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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte EDWARD SINOFSKY and
JON T. MCINTYRE

Appeal 2019-003111
Application 11/397,123
Technology Center 3700

Before JAMES P. CALVE, BRANDON J. WARNER, and FREDERICK C. LANEY, *Administrative Patent Judges*.

CALVE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the decision of the Examiner to reject claims 1–8 and 28. Appeal Br. 2. Claims 9–27 are cancelled. *Id.* at 17 (Claims App.). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

[1] "Appellant" refers to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Boston Scientific Scimed, Inc. as the real party in interest. Appeal Br. 2.

CLAIMED SUBJECT MATTER

The claimed device detects changes in properties of a target tissue mass that is treated with heat to shrink or necrose the tissue. Spec. ¶¶ 1, 3. An illumination element provides light to a target area and a sensing element receives light from the illumination element after the light is reflected from a target portion of the tissue. *Id.* ¶ 3. Reflectance changes at one or more wavelengths are monitored during treatment to determine when a desired level of treatment is completed. *Id.* ¶ 8. Claim 1, the sole independent claim, is reproduced below with disputed terms emphasized in italics.

> 1. A device, comprising:
> a tissue ablation device;
> a probe coupled to the tissue ablation device, the probe configured to detect changes in tissue properties comprising:
> an illumination element *configured to deliver light to an external surface of a target tissue*, and
> a sensing element *configured to receive light from the illumination element after reflection from the external surface of the target tissue*; and
> a controller configured to detect changes in spectral reflectance of the light received by the sensing element and configured to determine a change in a depth of ablation below the external surface of the target tissue, the controller configured to control energy delivery from the tissue ablation device to the target tissue based on the depth of ablation dete1mined by the controller.

REJECTIONS

Claims 1–4, 7, 8, and 28 are rejected under 35 U.S.C. § 102(b) as anticipated by Balbierz (US 2002/0026127 A1, pub. Feb. 28, 2002).

Claims 5 and 6 are rejected under 35 U.S.C. § 103(a) as unpatentable over Balbierz and Benaron (US 6,594,518 B1, iss. July 15, 2003).

ANALYSIS

Claims 1–4, 7, 8, and 28 Rejected as Anticipated by Balbierz

Appellant argues that Balbierz does not disclose all of the claimed illumination and sensing elements. *See* Appeal Br. 3–13. In particular,

> Appellant . . . submits that Balbierz does not teach or suggest an illumination element and a sensing element in the same probe, with the illumination element 'configured to deliver light to *an external surface* of a target tissue,' and the sensing element 'configured to receive light from the illumination element *after reflection* from the external surface of the target tissue,' as recited in claim 1.

Reply Br. 4–5, *see id.* at 7–8 (same); Appeal Br. 9–10.

Appellant argues that Balbierz fails to satisfy these claim limitations in two ways. First, because Balbierz emits incident light 22ib from emitter 22me *within* the volume 5sv of a target tissue site 5' and returning light 22rb is reflected back/returns from tumor mass 5" as a composite of interactions of the light within volume 5sv of target tissue site 5' to detector 22md, the illumination element is not configured to deliver light to an external surface of a target tissue and the sensing element is not configured to receive this light after reflection from *the external surface of the target tissue* for spectral analysis as claimed. Reply Br. 6–8. Second, Balbierz teaches at least two resilient members 18, one having emitter 22me and the other having detector 22md, positioned at separate locations to create an optical path *through* a sample of tissue rather than capturing any light that is reflected from an external surface of the tissue as claimed or providing the illumination and sensing elements as part of the same probe as claimed. Appeal Br. 9–10; Reply Br. 8. We address each argument in turn.

We first interpret "target tissue" in claim 1. The target tissue has an external surface that reflects light delivered from an illumination element. Appeal Br. 16 (Claims App.). Target tissue is treated by an ablation device and includes connective tissues, tumors, and fibroids. Spec. ¶ 1. "The treatment device delivers energy to the tissue mass targeted for treatment." *Id.* ¶ 6. Target tissue mass 16 may be located in an organ. *Id.* ¶ 10. A probe with an illumination element "provid[es] light to a target area" and a sensing element receives light from the illumination element "after reflection from a target portion of tissue." *Id.* ¶ 3. The probe 20 is "positioned adjacent to an external surface of the target tissue mass 16." *Id.* ¶ 10.

We thus interpret "*target* tissue" as tissue to which light is delivered and reflected therefrom. We agree with the Examiner that Balbierz teaches a target tissue as tumor mass 5" in Figures 2 and 5, as reproduced below.

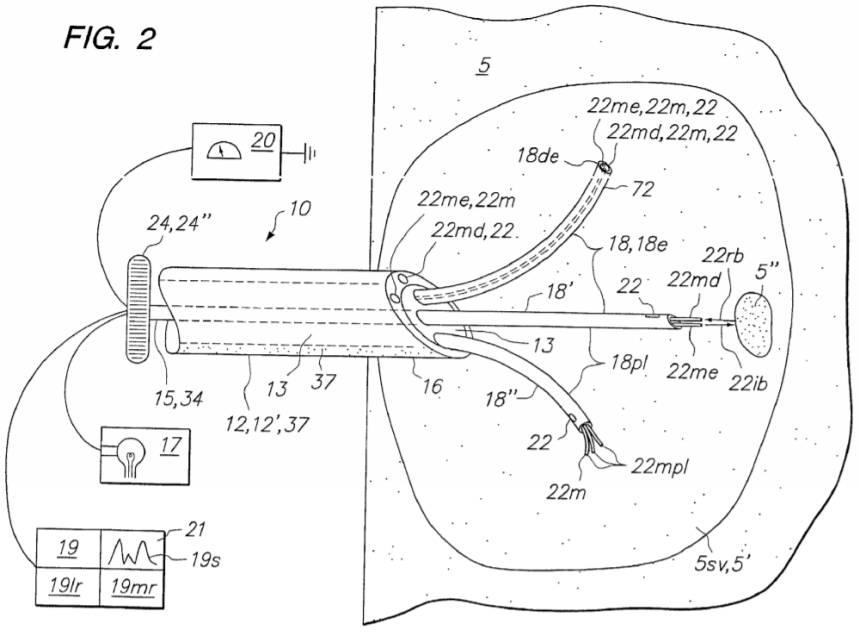

Figure 2 above illustrates member 18' with light emitting member 22me emitting incident beam 22ib that reflects as returning beam 22rb from tumor mass 5" to light detecting member 22md. Balbierz ¶¶ 48, 50; *see* Ans. 7.

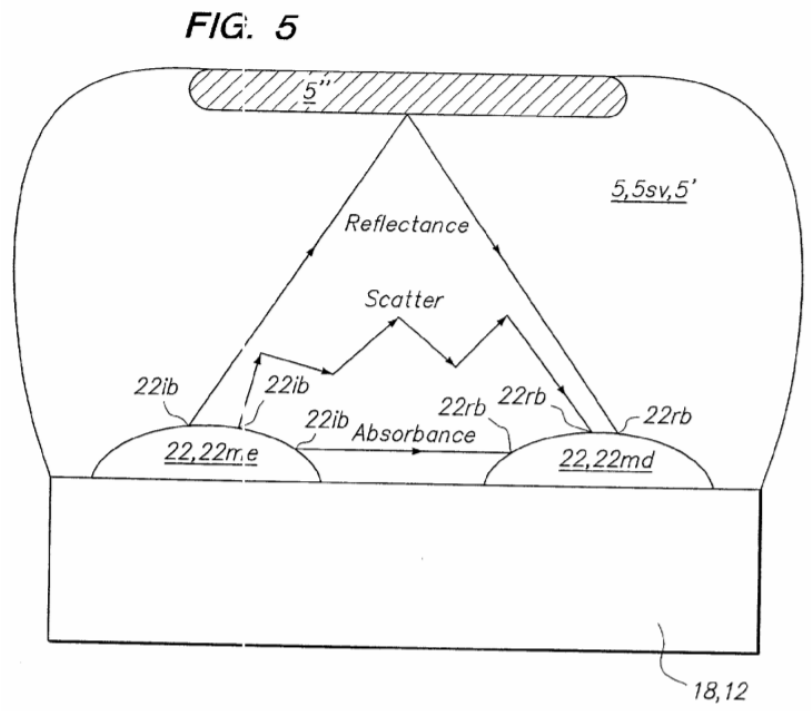

Figure 5 above illustrates a similar single resilient member 18 with light emitter 22me delivering light as incident probe beam 22ib to *exterior surface* of target tumor mass 5" and light detector 22md receiving light that is reflected from the exterior surface as returning light 22rb. Balbierz ¶ 50.

Appellant's Specification describes the claimed device being used to detect changes in tissue properties of ablated target tissue such as cancerous tumors. Spec. ¶¶ 12, 18. Appellant discloses that other tissue surrounding a target tissue mass (e.g., a tumor) can be ablated and checked for spectral reflectance monitoring with the illuminating and sensing element. *Id.* ¶ 12.

Therefore, the Specification discloses that a target tissue may be contained within other tissue. Even if Balbierz illuminates healthy tissue around a target tissue mass 16, Balbierz also detects changes in tumor mass 5" by illuminating an external surface of the target tissue (tumor mass 5") and sensing light reflected to a sensing element from the external surface of tumor mass 5" as claimed. Balbierz ¶¶ 45, 48, 50, 59, 64, 65, 74, Figs. 2, 5.

Although Balbierz may illuminate other tissue in sample volume 5sv that surrounds tumor mass 5", Balbierz delivers light to an external surface of "a target tissue" (tumor mass 5") and receives light after it is reflected from the external surface of tumor mass 5" as claimed. *Id.* The fact that Balbierz illuminates other tissue in sample volume 5sv in addition to illuminating a target tissue (tumor mass 5") is not precluded by claim 1.

Claim 1 recites "[a] device, *comprising*" and "a probe . . . *comprising* an illumination element . . . and a sensing element." Appeal Br. 16 (Claims App.). The use of the open-ended transition "comprising" for the claimed device and probe means that claim 1 reads on Balbierz so long as Balbierz discloses all of the limitations as recited in the body of claim 1, even though Balbierz may include additional features that perform other functions as well. *See In re Skvorecz*, 5 F.3d 1262, 1267 (Fed. Cir. 2009) (holding that the use of the transitional phrase "comprising" "means that the device may contain elements in addition to those explicitly mentioned in the claim."); *CIAS, Inc. v. All. Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007) ("In the patent claim context[,] the term 'comprising' is well understood to mean 'including but not limited to.'" (citation omitted)).

Balbierz's illuminating element is configured to deliver light to an external surface of "a target tissue" such as tumor mass 5" as illustrated in Figures 2 and 5 above. Appellant does not dispute that Balbierz delivers light to an exterior surface of tumor mass 5". Rather, Appellant argues that this exterior surface of tumor mass 5" does not correspond to the claimed "exterior surface" of "a target tissue" because tumor mass 5" is included within a larger tissue volume 5sv. Reply Br. 6–8.

This argument is not persuasive because it is not commensurate with the scope of claim 1, which broadly recites "a target tissue." We agree with the Examiner that tumor mass 5" of Balbierz is "a target tissue" as claimed. Appellant's Specification informs us that a target tissue broadly includes tumor masses such as Balbierz's tumor mass 5". Claim 1 only requires a device and probe with an illuminating element that can deliver light to an exterior surface of a target tissue and a sensing element that can receive that light as reflected from the external surface of the target tissue. Claim 1 does not recite a method of illuminating different types of tissues.

Balbierz's light emitting member 22me and light detecting member 22md can be optic fibers. Balbierz ¶¶ 50, 51. Light emitting member 22me can be coupled optically to a light emitting diode or diode laser 17 operable at a range of wavelengths to include 300 to 850 nm. *Id.* ¶ 58; Ans. 8.

Appellant discloses similar illumination and sensing element optic fibers. Spec. ¶ 15. Illumination element 23 produces laser light of 635 nm, which is in the range of Balbierz's light emitting member. *Id.* Appellant's arguments about the Figure 8 embodiment of Balbierz, which is not relied on by the Examiner, does not explain why elements cited by the Examiner are not configured as illumination and sensing elements, or why they don't deliver or receive light reflected from tumor mass 5". Appeal Br. 8–13.

In addition to illustrating emitter 22me delivering light to an exterior surface of tumor mass 5" and detector 22me receiving light reflected from tumor mass 5" in Figures 2 and 5, Balbierz discloses that the probe detects and records spectral information about *a* tissue spectra/profile from such optically induced tissue *reflectance* of incident light 22i in sample volume 5sv which includes tumor mass 5". *See* Balbierz ¶¶ 50, 59, 64, 65; Ans. 11.

Appellant's argument that Balbierz uses such reflectance to obtain a spectral profile 19s that serves as a fingerprint of the tissue type to provide a *composite* of light interactions within the entire sample volume 5sv is not persuasive for several reasons. First, claim 1 does not preclude the claimed device from delivering and receiving other light besides the light reflected from the external surface of a target tissue as Balbierz does. Claim 1 only requires the light reflected from an external surface of a target tissue to be received so a controller can detect changes in the spectral reflectance of the light received by the sensing element. Balbierz's device performs this function, as the Examiner correctly finds, as well as other functions. Balbierz ¶¶ 45, 48, 50, 59, 64, 65, 74, Figs. 2, 5.

Balbierz discloses that the device detects optical tissue interaction of metabolic chromophores 33 of cancerous tissue (not the surrounding tissue in the sample volume 5sv) and analyzes the spectral profile 19s of the tissue to predict the tissue type and/or tissue condition such as necrosis or thermal injury from ablation and heat treatment. *Id.* ¶ 65. The tissue types can have a signature profile 19s that is matched to a database of tissue profiles. *Id.* Balbierz analyzes *individual* spectral profiles 19s for particular properties of chromophores and tissue types. *Id.* ¶¶ 60, 65. Balbierz uses a controller to determine the depth of ablation of a target tissue from spectral profiles and reflected light as claimed. *Id.* ¶¶ 8, 45, 48, 53, 60, 64, 74–78.

Thus, Balbierz analyzes light reflected from an external surface of a target tissue (tumor mass 5") to determine a spectral profile used to identify the tissue and assess the degree of necrosis and ablation of tumor mass 5", e.g., by comparing ablated tissue to unablated tissue using emitters 22me and detectors 22md as claimed. *Id.* ¶¶ 8, 45, 48, 53, 60, 64, 65, 74–78.

Based on the foregoing analysis, Appellant's second argument that Balbierz measures optical properties of tissue between an emitter and detector rather than as light reflected from an external surface of a target tissue as claimed also is not persuasive. The fact that Balbierz's device can sense tissue optical properties by transmitting light from an emitter on one flexible element to a detector on another flexible element is not precluded by claim 1, which plainly recites a probe "comprising" an illumination element and a sensing element. As long as Balbierz's device includes an illumination and sensing element that are configured to perform the functions recited in claim 1, as discussed above, the device may include other elements that perform other functions, and the device will fall within the scope of claim 1. *In re Crish*, 393 F.3d 1253, 17 (Fed. Cir. 2004); *see* Reply Br. 8; Appeal Br. 9–10. The Examiner is not relying on Figures 8a–8d of Balbierz to anticipate claim 1. *See* Ans. 7, 10–11.

Appellant's conclusory argument that Balbierz does not receive and analyze light reflected from an external surface of target tissue or have a controller that detects changes in spectral reflectance of the light as claimed (Appeal Br. 13) is not persuasive of error in the Examiner's findings that Balbierz discloses these features and a controller as claimed. Ans. 10–13; *see* 37 C.F.R. § 41.37(c)(1)(iv) ("[A]rguments [in Appeal Brief] shall explain why the examiner erred as to each ground of rejection contested by appellant."); *In re Jung*, 637 F.3d 1356, 1365 (Fed. Cir. 2011) (noting the Board's long-standing practice under its rules to require an applicant to identify the alleged error in an examiner's rejections and holding "even assuming that the examiner had failed to make a prima facie case, the Board would not have erred in framing the issue as one of 'reversible error.'").

Moreover, to the extent Appellant argues patentability of the *device* of claim 1 over Balbierz based on alleged differences in a target tissue that is illuminated and detected by Balbierz's device rather than on the features and configuration of Balbierz's device that performs the claimed functions with a probe illuminating element and sensing element as claimed, any such differences in the material worked upon is not material to the patentability of claim 1 over Balbierz's device when Balbierz discloses all limitations of the device recited in claim 1 as discussed above. *See In re Casey*, 370 F.2d 576, 580 (CCPA 1967) ("It will be seen that the Lampert case pertains to the impropriety of relying on a method concept to distinguish a structural claim over the prior art and Rishoi and the others indicate that inclusion of the material or article worked upon by a structure being claimed does not impart patentability to the claims."); *see also In Re Rishoi*, 197 F.2d 342, 345 (CCPA 1974) ("In our opinion there is no patentable combination between a device and the material upon which it works.").

Thus, we sustain the rejection of claim 1, and claims 2–4, 7, 8, and 28, which are not argued separately by Appellant. *See* Appeal Br. 3–13.

Claims 5 and 6
Rejected over Balbierz and Benaron

Appellant argues that the Examiner's reliance on Benaron to teach features recited in claims 5 and 6 does not cure the deficiency of Balbierz as to claim 1, from which claims 5 and 6 depend. Appeal Br. 14–15.

Because we sustain the rejection of claim 1 as anticipated by Balbierz, there are no deficiencies for Benaron to cure in this regard. Thus, we also sustain the rejection of claims 5 and 6.

CONCLUSION

Claims Rejected	35 U.S.C. §	Reference/Basis	Affirmed	Reversed
1–4, 7, 8, 28	102(b)	Balbierz	1–4, 7, 8, 28	
5, 6	103(a)	Balbierz, Benaron	5, 6	
Overall Outcome			**1–8, 28**	

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