UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/340,127	12/29/2011	Saurav Paul	0B-1434USO/065513-000394	8243

67337 7590 09/18/2019

DYKEMA GOSSETT PLLC (STJ)
4000 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402

EXAMINER	
GHAND, JENNIFER LEIGH-STEWAR	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
09/18/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ASJM_Patents@abbott.com
MN-IPMail@dykema.com
Patents@dykema.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SAURAV PAUL and RIKI CHOU THAO

Appeal 2019-000803
Application 13/340,127
Technology Center 3700

Before DANIEL S. SONG, JEREMY M. PLENZLER, and LEE L. STEPINA, *Administrative Patent Judges*.

SONG, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

The Appellant[1] appeals under 35 U.S.C. § 134(a) from the Examiner's Final Office Action ("Final Act.") rejecting claims 1, 2, 5–17, and 24–36 in the present application. We have jurisdiction under 35 U.S.C. §§ 6(b) and 134(a).

We AFFIRM.

[1] The Appellant is St. Jude Medical, Atrial Fibrillation Division, Inc., which is identified as the real party in interest. Appeal Brief ("App. Br.") 4.

The claimed invention is directed to an ablation device. Abstract. Representative independent claim 35 reads as follows:

> 35. An ablation device for creating linear lesions, the device comprising:
>
> a flexible support structure defining a pre-formed closed loop capable of being retained in the absence of a deforming force; and
>
> an electrode disposed at a distal end of the closed loop of the flexible support structure;
>
> *wherein the electrode is configured to form a linear lesion, at least a portion of which is transverse to a longitudinal axis of the ablation device*.

App. Br. 26, Claims App'x (emphasis added).

REJECTIONS

1. The Examiner rejects claims 33 and 34 under 35 U.S.C. § 112, second paragraph as being indefinite. Final Act. 2.

2. The Examiner rejects claims 35 and 36 under 35 U.S.C. § 102(b) as anticipated by Pomeranz (US 5,800,482, iss. Sept. 1, 1998). Final Act. 3.

3. The Examiner rejects claims 1, 2, 5–17, 24–31, and 33–36 under 35 U.S.C. § 103(a) as unpatentable over Thao (US 2008/0161789 A1, pub. July 3, 2008) in view of Swanson (US 2003/0088244 A1, pub. May 8, 2003), Vanney (US 2005/0004440 A1, pub. Jan. 6, 2005), and Fleischman (US 5,836,947, iss. Nov. 17, 1998). Final Act. 4.

4. The Examiner rejects claims 32 and 35 under 35 U.S.C. § 103(a) as unpatentable over Thao in view of Swanson and Vanney. Final Act. 9.

ANALYSIS

Only those arguments actually made by the Appellant have been considered in this decision. Arguments that the Appellant could have made but chose not to make have not been considered and are deemed to be waived. *See* 37 C.F.R. § 41.37(c)(1)(iv); *In re Jung*, 637 F.3d 1356, 1365–66 (Fed. Cir. 2011); *Ex parte Frye*, 94 USPQ2d 1072, 1075–76 (BPAI 2010 (precedential)).

Rejection 1

The Examiner rejects claims 33 and 34 under 35 U.S.C. § 112, second paragraph, as being indefinite because the term "substantially transverse" is a relative term, which is "not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." Final Act. 2. The Examiner explains that "it is unclear to what degree the linear lesion must be in order to be 'substantially transverse' to the longitudinal axis." Final Act. 2.

The Appellant argues that the claims are not indefinite because "although the specification does not specifically define the term 'substantially transverse,' the drawings clearly do." App. Br. 12, citing Spec. Figs. 3B, 3C; MPEP § 2173.01. The Appellant also cites dictionary definitions of "transverse" and "substantially" to argue that "a linear lesion which is 'substantially transverse' to a longitudinal axis of the active deployment member is a linear lesion that is set crosswise from or made at right angles to the longitudinal axis of the active deployment member," which is depicted in Figures 3B and 3C. App. Br. 13. Thus, the Appellant

argues that a person of ordinary skill in the art would understand what "substantially transverse" means based on the plain and ordinary meaning and in view of the drawings. App. Br. 13.

We agree with the Appellant. Claims are in compliance with 35 U.S.C. § 112, second paragraph, if "the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986). The use of "substantially" does not per se render a claim indefinite. *See Verve, LLC V. Crane Cams, Inc.*, 311 F.3d 1116, 1120 ("It is well established that when the term 'substantially' serves reasonably to describe the subject matter so that its scope would be understood by persons in the field of the invention, and to distinguish the claimed subject matter from the prior art, it is not indefinite."). When a claim uses a word of degree, like "substantially," we examine the Specification to determine whether some standard for measuring that degree is provided and whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the Specification. *See Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984).

In the present rejection, the Examiner has not explained why the skilled artisan in view of the Specification would not understand the meets and bounds of substantially, and we thus reverse the rejection. Although the Specification lacks a textual standard for determining the degree to which at least a portion of the linear lesion must be transverse, the Specification is not entirely silent as to how the pertinent limitation should be interpreted

through the inclusion of Figures 3B and 3C. We agree with the Appellant that a person of ordinary skill would understand the claim language "substantially transverse" in view of Figures 3B and 3C, and the plain and ordinary meaning of the terms "substantially" and "transverse," to thereby understand that what is being claimed "is a linear lesion that is set crosswise from or made at right angles to the longitudinal axis of the active deployment member." App. Br. 13.

Therefore, in view of the above considerations, we reverse this indefiniteness rejection.

Rejection 2

The Examiner rejects claims 35 and 36 as anticipated, finding that Pomeranz discloses an ablation device as claimed in which "the electrode is configured to form a linear lesion (e.g. ablates tissues to form linear lesion), at least a portion of which is transverse to a longitudinal axis of the ablation device (e.g. ablation section conforms to the cardiac tissue Fig. 6C)." Final Act. 3, citing Pomeranz Fig. 6C.

The Appellant disagrees and argues that

> Even if one were to assume, *arguendo*, that a highly magnified version of Fig. 6C of Pomeranz may show a minute portion of the ablation section 16 that could be considered "transverse" to the longitudinal axis of the ablation device, Fig. 6C of Pomeranz does not disclose an electrode configured to form a linear lesion that is "transverse" to the longitudinal axis of the ablation device according to the plain and ordinary meaning of the word "transverse."

App. Br. 14–15.

We are not persuaded that the Examiner erred. The Appellant focuses on Figure 6C, but overlooks the recited language of claim 35, and the fact that Figure 6C was cited by the Examiner as an example of conforming the ablation section to tissue, as well as the disclosure of Pomeranz, which describes the manner in which Pomeranz's linear lesion catheter operates.

In particular, we first note that independent claim 35 does not recite that the ablation device is configured to only create linear lesions, which are transverse to the longitudinal axis of the device. Indeed, while the claim recites that the electrode is "configured to" form a linear lesion, a portion of which must be transverse, the claim does not recite, nor does the Specification describe, any specific structure or characteristic attributable to the electrode or the ablation device for attaining the recited lesion. Moreover, as noted, claim 35 recites that only a portion of the linear lesion need be transverse. Second, the claim recites that it is the resultant lesion, which at least a portion must be transverse to the longitudinal axis of the ablation device. The recited lesion is not part of the recited ablation device, and thus, the claim merely functionally recites the orientation of the recited portion of the lesion. Accordingly, the claim limitation at issue is satisfied if the linear lesion catheter of Pomeranz is designed to provide a linear lesion that is, at least in portion, transverse to the longitudinal axis of the ablation device in at least some instances.

Turning to Pomeranz, the position of its ablation section 16 is described as being adjustable via movement of the end of baffle wire 26 and tubing 34. *See* Pomeranz, col. 7, ll. 9–36; Figs. 6A–6D. Specifically, Pomeranz teaches that

> The height, location and size of the loop **22** may be adjusted to position the ablation section **16** of the apparatus against the desired surface within the heart chamber and to maintain contact between the ablation surface of the catheter and the target surface within the heart chamber. These adjustments can be made by moving end **26** and/or tubing **34** distally or proximally as needed, and also by rotating the main shaft **12**.
>
> For example, tubing **34** may be moved distally to advance ablation section **16** and to thereby increase its curvature as shown in FIG. **6**C, if such curvature will conform the ablation section **16** to the cardiac tissue **T**.

Pomeranz, col. 7, ll. 24–36.

Thus, the linear lesion ablation catheter 10 of Pomeranz is designed to form a linear lesion, at least a portion of which is transverse to the longitudinal axis of the ablation device by positioning its ablation section 16 at the middle of the loop at the distal end thereof, and advancing the same to conform to, and ablate, the tissue that is at a plane normal to the longitudinal axis of the ablation device.

Therefore, we agree with the Examiner that "Pomeranz teaches an apparatus . . . for linear lesion ablation which discloses an electrode (e.g. 16) that can be placed at various locations on the cardiac tissue of interest (e.g. Figs. 6C-6D) therefore the structure of the electrode inherently possess the functional limitation." Ans. 11.

Accordingly, we affirm Rejection 2.

Rejections 3 and 4

The Examiner rejects claims 1, 2, 5–17, 24–31, and 33–36 as unpatentable over Thao in view of Swanson, Vanney, and Fleischman (Rejection 3). Final Act. 4. As to independent claims 1 and 35, the

Examiner finds, *inter alia*, that Thao discloses an ablation device, which "may be formed in various shapes in order to better fit the contour of the target tissue including a noose, a spatula or the shape of the ostium of the pulmonary vein (e.g. paragraphs [0077], [0079])." Final Act. 4. Based thereon, the Examiner concludes that it would have been obvious to have implemented Thao as a "preformed closed loop." Final Act. 4. The Examiner also finds that "Thao discloses the device being used inside blood vessels and heart chambers (e.g. paragraph [0064])," and that it was known to use a closed loop with an electrode at a distal end thereof to provide lesions to tissue within the heart "in order to obtain and retain continuous uniform contact with the cardiac tissue across the entire length of the ablation electrode surface in the presence of the constant movement of the heart." Final Act. 4–5, citing Swanson, Figs. 3, 4, 6, 10, 12, 16–19; and Vanney Figs. 2–4. The Examiner specifically points out that Figure 3C of Vanney and Figures 19A and 19B of Swanson show electrodes on a distal end of a closed loop that form a linear lesion. Ans. 13–14. The Examiner further finds that Fleischman discloses a flexible loop that supports electrodes wherein the loop may be deployed and controllably deformed by a movable rod. Final Act. 5, citing Fleischman, Figs. 13, 15, 16.

Accordingly, based on the above findings, the Examiner concludes that it would have been obvious to have

> shape[d] the Thao device into the shape of a pre-formed/pre-shaped closed loop with an electrode disposed at a distal end of the closed loop that is retained . . . to obtain and retain continuous uniform contact with the cardiac tissue across the entire length of the ablation electrode surface in the presence of the constant movement of the heart . . . [and to have modified]

> the ablation device of Thao with the teachings of Fleischman to include an active deployment member.

Final Act. 5.

The Examiner relies on substantially the same findings and conclusions in rejecting independent claim 24. Final Act. 7–8. The Examiner also rejects independent claims 32 and 35 as unpatentable over Thao in view of Swanson and Vanney (Rejection 4), based on substantially the same findings and conclusions set forth relative to Rejection 3. Final Act. 9–10.

The Appellant argues independent claims 1, 24, 32, and 35 rejected in Rejections 3 and 4 as a group, noting that each of these claims recites "an electrode 'configured to form a linear lesion, at least a portion of which is transverse to a longitudinal axis of the ablation device.'" App. Br. 16; *see also id.* at 18. The Appellant argues that

> The fact that Thao's ablation catheter can be formed into a noose, a spatula . . . or any other shape in no way suggests that ***a linear lesion*** formed by the electrode of the ablation catheter is ***transverse to a longitudinal axis*** of the ablation device. . . . There is no reason to believe, for example, that Thao's noose-shaped or spatula-shaped ablation catheter would not produce a linear lesion that is ***parallel*** (as opposed to transverse) to the longitudinal axis of the catheter.

App. Br. 16–17.

The Appellant further argues that

> While Swanson and Vanney may teach various electrode configurations and lengths along loop structures, this in no way suggests that ***a linear lesion*** formed by the electrode of the ablation catheter is ***transverse to a longitudinal axis*** of the ablation device. At best, Swanson teaches a linear lesion pattern as shown in FIG. 33A; however, there is no disclosure,

> teaching, or suggestion that this linear lesion is ***transverse to a longitudinal axis*** of the ablation device.

App. Br. 17–18.

The Appellant's arguments are unpersuasive for reasons similar to those discussed above relative to Rejection 2 in that they overlook the recited language of the independent claims, the disclosures of the prior art applied, and reasoning provided by the Examiner in rejecting the claims. The claims do not recite that the ablation device must be configured to only create transverse linear lesions, and instead, recites that it is at least a portion of the resultant lesion, which must be transverse. Accordingly, the limitation at issue is satisfied by implementing the ablation catheter of Thao as a closed loop as suggested therein, and as known in the art, with an electrode disposed at the distal end thereof, such ablation catheter being designed to form a transverse linear lesion, at least a portion of which is transverse to the longitudinal axis, when applied to "obtain and retain continuous uniform contact with the cardiac tissue" (Final Act. 5) that is at a plane normal to the longitudinal axis of the ablation device.

Therefore, in view of the above considerations, we affirm the Examiner's obviousness rejection relative to independent claims 1, 24, 32, and 35. The Appellant relies on dependency for patentability of claims 2, 5–17, 25–31, 33, 34, and 36. App. Br. 18. Accordingly, the rejection of these dependent claims is also affirmed.

CONCLUSIONS

1. Rejection 1 of claims 33 and 34 as being indefinite is Reversed.
2. Rejection 2 of claims 35 and 36 as anticipated is Affirmed.

3. Rejections 3 and 4 of claims 1, 2, 5–17, and 24–36 as unpatentable are 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). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED