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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CORBETT W. STONE, MICHAEL F. HOEY,
ARTHUR G. BLANCK, LEN BRIGGS, MIKE PERRY, and
ROLFE TYSON GUSTUS

Appeal 2018-000387¹
Application 13/385,555
Technology Center 3700

Before BRETT C. MARTIN, MICHELLE R. OSINSKI, and
LEE L. STEPINA, *Administrative Patent Judges*.

STEPINA, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134 from the Examiner's decision to reject claims 1–3 and 5–29. We have jurisdiction under 35 U.S.C. § 6(b).

¹ The Appeal Brief indicates that Vessix Vascular, Inc. is the real party in interest. Appeal Br. 3.

We REVERSE.

CLAIMED SUBJECT MATTER

The claims are directed to a catheter-based treatment for luminal diseases, particularly for atherosclerotic plaque, vulnerable or hot plaque, and the like, and the invention allows the remodeling of body tissue using heat. Spec. ¶ 4. Claim 22, reproduced below with emphasis added, is illustrative of the claimed subject matter:

22. A method for inducing desirable temperature effects on a target body tissue disposed about a body lumen of a patient, the method comprising:

positioning a radially expandable member supported by a distal end of a catheter body within the lumen adjacent the target body tissue to be heated, the expandable member having a low profile insertion configuration and a larger profile configuration;

wherein the expandable member comprises a balloon having a plurality of flexible circuits adhesively bonded to an outer surface thereof, each flexible circuit including a polymeric substrate bearing a pair of electrodes, each pair of electrodes collectively defining a plurality of electrodes, the flexible circuits being sufficiently flexible to allow folding and inflation of the balloon;

expanding the expandable member to the larger profile configuration within the lumen so as to engage the plurality of electrodes mounted on the plurality of flexible circuits against a wall of the lumen, the plurality of electrodes defining a plurality of remodeling zones in a tissue treatment area that extend about a circumference of the body lumen;

energizing the plurality of electrodes to transmit a remodeling energy to each of the plurality of remodeling zones, with a controller having a power source electrically coupled to the plurality of electrodes; and

heating collateral healthy tissue in at least some remodeling zones in the tissue treatment area with the remodeling energy without causing thermal damage, and heating

both the target body tissue and collateral healthy tissue in remodeling zones including the target tissue so as to efficaciously alter the target tissue while inhibiting damage to collateral healthy tissue of the wall of the lumen.

Appeal Br. 20–21 (Claims App.).

REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

| | | |
|---------|--------------------|---------------|
| Kordis | US 5,499,981 | Mar. 19, 1996 |
| Danaek | US 2003/0233099 A1 | Dec. 18, 2003 |
| Steinke | US 2005/0096647 A1 | May 5, 2005 |
| Carmel | US 2006/0089638 A1 | Apr. 27, 2006 |

REJECTIONS

I. Claims 22–28 are rejected under 35 U.S.C. § 103(a) as unpatentable over Steinke, Danaek, and Kordis.

II. Claims 1–3 and 5–21 are rejected under 35 U.S.C. § 103(a) as unpatentable over Steinke, Danaek, Kordis, and Carmel.

OPINION

Rejection I, Claims 22–28

The Examiner finds that Steinke discloses many of the steps recited in claim 22, including positioning a radially expandable member comprising a balloon adjacent to target body tissue to be heated, the expandable member comprising a plurality of flexible circuits attached thereto. Final Act. 2–3. However, the Examiner finds Steinke does not disclose “the flexible circuits being sufficiently flexible to allow folding and inflation of the balloon; and

that the flexible circuits are *adhesively bonded* to the expandable member.” *Id.* at 3 (emphasis added). The Examiner relies on the teachings of Danaek to remedy this deficiency. *Id.* at 4. Specifically, the Examiner finds Danaek teaches an expandable balloon that has flexible circuits attached to it, and these circuits are flexible enough to allow for inflation of the balloon. *Id.* (citing Danaek ¶ 23, Fig. 10). The Examiner also finds that Danaek teaches “each flexible circuit [is] adhesively bonded to the surface of the expandable member.” *Id.* (citing Danaek ¶ 146).

The Examiner states, “Steinke and Danaek teach different flexible electrode constructions disposed on the surfaces of expandable members of intraluminal catheters” and, therefore, “it would have been obvious to one of ordinary skill in the art at the time that the invention was made to substitute one known flexible electrode construction for the other in order to achieve the predictable result of a flexible electrode construction disposed on an expandable member[] of an intraluminal catheter.” *Id.*

As for the recited adhesive connection to the expandable member, the Examiner reasons that it would have been obvious “to adhesively bond the flexible electrode to the balloon member, since this attachment method is specifically disclosed by Danaek as a means of attaching the energy delivery device to the expandable member.” *Id.* at 5.

Appellants contend “there does not appear to be any teaching in Danaek of a ‘flexible electrode construction’ in which a flexible circuit is adhesively bonded to an *outer surface* of anything, much less an outer surface of a balloon.” Appeal Br. 10. Rather, Appellants contend, “Danaek describes a printed circuit that is situated *around* a leg of an expandable basket, rather than being adhesively bonded to an outer surface of a

balloon.” *Id.* (emphasis modified). Appellants contend that Danaek discloses the use of an adhesive *only* for securing a printed circuit around a leg of an expandable basket, not for bonding flexible circuits to the outer surface of a balloon.

In response, the Examiner states:

the structure of Steinke already provides for electrodes on a surface of a balloon. Danaek is only utilized to demonstrate that flex circuit constructions were known in the art and that substitution of this known electrode construction for other known constructions would have yielded predictable results. Danaek is further utilized to teach that adhesives were a known means for attaching said electrode construction to the surface of an expandable member. The fact that Danaek allegedly teaches flexible circuits in the context of a basket expandable member therefore does not impact the conclusion of obviousness.

Ans. 6.

In reply, Appellants reiterate the assertion that “there does not appear to be any teaching [in] the cited art of a ‘flexible electrode construction’ in which a flexible circuit is adhesively bonded to an *outer surface* of anything (as opposed to being wrapped around and attached to itself), much less an outer surface of a *balloon*, which has a shape and mechanical properties that are remote from those of a *leg of an expandable basket* as described by Danaek.” Reply Br. 9. Appellants also point out that the legs of the expandable basket disclosed by Danaek are made of stainless steel or nitinol, unlike the materials from which an expandable balloon is made. *See id.* at 9–10.

Appellants have the better position. The Examiner’s finding that Danaek discloses flexible circuit constructions is supported by a preponderance of the evidence. *See Danaek* ¶ 23 (“Other examples of the

energy transfer element include a polymeric heating element, an electrically conductive paint, or a printed flex circuit which are on a portion of the leg.”). However, we agree with Appellants that this specific teaching relates only to the attachment of a printed flex circuit to a *leg* of an expandable basket, not a balloon. The Examiner’s statement of the rejection of claim 22, on page 4 of the Final Office Action, refers to an expandable member (i) “comprising a balloon,” (ii) that “includes a plurality of flexible circuits attached thereto,” (iii) “the flexible circuits being sufficiently flexible to allow folding and inflation of the balloon,” (iv) with “each flexible circuit adhesively bonded to the surface of the expandable member.” In other words, the statement of the rejection appears to find that a *single embodiment* of the expandable member satisfies criteria (i)–(iv). Such a finding is not supported by a preponderance of the evidence. This is illustrated by the quotation from paragraph 146 of Danaek found on page 4 of the Final Office Action, which states “In any variation of the invention the use of adhesives or other coatings may also be used to secure the energy transfer element.” This quotation omits the words “to the basket leg **106**” at the end of the sentence. Specifically, the full sentence at issue from paragraph 146 of Danaek states, “In any variation of the invention the use of adhesives or other coatings may also be used to secure the energy transfer element to the basket leg **106**.” Underlining added. In other words, the language that was omitted in the Examiner’s reproduced quotation limits the use of adhesive to basket legs (in contrast to use with a balloon). The Examiner does not adequately explain how attachment of a flexible electrode to a *basket leg* by adhesive bonding renders it obvious to attach a flexible electrode to a *balloon* by adhesive bonding in light of the

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differences between basket legs and balloons identified by Appellants.
Reply Br. 9–10.

Accordingly, we do not sustain the Examiner’s rejection of claim 22 and claims 23–28 depending therefrom as unpatentable over Steinke, Danaek, and Kordis.

Rejection II; Claims 1–3 and 5–21

Independent claims 1 and 21 require “flexible circuits each adhesively bonded to an outer surface of the balloon” and “a plurality of flex circuits distributed about the balloon, each flex circuit including a polymeric substrate . . . the polymeric substrate being adhesively bonded to an outer surface of the balloon,” respectively. Appeal Br. 15, 19 (Claims App.). To address these claim requirements, the Examiner relies on the same findings of fact regarding Danaek discussed above with respect to Rejection I. Final Act. 9, 16. Accordingly, for the same reasons discussed above regarding Rejection I, we do not sustain the Examiner’s rejection of claims 1 and 21, and associated dependent claims 2, 3, and 5–20, as unpatentable over Steinke, Danaek, Kordis, and Carmel.

DECISION

The Examiner’s decision to reject claims 1–3 and 5–29 is reversed.

REVERSED