judges*.

FINAMORE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant² appeals from the Examiner's decision to reject claims 1–11, 14, and 16–21. We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE.

¹ The citations herein refer to the Specification filed May 24, 2016 (“Spec.”), Final Office Action mailed September 5, 2017 (“Final Act.”), Appeal Brief filed February 5, 2018 (“Appeal Br.”), Examiner’s Answer mailed May 17, 2018 (“Ans.”), and Reply Brief filed July 17, 2018 (“Reply Br.”).

² “Appellant” refers to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real parties in interest as Medtronic, Inc. and its parent entity, Medtronic plc. Appeal Br. 2.

SUBJECT MATTER ON APPEAL

The invention relates to prosthetic heart valves. Spec. ¶ 2. Claims 1 and 19 are independent. Appeal Br., Claims App. Independent claim 1, reproduced below, is illustrative of the claimed subject matter.

1. A valve prosthesis comprising:
an expandable frame comprising an outflow portion and an inflow portion connected to the outflow portion, the frame having a longitudinal axis and defining a central lumen extending between the outflow portion and the inflow portion, wherein the frame is generally cylindrical in a fully expanded configuration,
wherein, when the frame is in a fully expanded configuration, (i) an outer surface of the inflow portion is concave, (ii) the inflow portion has an upper inflow portion defining an upper edge, a lower inflow portion defining a lower edge, and a waist between the upper edge and the lower edge, (iii) the upper inflow portion flares outwardly from the longitudinal axis and the central lumen of the frame to greater extent than the lower inflow portion, (iv) a transverse distance from the upper inflow portion to the longitudinal axis of the frame increases from the waist to the upper edge, and (v) a transverse distance from the lower inflow portion to the longitudinal axis of the frame increases from the waist to the lower edge,
wherein the outflow portion comprises (i) an undulating upper outflow portion having peaks and valleys, (ii) an undulating middle outflow portion having peaks and valleys, and (iii) an undulating lower outflow portion having peaks and valleys, wherein the valleys of the undulating upper outflow portion are connected to the peaks of the undulating middle inflow portion, and wherein the valleys of the undulating middle outflow portion are connected to the peaks of the undulating lower outflow portion,

wherein the valleys of the undulating lower outflow portion are connected to the inflow portion along the waist via posts.

Id. (claim status identifier and underlining omitted).

REJECTIONS

Claims Rejected	35 U.S.C. §	References/Basis
20, 21	112(a)	Written Description
1-9, 14, 16-21	102(a)(1)	Essinger '157 ³
1-4, 8-11, 14, 16-18, 21	102(a)(1)	Essinger '398 ⁴

ANALYSIS

Written Description

Claim 20 recites “a transverse distance from the upper portion to the longitudinal axis of the frame *continuously* increases from the waist to the upper edge” and “a transverse distance from the lower portion to the longitudinal axis of the frame *continuously* increases from the waist to the lower edge.” Appeal Br., Claims App. (emphasis added). Claim 21 similarly recites “the transverse distance from the upper inflow portion to the longitudinal axis of the frame *continuously* increases from the waist to the upper edge” and “the transverse distance from the lower inflow portion to

³ Essinger et al., US 2011/0022157 A1, pub. Jan. 27, 2011 (“Essinger '157”).

⁴ Essinger et al., US 2012/0271398 A1, pub. Oct. 25, 2012 (“Essinger '398”).

the longitudinal axis of the frame *continuously* increases from the waist to the lower edge.” *Id.* (emphasis added).

The Examiner finds claims 20 and 21 lack written description support because the originally-filed disclosure does not describe that the recited transverse distances continuously increase. Final Act. 3. The Examiner acknowledges Figure 6 shows that the recited transverse distances increase, but finds one of ordinary skill would not be able to ascertain from the figures whether the change is continuous. *Id.*; Ans. 18. According to the Examiner “the term ‘continuously’ brings in the parameter of rate/pitch, which is clearly **NOT** disclosed or taught in the originally[-]filed disclosure of the current application.” Ans. 18 (emphasis in original).

On the other hand, Appellant argues Figure 6 shows the recited transverse distances continuously increasing in that the upper inflow portion and the lower inflow portion only extend farther away from the longitudinal axis when traveling from the waist to the corresponding edge, and do not extend back toward the longitudinal axis. Appeal Br. 30; *see also* Reply Br. 15 (“[T]he transverse distance does not decrease at any point moving from the waist to the upper/lower edge.” (emphasis omitted)). Per Appellant, “the term ‘continuously’ does not suggest that a rate/pitch is constant, but rather that the rate/pitch exists and is always extending in the same direction.” Reply Br. 15.

At the center of this dispute is the meaning of the claim term “continuously.” When construing claims,

the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage

as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997). If the specification does not assign or suggest a particular definition to a claim term, it is appropriate to consult a general dictionary definition of the term for guidance in determining the ordinary and customary meaning of the claim term as viewed by a person of ordinary skill in the art. *Comaper Corp. v. Antec, Inc.*, 596 F.3d 1343, 1348 (Fed. Cir. 2010).

“Continuous” ordinarily means “[u]ninterrupted in time, sequence, substance, or extent.” *Continuous*, American Heritage Dictionary of the English Language (5th ed. 2016), <https://www.thefreedictionary.com/continuous> (last visited June 28, 2020). Appellant's Specification does not include the word “continuous” or any form thereof. Nonetheless, the Specification describes, with reference to Figures 6–9, that the upper and lower inflow portions flare outwardly from the longitudinal axis of the frame. Spec. ¶¶ 39–41. As shown in at least Figure 6, the transverse distance from the upper portion to the longitudinal axis increases, without interruption, when moving from the waist to the upper edge, and the transverse distance from the lower portion to the longitudinal axis always increases when moving from the waist to the lower edge. Thus, the ordinary meaning of “continuous” is consistent with the Specification's description of how the transverse distances increase.

In accordance with the broadest reasonable interpretation, “continuous” encompasses “uninterrupted,” such that the claim term “continuously increases” covers an uninterrupted increase, such as the

uninterrupted increase in the transverse distances shown in Figure 6. As Figure 6 shows that the transverse distance from the upper portion to the longitudinal axis of the frame continuously increases from the waist to the upper edge, and that the transverse distance from the lower portion to the longitudinal axis continuously increases from the waist to the lower edge, the Examiner has not demonstrated persuasively that claims 20 and 21 lack written description support. We, therefore, do not sustain the rejection of claims 20 and 21.

Anticipation Based on Essinger '157

In rejecting independent claim 1, the Examiner relies on certain figures of Essinger '157. Final Act. 4–6. The Examiner finds the recited frame and inflow portion are shown in Figure 1A. *Id.* at 4–5. The Examiner further finds Figure 7 shows the recited outflow portion, including the undulating upper, middle, and lower portions thereof. *Id.* at 5–6. The Examiner also finds the recited posts are shown in Figure 4. *Id.* at 6.

In rejecting independent claim 19, the Examiner likewise relies on certain figures of Essinger '157. *Id.* at 9–10. The Examiner finds Figure 5 shows the recited frame, as well as the recited inflow portion including a plurality of closed cells. *Id.* The Examiner also finds Figures 7 and 4 show the recited outflow portion and posts, similar to the rejection of independent claim 1. *Id.*

Appellant argues the Examiner relies on separate and distinct embodiments of Essinger '157 to reject each of independent claims 1 and 19, and has not shown Essinger '157 discloses all of the claim elements as arranged in the claim, as anticipation requires. Appeal Br. 10–18; Reply

Br. 2–4. According to Appellant, Essinger '157 does not describe any interrelation between Figures 1A, 4, and 7, and Figures 4 and 7 show embodiments that are different than that shown in Figure 1A. Appeal Br. 11; Reply Br. 3–4.

In response, the Examiner explains:

Separate embodiments were not used together to make the rejection of claims 1 and 19; instead the rejections depend on one embodiment, as illustrated in Figure 7, and other figures were used for illustrative purposes, to make it easier to see/point out features of the inflow portion which are part of the embodiment of Figure 7, however not as clearly illustrated in the figure.

Ans. 15. The Examiner also provides an annotated version of Figure 7, reproduced below, identifying the features the Examiner originally identified in Figure 7, as well as the features the Examiner originally identified in Figures 1A, 4, and 5. Ans. 5.

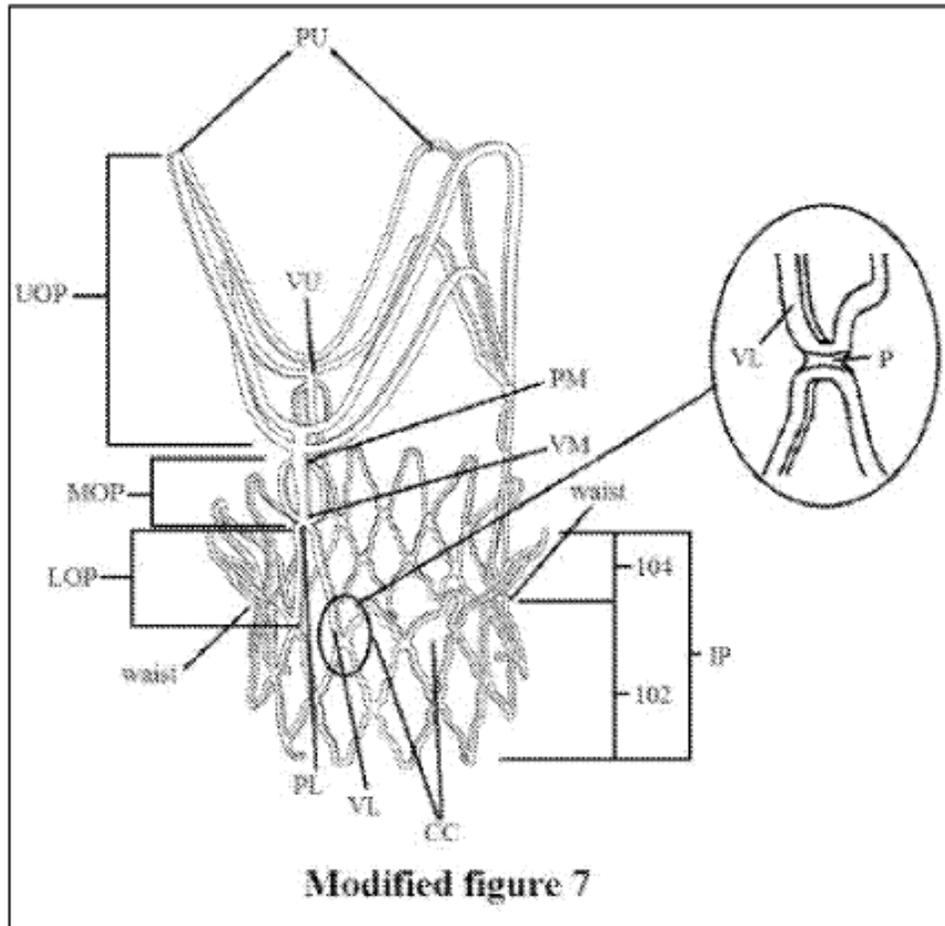
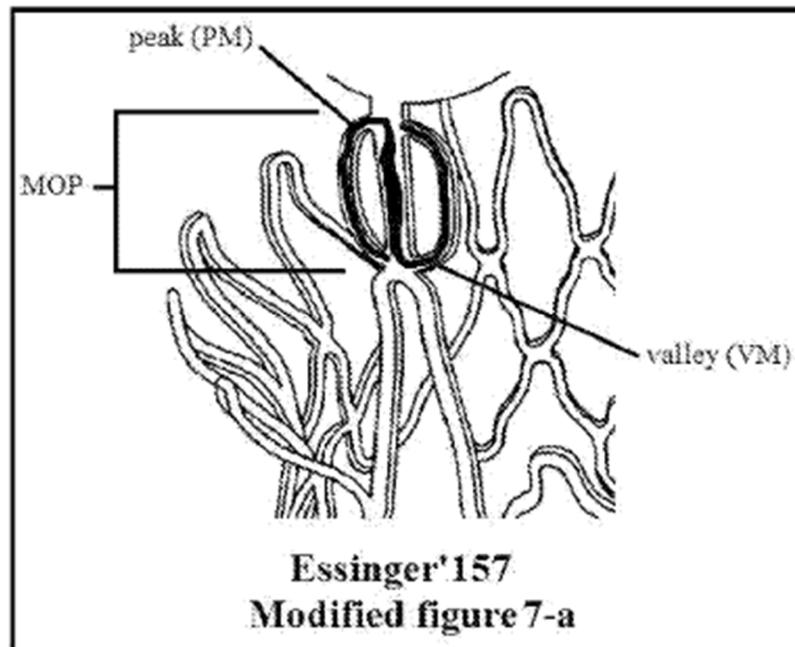


Figure 7 shows the stent component in an expanded configuration. Essinger '157 ¶ 31. The Examiner annotated the figure to label the inflow portion as "IP." The Examiner identifies the waist of the inflow portion, and labels the closed cells of the inflow portion as "CC." The Examiner also labels the upper, middle, and lower outflow portions as "UOP," "MOP," and "LOP," respectively. The Examiner respectively labels the peaks of the upper, middle, and lower outflow portions as "PU," "PM," and "PL," and similarly labels the valleys of the upper, middle, and lower outflow portions as "VU," "VM," and "VL," respectively. The Examiner also magnifies a juncture of the inflow portion and a valley of the lower outflow portion and, at this magnified juncture, adds lines to delineate the inflow portion and

lower outflow portion and identifies a post, which the Examiner labels as “P.”

Even if the Examiner’s finding of anticipation relies on a single embodiment, namely the embodiment shown in Figure 7, we agree with Appellant that the Examiner has not demonstrated persuasively that this embodiment discloses “an undulating middle outflow portion having peaks and valleys,” as recited in independent claims 1 and 19. In finding the embodiment shown in Figure 7 discloses this limitation, the Examiner explains: “According to the Oxford Dictionary the definition of the word ‘undulate’ is ‘move or go with a smooth up and down motion.’” Ans. 16. The Examiner finds the recited undulating middle outflow portion is shown in Figure 7, and the Examiner provides an annotated version of a portion of Figure 7, reproduced below, identifying the undulating middle outflow portion. *Id.*



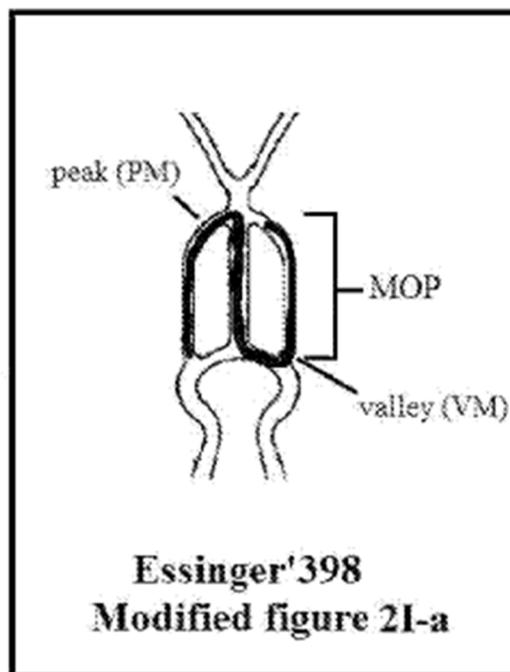
The Examiner's annotated version of Figure 7 shows the middle portion of the figure, thereby depicting the middle of the expanded stent, which includes a bifurcated circular structure. The Examiner annotated the figure to identify the bifurcated circular structure as the middle outflow portion ("MOP"). To show that the middle outflow portion undulates, the Examiner further annotated the figure to include a line that begins at the bottom of the bifurcated circular structure, extends up the left side, goes down the middle portion, extends up the right side, and ends at the top of the bifurcated circular structure. The Examiner also annotated the figure to identify the portion of the line near the top of the bifurcated circular structure as a peak of the undulating middle outflow portion ("PM") and the portion of the line near the bottom of the bifurcated circular structure as a valley of the undulating middle outflow portion ("VM").

The dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer that the prior art discloses the claimed invention. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003). Regardless of whether the line the Examiner added to the bifurcated circular structure undulates, the bifurcated circular structure itself does not. Absent the Examiner's line, the portions near the top and bottom of the bifurcated circular structure that the Examiner identifies as the peak and valley, respectively, appear to be the top of a bottom of a circle, which has no peaks or valleys. As the alleged undulation and the peaks and valleys are apparent only with the Examiner's line, which is not part of Figure 7 or otherwise described in Essinger '157, the Examiner has not demonstrated persuasively that a person of ordinary skill in the art would have understood that the embodiment shown in Figure 7 discloses "an

undulating middle outflow portion having peaks and valleys,” as recited in independent claims 1 and 19. We, therefore, do not sustain the rejection of independent claims 1 and 19 and claims 2–8, 14, 16–18, 20, and 21 depending therefrom.

Anticipation Based on Essinger '398

The anticipation rejection premised on Essinger '398 suffers from a similar deficiency as the anticipation rejection based on Essinger '157. The Examiner finds Figure 2I of Essinger '398 discloses “an undulating middle outflow portion having peaks and valleys,” as recited in independent claim 1. Final Act. 12–13; Ans. 16. The Examiner provides an annotated version of a portion of Figure 2I, reproduced below, identifying the undulating middle outflow portion. Ans. 16.



The Examiner’s annotated version of Figure 2I shows the middle portion of the figure, which depicts the middle of the expanded stent including a

bifurcated dome-shaped structure. The Examiner annotated the figure to identify the bifurcated dome-shaped structure as the middle outflow portion (“MOP”). To show that the middle outflow portion undulates, the Examiner further annotated the figure to include a line that begins at the bottom of the bifurcated dome-shaped structure, extends up the left side, goes down the middle portion, extends up the right side, and ends at the top. The Examiner also annotated the figure to identify the portion of the line near the top of the bifurcated dome-shaped structure as a peak of the undulating middle outflow portion (“PM”) and the portion of the line near the bottom of the bifurcated dome-shaped structure as a valley of the undulating middle outflow portion (“VM”).

Irrespective of whether the line the Examiner added to the bifurcated dome-shaped structure undulates, the bifurcated dome-shaped structure itself does not. Absent the Examiner’s line, the identified peak appears to be the top of a dome, which is devoid of peaks, and the identified valley appears to be the bottom of a rectangle, which has no valleys. As the alleged undulation and the peaks and valleys are evident only with the Examiner’s line, which is not part of Figure 2I or otherwise described in *Essinger* ’398, the Examiner has not demonstrated persuasively that a person of ordinary skill in the art would have understood that Figure 2I discloses “an undulating middle outflow portion having peaks and valleys” recited in independent claim 1. We, therefore, do not sustain the rejection of independent claim 1 and claims 2–4, 8–11, 14, 16–18, and 21 depending therefrom.

CONCLUSION

We do not sustain the rejection of claims 20 and 21 under 35 U.S.C. § 112(a) for failing to comply with the written description requirement. We also do not sustain the rejection of claims 1–9, 14, and 16–21 under 35 U.S.C. § 102(a)(1) as anticipated by Essinger '157 or the rejection of claims 1–4, 8–11, 14, 16–18, and 21 under 35 U.S.C. § 102(a)(1) as anticipated by Essinger '398.

DECISION SUMMARY

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
20, 21	112(a)	Written Description		20, 21
1–9, 14, 16–21	102(a)(1)	Essinger '157		1–9, 14, 16–21
1–4, 8–11, 14, 16–18, 21	102(a)(1)	Essinger '398		1–4, 8–11, 14, 16–18, 21
Overall Outcome:				1–11, 14, 16–21

REVERSED