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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ASSAF GOVARI and ATHANASSIOS PAPAIOANNOU

Appeal 2020-000232
Application 13/648,449
Technology Center 3700

Before JOHN C. KERINS, MICHAEL J. FITZPATICK, and MICHELLE R. OSINSKI, *Administrative Patent Judges*.

KERINS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1, 2, and 6–9, all of the claims pending in the application. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM IN PART.

[1] The term "Appellant" is used herein to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Biosense Webster (Israel) Ltd., as the real party in interest. Appeal Br. 1.

THE CLAIMED SUBJECT MATTER

Appellant's invention relates to a method and apparatus for ablation of tissue. Claims 1 and 6 are illustrative, and are reproduced below:

1. A method of ablation, comprising the steps of:

inserting a probe into a body of a living subject, the probe having an ablation electrode;

prior to ablation and prior to the probe being put into a contacting relationship with tissue:

selecting a contact force between the ablation electrode and a target tissue, a power level and a time interval;

calculating a predicted lesion size that would result from placing the ablation electrode in the contacting relationship with the target tissue at the contact force while applying energy at the power level via the ablation electrode to the target tissue for ablation thereof for the time interval by modeling the lesion size as a nonlinear function of the contact force, the power level and the time interval;

iterating the step of calculating a predicted lesion size by increasing the contact force while keeping the power level and the time interval constant until a saturation point, wherein the saturation point is determined to be when a further increase in the contact force fails to result in an increase of the lesion size, wherein each iterative lesion size has a corresponding known contact force, power level and time interval;

establishing that one of the calculated predicted lesion sizes corresponding to an iteration is suitable for ablation;

urging the ablation electrode into the contacting relationship with the target tissue; and

ablating the target tissue using the corresponding known contact force, power level and time interval of the one of the iterative lesion sizes established to be suitable for ablation.

6. An ablation apparatus, comprising:

a flexible catheter adapted for insertion into a heart of a living subject and having a distally disposed ablation electrode to be brought into contact with a target tissue in the heart;

an ablator, operative to apply a dosage of energy to the target tissue at a power level so as to ablate the target tissue;

an impedance measuring system, comprising a body surface electrode to be attached to the living subject, having circuitry for passing an electrical current between the body surface electrode and the distally disposed ablation electrode;

a processor for predicting a lesion size prior to contact between the distally disposed ablation electrode and the target tissue that would result according to a relationship between a chosen contact force between the ablation electrode and the target tissue, the power level of the energy to be delivered by the ablator and a time interval during which the dosage of energy at the power level is passed through the ablation electrode, wherein the processor is operative to execute iterations of predicting the lesion size that would result as a non-linear function of a parameter selected from the chosen contact force, power level and time interval until a saturation point is found, wherein an increase of the parameter fails to result in an increased predicted lesion size;

control circuitry for operating the ablator, at values of the chosen contact force, the power level and the time interval in a selected iteration of the iterations of the step of predicting the lesion size; and

a monitor linked to the processor, which is operative to display a visual indication of the predicted lesion size.

THE REJECTIONS

The Examiner rejects:

(i) claims 1 and 2 under 35 U.S.C. § 103(a) as being unpatentable over Govari (US 2011/0152856 A1, published June 23, 2011) in view of Kruecker (US 2011/0251607 A1, published Oct. 13, 2011) and Lambert (WO 2012/092275 A1, published July 5, 2012); and

(ii) claims 6–9 under 35 U.S.C. § 103(a) as being unpatentable over Govari in view of Keidar (US 2004/0147920 A1, published July 29, 2004) and Lambert.

ANALYSIS

Claims 1 and 2--Unpatentability over Govari, Kruecker, and Lambert

The Examiner finds that Govari discloses a method that includes most of the steps of claim 1, with the exceptions that: Govari does not disclose that the "selecting, calculating, iterating, and establish[ing]" steps occur prior to the ablation probe being put into contact with tissue; and Govari fails to disclose calculating a predicted lesion size by modeling the saturation point at which an increase in contact force of the probe does not result in an increased predicted lesion size, as a non-linear function of contact force, and iterating the calculation until the saturation point is determined. Final Act. 5, 7.

The Examiner relies on Kruecker as disclosing ablation planning steps that are conducted either prior to or after the probe is placed into contact

with tissue to be ablated, including iterative steps to calculate a predicted lesion size. *Id.* at 5. The Examiner concludes that it would have been obvious to modify the Govari method to perform its ablation planning steps prior to contacting the probe to tissue, since Kruecker identifies that iterative ablation planning steps can be performed either prior to or after the probe is inserted and put into contact with tissue. *Id.* at 5–6.

The Examiner relies on Lambert as disclosing the modeling of the saturation point that Govari lacks, taking the position that Lambert includes a processor that predicts a lesion size as a non-linear function of one of contact force, power level, and time interval, until a saturation point is found. *Id.* at 7–8. The Examiner concludes that it would have been obvious to modify the Govari process to involve saturation point information to "provide the benefit of taking into account the asymptotic nature of lesion formation as taught by Lambert." *Id.* at 8. The Examiner further explains in the Answer that:

> Lambert is relied upon to teach the relationship between an acceptable lesion size and saturation point as *Lambert teaches predicting lesion size* as a function of the contact force, power level, or time interval parameter *until a saturation point is found*, where the saturation point is when an increase of the chosen parameter fails to result in an increased predicted lesion size.
>
> and
>
> Lambert is only used to teach the relationship of ablation size and a saturation point with the respective parameters of power, time and force, and is not relied upon for the teaching of performing the iterations before ablation or contact of a probe with the tissue that are taught by Govari in view of Kruecker.

Ans. 5, 7 (emphasis added). Because the former statement alludes to Lambert being relied on as teaching finding a saturation point via predicting

lesion size(s) until that point is ascertained, we understand the latter statement to mean that Lambert is not relied on in any manner for the timing of performing iterative steps, namely for performing such iterative steps prior to ablation or contact of a probe with tissue to be ablated.

Appellant challenges the rejection, in part, on the Examiner's reliance on the disclosure of Lambert relating to how Lambert addresses the recognition that an ablation process of this type is subject to saturation effects.[2] In particular, Appellant argues that:

> Lambert does not disclose iterating the step of making a prediction by increasing one of the contact force, the power level and the time interval until a saturation point is found, wherein a further increase fails to result in an increased predicted lesion size, and establishing that one of the iterations of the step of making a prediction predicts a desired lesion size. Instead Lambert only states each of the F (force), E (energization parameter - power, voltage, current) and t (duration time) parameters is taken into account through an exponential term that models saturation effects. It does not iterate until the saturation point is found.

Appeal Br. 7–8 (emphasis omitted).

Appellant's characterization of the teachings of Lambert is largely on point, and undermines the Examiner's finding and interpretations as to what Lambert teaches. Like Appellant, we see no indication that Lambert

[2] Although Lambert does not describe the existence of a particular saturation "point," both Appellant and Lambert are consistent in describing that the saturation phenomenon involves a recognition that for the set of parameters/variables, time, power, and probe contact force, there is a nonlinear relationship between an increase in the value of one of the parameters selected to be variable, and increase in lesion size, and that, at some point, increasing the value results in effectively no increase in lesion size. *See, e.g.*, Spec. ¶ 39; Lambert, p. 4, ll. 8–29 and p. 15, l. 21–p. 16, l. 21.

performs iterative steps or other procedure to find what Lambert might determine to be a saturation "point." Rather, saturation effects are modeled in an exponential term that is used in an equation to "predict," in a lesion size index (LSI) model, the size of a lesion, given values of probe contact force, current (related to power), and duration time. Lambert, p. 15, l. 28–p. 16, l. 21.

With respect to Lambert's use of the term "predict," in discussing lesion size, we note, as does Appellant, that it is not used in the sense of performing pre-procedure iterations of varying contact force to obtain successively increasing predicted lesion sizes with the goal of determining a saturation point. Rather, Lambert "predict(s)" (p. 3, ll. 22–24), or perhaps more aptly, "evaluate(s)" (p. 4, ll. 3–4) a size of a lesion created in an ablation process, in the sense that, after a lesion is created, the LSI equation is used to advise medical personnel of the approximate size of the lesion (generally plural lesions) without having to perform, for example, post-ablation electrical continuity measurements to assess the likelihood that the procedure was successful. *See generally*, Lambert, p. 2, l. 20–p. 3, l. 14.

Finally, we further fail to see where Lambert discusses any particular "relationship between an acceptable lesion size and saturation point," as asserted by the Examiner in the above quote.

In view of the above, the Examiner's proposed modification to the Govari process in view of Lambert to include a non-linear modeling of a saturation point, falls short of rendering obvious a step of iteratively calculating predicted lesion sizes by increasing contact force values until a saturation point is determined, and the Examiner's position that Lambert actually determines a saturation point, whether by iterative calculations or

some other manner, is not supported by rational underpinnings. The rejection of claim 1 as being unpatentable over Govari, Kruecker, and Lambert is not sustained. As claim 2 depends from claim 1, the rejection is not sustained as to claim 2, either.

Claims 6–9--Unpatentability over Govari, Keidar, and Lambert

Independent claim 6 is directed to an ablation apparatus, whereas independent claim 1 discussed above is directed to an ablation method.

The Examiner includes reference to, and relies on, Keidar as teaching an impedance measuring system as recited in claim 6, a limitation not present in claim 1. Final Act. 10. Appellant argues only that Keidar does not mention use of an actual or estimated contact force to predict a lesion size. Appeal Br. 9. Because the Examiner does not rely on Keidar as providing that function or ability, the argument fails to apprise us of error in the Examiner's inclusion of Keidar in the rejection, which involves modifying Govari in view of Keidar to provide the Govari system with the claimed impedance measuring system.

The Examiner does not include Kruecker in this ground of rejection because claim 6 does not recite the temporal aspect step present in claim 1 of performing iterative calculations of lesion size prior to ablation and prior to a probe being put into a contacting relationship with tissue. Instead, claim 6 requires only that a processor is "for" predicting a lesion size prior to contact between an ablation electrode and target tissue. The Examiner finds that the processor (console 24) in Govari is capable of so doing. Final Act. 9.

In a similar vein, the language in claim 6 reciting that the "processor is operative to execute iterations of predicting the lesion size," from a non-

linear function of one of contact force, power level, and time interval, until a saturation point is found, requires only that the processor be configured to perform such iterations, and not that the system actually perform those steps.

The Examiner finds that Govari teaches a processor configured to execute iterations of predicting lesion sizes based on varying one of contact force, power level, and time interval. Final Act. 9, citing Govari ¶ 27. The Examiner additionally finds that Lambert discloses an ablation apparatus having a processor that predicts lesion sizes as a non-linear function of one of contact force, power level, and time interval, and recognizes and factors into the predictive model a saturation effect. Final Act. 10–11. The Examiner concludes that it would have been obvious to employ the non-linear function modeling of Lambert in the lesion size predictions performed by the processor in Govari, in order to take advantage of the benefit of Lambert's teaching that lesion formation size has an asymptotic relationship with the parameters of contact force, power, and time interval. *Id.* at 11.

Appellant leads with the argument that an important feature of the invention that distinguishes over the cited references "is the fact that the processor for predicting lesion size is configured to make such determination **prior to** the catheter engaging tissue." Appeal Br. 8. Appellant does not adequately explain how Govari's processor is not so configured. The processor receives input values for contact force, power, and time duration. *See, e.g.*, Govari ¶ 58 (controller may report indication of expected ablation volume at estimated ablation time, and energy dosage and mechanical force). Although, in practice, as noted by Appellant (Appeal Br. 9), Govari acquires and inputs an actual value of a measured contact force, the processor is fully capable of computing a predicted lesion size with a contact

force value selected by a user as an estimated or desired contact force value. *Cf.*, Govari ¶ 51 ("Similarly, by fixing the desired size of the ablation zone, the required force can be computed at a given RF power and application time or for a given total energy dosage at different combinations of application time and RF power."). Stated simply, it matters not to the processor how and where the input value indicative of contact force was generated.

Appellant's arguments directed to Lambert, specifically, mainly focus on the fact that the Lambert process for predicting lesion size takes place during or just after the time that the lesion is formed, and "not prior to ablation as claimed." Appeal Br. 9–10 (emphasis omitted). Not only does the Examiner not rely on Lambert as to the timing of when the lesion size is predicted, but, unlike claim 1, there is no positive limitation in claim 6 that a lesion size prediction step necessarily occurs prior to ablation. Rather, claim 6 only requires the capability of doing so.

Appellant again, as with claim 1, points out that "Lambert does not disclose iterating the step of making a prediction" of lesion size, until a saturation point is found. Appeal Br. 10 (emphasis omitted). As before, we agree with Appellant, but, in the case of claim 6, that is not germane. Claim 6 requires only that a processor be provided that is "operative to execute iterations of predicting the lesion size," the Govari processor being operative to execute such iterations. As modified in accordance with the non-linear modeling taught by Lambert, which takes into account saturation effects, for predicting lesion size, Govari, too, is configured to operate to execute iterations until a saturation point is found.

Claim 6, unlike claim 1, includes no requirement that iterative steps to find the saturation point actually be performed, which, in terms of the rejections at hand, results in us sustaining the rejection of claim 6, while at the same time not sustaining the rejection of claim 1.

Claims 7–9 depend from claim 6, and the same three references that are applied in rejecting claim 6 are applied against claims 7–9. Appellant argues that the rejection does not specifically state how or why claims 7–9 are rejected, but instead the rejection refers back to claims 3–5 and the rationale applied against those claims. Appeal Br. 10. As pointed out by the Examiner, detailed grounds specific to claims 7–9 appear at pages 11–16 of the Final Action. Ans. 8. The Examiner is correct, and Appellant's argument is not supported in the record.

Appellant otherwise repeats and relies on arguments advanced for the patentability of claim 6 as reasons why the rejection of claims 7–9 is in error. Appeal Br. 10–11. As addressed above with respect to claim 6, the arguments do not apprise us of error in the rejection. The rejection of claims 7–9 is therefore sustained.

DECISION

The rejection of claims 1 and 2 as being unpatentable over Govari, Kruecker, and Lambert is reversed.

The rejection of claims 6–9 as being unpatentable over Govari, Keidar, and Lambert is affirmed.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 2	103(a)	Govari, Kruecker, Lambert		1, 2
6–9	103(a)	Govari, Keidar, Lambert	6–9	
Overall Outcome			6–9	1, 2

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