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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MARTIN R. WILLARD, DEREK C. SUTERMEISTER, KENNETH R. LARSON, TIMOTHY A. OSTROOT, and PATRICK A. HAVERKOST

Appeal 2019-001296
Application 14/516,014
Technology Center 3700

Before MICHAEL L. HOELTER, ANNETTE R. REIMERS, and JEREMY M. PLENZLER, *Administrative Patent Judges*.

REIMERS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant[1] appeals under 35 U.S.C. § 134(a) from the Examiner's decision to reject claims 1–6, 8, and 11–23. Claims 7, 9, and 10 have been canceled. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[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 Boston Scientific Scimed, Inc. Appeal Brief ("Appeal Br.") 3, filed Sept. 4, 2018.

CLAIMED SUBJECT MATTER

The claimed subject matter "generally pertains to percutaneous and intravascular devices for nerve modulation and/or ablation." Spec. 1:11–12, Fig. 2. Claims 1, 13, and 18 are independent.

Claim 1 is illustrative of the claimed subject matter and recites:

> 1. A medical device, the medical device comprising:
>
> an elongate shaft having a proximal end region, a distal end region, and a lumen extending therebetween;
>
> an expandable member coupled to the distal end region of the elongate shaft, wherein the expandable member is an inflatable cylindrical balloon;
>
> one or more electrical conductors extending from the proximal end region to the expandable member, the one or more electrical conductors having a distal end region secured directly to an outer surface the expandable member; and
>
> one or more energy delivery regions positioned on the expandable member and coupled to the one or more electrical conductors;
>
> wherein the one or more energy delivery regions are formed from a distal portion of the one or more electrical conductors;
>
> wherein the one or more electrical conductors are each at least partially coated with an insulator[;]
>
> wherein the one or more energy delivery regions are defined by one or more regions of the one or more electrical conductors that are free of the insulator; and
>
> wherein at least a portion of the one or more regions of the one or more electrical conductors that are free of the insulator is wound in a serpentine manner.

REJECTIONS[2]

I. Claims 1–6, 11, 13, 21, and 22 stand rejected under 35 U.S.C. § 103 as unpatentable over Clayman (US 5,779,698, issued July 14, 1998) and Stern (US 5,713,942, issued Feb. 3, 1998).

II. Claims 8 and 14–16 stand rejected under 35 U.S.C. § 103 as unpatentable over Clayman, Stern, and Salahieh (US 2010/0204560 A1, published Aug. 12, 2010).

III. Claims 12 and 17 stand rejected under 35 U.S.C. § 103 as unpatentable over Clayman, Stern, and Dimmer (US 2012/0310233 A1, published Dec. 6, 2012).

IV. Claims 18–20 and 23 stand rejected under 35 U.S.C. § 103 as unpatentable over Clayman, Stern, Salahieh, and Dimmer.

ANALYSIS

Rejection I

Claims 1–6, 11, 13, 21, and 22

Independent claim 1 is directed to a medical device including one or more energy delivery regions defined by one or more regions of one or more electrical conductors that are free of the insulator, "wherein at least a portion of the one or more regions of the one or more electrical conductors that are

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[2] We note the Examiner has objected to a number of the claims for informalities. Final Office Action ("Final Act.") 2–4, dated Feb. 7, 2018. In the Advisory Action ("Advisory Act."), dated April 24, 2018, the Examiner indicates that Appellant's "amendments are sufficient to overcome the claim objections set forth in the [final] office action. Accordingly, the amendment is entered as it is deemed to place the application in better form for appeal." Advisory Act. 1, 2.

free of the insulator is wound in a serpentine manner." Appeal Br. 15 (Claims App.).

The Examiner finds that Clayman discloses the medical device of claim 1 substantially as claimed except "Clayman fails to disclose at least a portion of the one or more regions of the one or more electrical conductors that are free of the insulator is wound in a serpentine manner." Final Act. 6. The Examiner looks to the teachings of Stern for this limitation. *See id.* In particular, the Examiner finds that Stern "disclose[s] a medical device comprising one or more energy delivery regions that are the distal end of one or more wire conductors (170, 172) on a balloon (14) that are wound in a serpentine manner." *Id.* The Examiner reasons that a skilled artisan would have been motivated "to modify the invention of [Clayman] such that at least a portion of the one or more regions of the one or more electrical conductors that are free of the insulator is wound in a serpentine manner in order to provide the benefit of promoting a uniform heating of the area as taught by Stern." *Id.* (citing Stern 4:35–57, 6:61–67, Fig. 9).

In the Answer, the Examiner further clarifies that "the proposed modification is to modify the circular electrode pads (100) of Clayman such that the electrode surface area is a serpentine electrode rather than a circular electrode" and that such a modification "provides the benefit/advantage of presenting a uniform current density across the electrode area in view of the teachings of Stern, thus more uniformly treating tissue across the electrode area by cutting, vaporizing, incising, removing or other alteration across the electrode area." Ans. 6;[3] *see also id.* at 6–7 ("Stern clearly teaches the

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[3] Examiner's Answer ("Ans."), dated Oct. 5, 2018.

benefit/advantage to modify an electrode pad (100) of Clayman with a serpentine electrode pattern to present a uniform current density across the electrode area in view of the teachings of Stern, thus more uniformly treating tissue across the electrode area of Clayman.").

Appellant contends that "promotion of uniform heating as taught in Stern is antithetical to the sharply defined cutting of Clayman and the proposed modification would render the prior art being modified (Clayman) unsatisfactory for its intended purpose." Reply Br. 8;[4] *see also* Appeal Br. 10, 12. According to Appellant, "uniform current density for uniform heating as taught by Stern is at cross[-]purposes with the high current density for cutting as desired by Clayman." Reply Br. 14; *see also id.* at 11 ("[E]qualizing current density across a surface is at cross-purposes with creating high current density for purposes of cutting, vaporizing, incising, etc."); Clayman 1:26–28 ("With a low current density, heat is generated but no cut is achieved. With a high current density, fast cutting occurs.").

In support of this argument, Appellant explains that "when Stern discusses equalizing current density across the surface area of the electrode such that uniform heating is achieved," "this is [in] conjunction with a large surface area electrode that is designed [to] provide equalized current density over the *entire* surface of an endometrium in order to uniformly provide heating of the endometrium." Reply Br. 11; *see also id.* at 7–8, 9 ("Stern's reason for selecting a serpentine electrode pattern is that it allows uniform heating over the entire surface of the device and thus allows [radio frequency (RF)] current to be passed through the entire surface of the

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[4] Reply Brief ("Reply Br."), filed Nov. 28, 2018.

endometrium in order to destroy the cells of the endometrial lining."); Appeal Br. 11.

In contrast to Stern, Appellant explains that Clayman discloses "an angioplasty catheter for increasing the patency blood vessels, which offers many advantages, including the fact that cutting of the vessel is accomplished in a very controlled, limited, atraumatic and accurate procedure, which results in a larger diameter for the vessel without the excessive injury and trauma which invites restenosis" and "a radiofrequency cutting element is preferred for a number of reasons, including the fact that cutting can be very sharply defined leading to a clean incision." Reply Br. 10; *see also* Appeal Br. 11–12. Based on these arguments, Appellant concludes that "the function of the electrode [of Clayman] would be changed from a role of a precise cutting element that minimizes tissue trauma to the role of an element that causes uniform tissue destruction." Reply Br. 14; *see also* Appeal Br. 13.

Appellant has the better position here. Clayman discloses that "[c]urrent density is . . . dependent upon the area the active cutting electrode presents to the patient's tissue. The ***smaller this area*** the higher the current density." Clayman 1:31–34 (emphasis added); *see also id.* at 3:44–55 ("A printed circuit is disposed on the exterior surface of the balloon and includes a plurality of *discrete areas* of electrically conductive material. . . . the *discrete areas* can be energized to electrosurgically remove the material defining the body conduit." (emphasis added)). Clayman further discloses that discrete pads 100 formed on exterior surface 95 of balloon 75 may be covered with a coating 115 of insulation, "coating 115 can be cut to form a narrow slit 117 over each of pads 100," and "[t]he area of th[e] slit 117 can be controlled to *reduce the exposure* of the associated pad 100 thereby *increasing the current density* at each of the slits 117." Clayman 10:47–52 (emphases added), Figs. 9, 12;[5] *see also id.* at 9:66–10:1; *id.* at Abstract ("An overlying insulation layer can be provided with a slot to *limit the exposure* of the conductor to the obstruction thereby *increasing the current density* in the electrosurgical procedure." (emphases added)).

In contrast, Stern discloses that a radio frequency (RF) "current is passed through *substantially the entire surface* of the endometrium" and the invention "provide[s] electrodes having a specific configuration . . . so that uniform heating is achieved *over the entire electrode surface* . . . thereby creating a uniform density of edges and equalizing the current density across the [entire] surface area of the electrode." Stern 2:5–7 (emphasis added); *see also id.* at 2:29–36 (emphasis added); *id.* at Abstract.

Stern also discloses that "[u]niform heating is . . . obtained by extending the electrodes in a pattern of lines, such as the serpentine pattern structure" of Figure 9 and "[a]s a result of th[is] kind[] of construction[], the treatment method of the present invention as well as the electrode elements

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[5] We acknowledge that the Examiner cites to Figure 12 of Clayman. *See* Final Act. 4–5. However, Clayman discloses that in the embodiment illustrated in Figures 12–14, "structural elements which are similar to those previously discussed are designated by the same reference numeral followed by the lower case letter 'a'." Clayman 10:66–11:3. We also note that Figure 12 of Clayman illustrates discrete pads 100*a*, insulation layer (coating) 115*a*, and slit 117*a*. *See id.* at 10:66–11:16, Fig. 12. Additionally, we could not find any discussion of "pads 100[*a*] [being] free from insulation layer 115a" at column 11, lines 5 through 43, of Clayman. *See* Final Act. 5; *see also* Clayman 11:15–16 ("The insulation layer 115*a* can be similarly printed over the pads 100*a* and the leads 124.")

provide an increased current density as a function of the 'electrode edge length' available for heating." Stern 7:50–56, Fig. 9; *see also id*. at 6:61–67.

Based on the disclosures of Clayman and Stern, we agree with Appellant that these references appear to be at cross-purposes with one another. In particular, Clayman describes increased current density via limited exposure of the electrode current across a small/discrete area of the electrode; whereas, Stern describes increased current density via more uniform exposure of the electrode current across the entire surface area of the electrode.

Additionally, Clayman discloses that "[v]aporizing, cutting, incising. removing or other altering of the material, such as the plaque 80, is accomplished by the arcing of radiofrequency current from the electrode, such as the pad 100 to the material" and "[t]o facilitate this arcing, it is desirable that the pad 100 *not be placed in direct touching contact with* the material, but rather that *a slight gap* be maintained between the pad 100 and the tissue." Clayman 10:53–59 (emphases added); *see also id.* at 1:55–57 ("The current utilized in electrosurgical cutting is in the radiofrequency range and operates by jumping across an air gap to the tissue."). Further, Stern discloses that "[e]lectric current flowing through the tissue causes resistive heating" and "[t]he power density diminishes with distance from [the tissue to] the electrode." Stern 4:18–20.

As such, even assuming for the sake of argument that the teachings of Clayman and Stern could be combined as proposed by the Examiner, the "uniform current density" of the serpentine pattern of Stern would appear to decrease/diminish, not increase, the current density of Clayman, as Clayman requires that a slight gap be maintained between pad 100 and the tissue and as taught by Stern, current density decreases/diminishes with distance between the tissue and the electrode. Clayman also discloses, as expressed above, that "[w]ith a low current density, heat is generated but no cut is achieved. With a high current density, fast cutting occurs." Clayman 1:26–28. Thus, based on the above teachings of Clayman and Stern, as heat is generated but *no cut is achieved* with low/decreased current density, we do not agree with the Examiner's finding that "a 'uniform' clean *cut/incision* would be achieved in the modified device of Clayman in view of the teachings of Stern." Ans. 5 (emphasis added).

Moreover, as Clayman describes "electrosurgical procedures" and recites that "in the case of electrosurgical angioplasty, cutting of the vessel is accomplished in a very controlled, limited, atraumatic, and *accurate* procedure" (Clayman 2:51–53), we fail to see and the Examiner fails to explain adequately how modifying the circular electrode pads of Clayman to include the uniform current density of the serpentine pattern of Stern would lead to "a more precise" cut by the modified Clayman device. *See* Ans. 7; *see also* Reply Br. 11–12 ("[T]he device of Clayman [is] designed to perform sharply defined cutting and would not be expected to benefit from uniform heating[/current density] as taught in Stern."); *id.* at 7, 10; Appeal Br. 9, 11; Clayman 1:66–2:2.

Similar to independent claim 1, independent claim 13 is directed to a medical device and recites "at least a portion of the one or more wire conductors is wound in a serpentine manner." *See* Appeal Br. 17 (Claims App.). The Examiner relies on the same unsupported findings in Clayman and Stern as those discussed above in support of the rejection of claim 1.

See Final Act. 4–6, 7–8. As such, the Examiner's findings with respect to Clayman and Stern are deficient for claim 13 as well.

Accordingly, for the above reasons, we do not sustain the Examiner's rejection of claims 1–6, 11, 13, 21, and 22 as unpatentable over Clayman and Stern.

Rejections II–V

Claims 8, 12, 14–20, and 23

Independent claim 18 is directed to a medical device and recites similar claim language as that discussed above for claim 1. Appeal Br. 15, 18 (Claims App.). The Examiner relies on the same unsupported findings in Clayman and Stern for Rejections II–V as those discussed above for Rejection I. *See* Final Act. 8–13. The Examiner does not rely on the teachings of Salahieh or Dimmer to remedy the deficiencies of Clayman and Stern.

Accordingly, for reasons similar to those discussed above for Rejection I, we do not sustain Rejections II–V.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1–6, 11, 13, 21, 22	103	Clayman, Stern		1–6, 11, 13, 21, 22
8, 14–16	103	Clayman, Stern, Salahieh		8, 14–16

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
12, 17	103	Clayman, Stern, Dimmer		12, 17
18–20, 23	103	Clayman, Stern, Salahieh, Dimmer		18–20, 23
Overall Outcome				1–6, 8, 11–23

REVERSED