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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ISAAC OSTROVSKY, VICTOR SHUKHAT,
ALFRED P. INTOCCIA, JON T. MCINTYRE, and
TY FAIRNENY

Appeal 2014-009608
Application 11/374,811
Technology Center 3700

Before LYNNE H. BROWNE, LISA M. GUIJT, and
JEFFREY A. STEPHENS, *Administrative Patent Judges*.

STEPHENS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants[1] seek our review under 35 U.S.C. § 134(a) from the Examiner's Final Office Action ("Final Act.") rejecting claims 1, 4, 5, 7–23, and 25–30, which are all the claims pending in the application. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

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[1] The real party in interest is identified as Boston Scientific Scimed, Inc. App. Br. 2.

Claimed Subject Matter

Claims 1 and 15, reproduced below, are illustrative of the claimed subject matter.

1. A device for heating tissue, comprising:

a housing sized for insertion through a naturally occurring body orifice to a target location within a lumen;

a heat generating element focusing thermal energy on a target area separated from an outside of the housing so that, when the housing is in the target location, the target area is within tissue surrounding the lumen at a predetermined depth from a lumenal wall wherein the heat generating clement comprises an array of ultrasound transducers positioned within the housing and an acoustic reflector positioned over an outer surface of the housing and over the array of transducers, the acoustic reflector extending away from the housing in a first direction by a first predetermined distance toward the target area so that acoustic energy from the ultrasound transducers is focused away from the transducers in the first direction by a second predetermined distance greater than the first predetermined distance;

a temperature sensing element sensing data corresponding to a temperature of tissue in the target area; and

a processor controlling the heat generating element in response to the data sensed by the sensing element.

15. A system for thermal tissue therapy, comprising:

a housing sized for insertion through a naturally occurring body orifice to a target location within a lumen;

a temperature sensing element generating a signal corresponding to a temperature of target tissue;

an energy delivery element within the housing;

an acoustic reflector positioned over an outer wall of the housing and extending away from the housing in a first direction by a first predetermined distance toward the target location so that energy from the energy delivery element is focused away from the energy delivery element in the first direction by a second predetermined distance greater than the first predetermined distance;

> a temperature acquisition module computing the target tissue temperature based on the signal of the temperature sensing element; and
>
> an electronic processor controlling an amount of power supplied to the energy delivery element based on the target tissue temperature.

Rejections

1. Claims 1, 5, 7, 8, 10–12, 15, 16, 18–22, and 26–28 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Lele (US 4,938,217, issued July 3, 1990) (hereinafter "Lele '217"), Lele (US 4,960,109, issued Oct. 2, 1990) (hereinafter "Lele '109"), Cline et al. (US 5,873,845, issued Feb. 23, 1999), and Sherman et al. (US 5,735,280, issued Apr. 7, 1998). Final Act. 2–9.

2. Claims 4, 14, 17, and 25 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Lele '217, Lele '109, Cline, Sherman, and Crowley et al. (US 2004/0133109 A1, published July 8, 2004). Final Act. 9–10.

3. Claims 9 and 23 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Lele '217, Lele '109, Cline, Sherman, and Chen (US 4,821,838, issued Apr. 18, 1989). Final Act. 10–11.

4. Claim 13 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Lele '217, Lele '109, Cline, Sherman, and Vitek et al. (US 6,506,171 B1, issued Jan. 14, 2003). Final Act. 11–12.

5. Claim 29 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Lele '217, Lele '109, Cline, Sherman, and Cox (US 6,083,232, issued July 4, 2000). Final Act. 12–13.

6. Claim 30 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Lele '217, Lele '109, Cline, Sherman, and Snyder (US 4,757,821, issued July 19, 1988). Final Act. 13–14.

ANALYSIS

Claims 1, 4, 5, 7–14, 20–23, and 25–30

Appellants argue Sherman does not teach "a temperature sensing element sensing data corresponding to a temperature of tissue in the target area," as recited in claim 1. App. Br. 6. In particular, Appellants point out the "target area" recited in claim 1 is "separated from an outside of the housing so that, when the housing area is in the target location" within a lumen, "the target area is within tissue surrounding the lumen at a predetermined depth from a lumenal wall." App. Br. 6–7. Appellants contend Sherman's temperature sensing devices are located at or near the transducer and only read the temperature of portions of tissue adjacent to the sensing devices. *Id.*

We agree with Appellants that the cited portions of Sherman do not teach a temperature sensing device that senses data corresponding to a temperature of tissue that is located at a predetermined depth from the wall of the lumen where the device housing is located. Although we agree with the Examiner (Ans. 15) that claim 1 does not specify the location of the temperature sensing element relative to the heat generating element, the claim specifies the location of the tissue with the temperature of interest. Under the language of the claim, the tissue in the target area is located at a predetermined depth from the lumenal wall where the housing and heat generating element are located. In contrast, the cited portions of Sherman

teach that the temperature sensor is located with the heat generating element, and the Examiner does not provide reasoning for including Sherman's temperature sensing element at some other location. As shown in Figure 2 of Sherman, temperature sensing devices 28 are surrounded by piezo-electric transducer or crystal 24, which is inserted in a lumen. *See also* Sherman col. 6, ll. 15–17. Sherman also teaches that the temperature is sensed at the location of the transducer where the temperature sensors are located, and the cited portions of Sherman do not teach techniques for sensing temperature of tissue located a predetermined depth from the luminal wall. *See* Sherman col. 3, ll. 32–35 ("Thus, providing a crystal with relatively rapid thermal conductivity, *sensing the temperature at the crystal*, and controlling the energy supplied to the crystal for ablation are desirable." (emphasis added)); *see also* Sherman col. 13, ll. 34–49.

The Examiner also finds that even if Sherman teaches sensing temperature at a luminal wall instead of measuring temperature of a tissue at a predetermined depth from the luminal wall, the temperature of the luminal wall would "correspond" to the temperature of tissue in the target area. Ans. 15. In support of this finding, the Examiner construes the claim phrase "sensing data ***corresponding*** to the temperature of the tissue in the target area" to include "any data related to the temperature of the target area, including temperature of tissue near or away from the target area, as long as it is still related in some way to the target area." *Id.* We agree with Appellants that this interpretation is overly broad. As argued by Appellants (Reply Br. 5), we interpret the claim phrase "sensing data corresponding to a temperature of tissue in the target area" to require that the data originate from the target area. As discussed above, Sherman teaches a temperature

sensor gathering data at the luminal wall, rather than a predetermined depth from it.

For the reasons given above, we do not sustain the rejection of claim 1 under 35 U.S.C. § 103(a) as obvious over Lele '217, Lele '109, Cline, and Sherman.[2] For the same reasons, we do not sustain the rejections of claims 4, 5, 7–14, and 30, which depend from claim 1. Specifically, we do not sustain the rejections under 35 U.S.C. § 103(a) of: (1) claims 5, 7, 8, and 10–12 as obvious over Lele '217, Lele '109, Cline, and Sherman; (2) claims 4 and 14 as obvious over Lele '217, Lele '109, Cline, Sherman, and Crowley; (3) claim 9 as obvious over Lele '217, Lele '109, Cline, Sherman, and Chen; (4) claim 13 as obvious over Lele '217, Lele '109, Cline, Sherman, and Vitek; and (5) claim 30 as obvious over Lele '217, Lele '109, Cline, Sherman, and Snyder.

Appellants also argue the rejections of independent claim 20 and its dependents are in error for the same reasons as claim 1. App. Br. 12–13. We interpret claim 20 to require that "a target portion of an endopelvic fascia" be located a predetermined distance away from the probe (i.e., "a second predetermined distance greater than the first predetermined distance"). Thus, for the same reasons discussed in relation to claim 1, we agree with Appellants that the cited portions of Sherman do not teach "a temperature measuring element generating a signal corresponding to a temperature of the target portion of the endopelvic fascia," as recited in claim 20. Accordingly, we do not sustain the rejection of claim 20 or its

[2] Because the issue of whether the cited combination of references teaches the temperature sensing element recited in claim 1 is dispositive as to this claim, we do not reach additional issues raised by Appellants related to claim 1.

dependents, claims 21–23 and 25–29. Specifically, we do not sustain the rejections under 35 U.S.C. § 103(a) of: (1) claims 20–22 and 26–28 as obvious over Lele '217, Lele '109, Cline, and Sherman; (2) claim 25 as obvious over Lele '217, Lele '109, Cline, Sherman, and Crowley; (3) claim 23 as obvious over Lele '217, Lele '109, Cline, Sherman, and Chen; and (4) claim 29 as obvious over Lele '217, Lele '109, Cline, Sherman, and Cox.

Claims 15–19

Appellants argue independent claim 15 recites limitations substantially similar to those of claim 1, and that the rejections of claim 15 and its dependents are in error for the same reasons argued in support of claim 1. App. Br. 12. We are not persuaded by Appellants' arguments.

Claim 15 recites "a temperature sensing element generating a signal corresponding to a temperature of target tissue." Unlike claim 1's "target area," however, the "target tissue" in claim 15 is not specified to be located at a predetermined distance from the wall of the lumen or from the housing. Claim 15 recites an acoustic reflector "extending away from the housing in a first direction by a first predetermined distance *toward the target location* so that energy from the energy delivery element is focused away from the energy delivery element in the first direction by a second predetermined distance greater than the first predetermined distance" (emphasis added), but the claim does not equate the tissue located at the second predetermined distance to the "target tissue" recited in connection with the temperature sensing element. Accordingly, Appellants' arguments regarding the temperature sensing element in claim 1 do not apprise us of error in the rejection of claim 15.

Appellants also argue Cline does not teach "an acoustic reflector positioned over an outer wall of the housing and extending away from the housing in a first direction by a first predetermined distance toward the target location so that energy from the energy delivery element is focused away from the energy element in the first direction by a second predetermined distance greater than the first predetermined distance" ("the acoustic reflector limitation"), as recited in claim 15. *See* App. Br. 13 (arguing similar limitation in claim 1), 15 (arguing rejection of claim 15 should be overturned). According to Appellants, "Cline is not configured in any way to focus the acoustic energy from the ultrasound transducers." App. Br. 14. In arguing "Cline only describes altering a size of an area on which energy is focused" (*id.*), however, Appellants acknowledge Cline teaches focusing energy. To the extent Appellants argue the shape of the transducer in Cline focuses the energy, claim 15 does not recite that only the acoustic reflector focuses the energy. We agree with the Examiner (Ans. 17) that Cline's teachings as to the effect of the refractor plate (*see* Cline col. 3, ll. 55–64) teach that it can change the direction of the sound waves towards or away from normal, which changes the focal point. In addition, whether the shape or diameter of the focal area is increased or decreased, Cline's refraction plate 410 is involved in directing the energy to focal region 420, which is located further from the transducer than the refraction plate. We agree with the Examiner that Cline thus teaches the acoustic reflector limitation of claim 15.

Accordingly, for the reasons discussed above and by the Examiner, we are not apprised of error in the Examiner's rejection of claim 15 under 35 U.S.C. § 103(a) as unpatentable over Lele '217, Lele '109, Cline, and

Sherman. Thus, we sustain the rejection of claim 15, and, for the same reasons, the rejections of dependent claims 16–19, which Appellants argue are in error for the same reasons as the rejection of claim 15 (App. Br. 15–16). Specifically, we sustain the rejections of claims 16, 18, and 19 under 35 U.S.C. § 103(a) as obvious over Lele '217, Lele '109, Cline, and Sherman, and claim 17 as obvious over Lele '217, Lele '109, Cline, Sherman, and Crowley.

DECISION

We reverse the Examiner's decision to reject claims 1, 4, 5, 7–14, 20–23, and 25–30. We affirm the Examiner's decision to reject claims 15–19.

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-IN-PART